

117TH CONGRESS
2D SESSION

S. 4348

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 26, 2022

Mrs. MURRAY (for herself and Mr. BURR) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Food and Drug Administration Safety and Landmark
6 Advancements Act of 2022” or the “FDASLA Act of
7 2022”.

1 (b) TABLE OF CONTENTS.—The table of contents for
 2 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—FEES RELATING TO DRUGS

- Sec. 101. Short title; finding.
- Sec. 102. Definitions.
- Sec. 103. Authority to assess and use drug fees.
- Sec. 104. Reauthorization; reporting requirement.
- Sec. 105. Sunset dates.
- Sec. 106. Effective date.
- Sec. 107. Savings clause.

TITLE II—FEES RELATING TO DEVICES

- Sec. 201. Short title; finding.
- Sec. 202. Definitions.
- Sec. 203. Authority to assess and use device fees.
- Sec. 204. Accreditation programs.
- Sec. 205. Sunset dates.
- Sec. 206. Effective date.
- Sec. 207. Savings clause.

TITLE III—FEES RELATING TO GENERIC DRUGS

- Sec. 301. Short title; finding.
- Sec. 302. Authority to assess and use human generic drug fees.
- Sec. 303. Reauthorization; reporting requirements.
- Sec. 304. Sunset dates.
- Sec. 305. Effective date.
- Sec. 306. Savings clause.

TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL
 PRODUCTS

- Sec. 401. Short title; finding.
- Sec. 402. Definitions.
- Sec. 403. Authority to assess and use biosimilar biological product fees.
- Sec. 404. Reauthorization; reporting requirements.
- Sec. 405. Sunset dates.
- Sec. 406. Effective date.
- Sec. 407. Savings clause.

TITLE V—IMPROVING REGULATION OF DRUGS AND BIOLOGICAL
 PRODUCTS

- Sec. 501. Alternatives to animal testing.
- Sec. 502. Safer disposal of opioids.
- Sec. 503. Clarifications to exclusivity provisions for first interchangeable biosimilar biological products.
- Sec. 504. Improvements to the Purple Book.
- Sec. 505. Therapeutic equivalence evaluations.
- Sec. 506. Modernizing accelerated approval.

TITLE VI—OTHER REAUTHORIZATIONS

- Sec. 601. Reauthorization of the critical path public-private partnership.
- Sec. 602. Reauthorization of the best pharmaceuticals for children program.
- Sec. 603. Reauthorization of the humanitarian device exemption incentive.
- Sec. 604. Reauthorization of the pediatric device consortia program.
- Sec. 605. Reauthorization of provision pertaining to drugs containing single enantiomers.
- Sec. 606. Reauthorization of orphan drug grants.
- Sec. 607. Reauthorization of certain device inspections.

TITLE VII—ENHANCING FDA HIRING AUTHORITIES

- Sec. 701. Enhancing FDA hiring authority for scientific, technical, and professional personnel.
- Sec. 702. Strategic workforce plan and report.

TITLE VIII—ADVANCING REGULATION OF COSMETICS, DIETARY SUPPLEMENTS, AND LABORATORY DEVELOPED TESTS

Subtitle A—Cosmetics

- Sec. 801. Short title.
- Sec. 802. Amendments to cosmetic requirements.
- Sec. 803. Enforcement and conforming amendments.
- Sec. 804. Records inspection.
- Sec. 805. Tale-containing cosmetics.
- Sec. 806. PFAS in cosmetics.
- Sec. 807. Funding.

Subtitle B—Dietary Supplements

- Sec. 811. Regulation of dietary supplements.

Subtitle C—In Vitro Clinical Tests

- Sec. 821. Short title; table of contents.
- Sec. 822. Definitions.
- Sec. 823. Regulation of in vitro clinical tests.
- Sec. 824. Enforcement and other provisions.
- Sec. 825. Transition.
- Sec. 826. Emergency use authorization.
- Sec. 827. Antimicrobial susceptibility tests.
- Sec. 828. Combination products.
- Sec. 829. Resources.
- Sec. 830. Authorization of appropriations.

TITLE IX—OTHER PROVISIONS

- Sec. 901. Facilities management.
- Sec. 902. Annual report on inspections.
- Sec. 903. User fee program transparency and accountability.
- Sec. 904. OTC hearing aids final rule.
- Sec. 905. Enhance intra-agency coordination and public health assessment with regard to compliance activities.

1 **TITLE I—FEES RELATING TO**
2 **DRUGS**

3 **SEC. 101. SHORT TITLE; FINDING.**

4 (a) **SHORT TITLE.**—This title may be cited as the
5 “Prescription Drug User Fee Amendments of 2022”.

6 (b) **FINDING.**—Congress finds that the fees author-
7 ized by the amendments made in this title will be dedi-
8 cated toward expediting the drug development process and
9 the process for the review of human drug applications, in-
10 cluding postmarket drug safety activities, as set forth in
11 the goals identified for purposes of part 2 of subchapter
12 C of chapter VII of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 379g et seq.), in the letters from the Sec-
14 retary of Health and Human Services to the Chairman
15 of the Committee on Health, Education, Labor, and Pen-
16 sions of the Senate and the Chairman of the Committee
17 on Energy and Commerce of the House of Representa-
18 tives, as set forth in the Congressional Record.

19 **SEC. 102. DEFINITIONS.**

20 Section 735 of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 379g) is amended—

22 (1) in paragraph (1), in the matter following
23 subparagraph (B), by striking “an allergenic extract
24 product, or” and inserting “does not include an ap-
25 plication with respect to an allergenic extract prod-

1 uct licensed before October 1, 2022, does not include
2 an application with respect to a standardized aller-
3 genic extract product submitted pursuant to a notifi-
4 cation to the applicant from the Secretary regarding
5 the existence of a potency test that measures the al-
6 lergenic activity of an allergenic extract product li-
7 censed by the applicant before October 1, 2022, does
8 not include an application with respect to”;

9 (2) in paragraph (3), in the matter following
10 subparagraph (C)—

11 (A) by inserting “licensed before October
12 1, 2022, a standardized allergenic extract prod-
13 uct submitted pursuant to a notification to the
14 applicant from the Secretary regarding the ex-
15 istence of a potency test that measures the al-
16 lergenic activity of an allergenic extract product
17 licensed by the applicant before October 1,
18 2022,” after “an allergenic extract product”;

19 (B) by adding at the end the following: “If
20 a written request to place a product in the dis-
21 continued section of either of the lists described
22 in subparagraph (C) is submitted to the Sec-
23 retary on behalf of an applicant, and the re-
24 quest identifies the date the product is, or will
25 be, withdrawn from sale, then, for purposes of

1 assessing the prescription drug program fee
2 under section 736(a)(2), the Secretary shall
3 consider such product to have been included in
4 the discontinued section on the later of (i) the
5 date such request was received, or (ii) if the
6 product will be withdrawn from sale on a future
7 date, such future date when the product is
8 withdrawn from sale. For purposes of subpara-
9 graph (C), a product shall be considered with-
10 drawn from sale once the applicant has ceased
11 its own distribution of the product, whether or
12 not the applicant has ordered recall of all pre-
13 viously distributed lots of the product, except
14 that a routine, temporary interruption in supply
15 shall not render a product withdrawn from
16 sale.”; and

17 (C) by adding at the end the following:

18 “(12) The term ‘skin-test diagnostic product’—

19 “(A) means a product—

20 “(i) for prick, scratch, intradermal, or
21 subcutaneous administration;

22 “(ii) expected to produce a limited,
23 local reaction at the site of administration
24 (if positive), rather than a systemic effect;

1 “(iii) not intended to be a preventive
2 or therapeutic intervention; and

3 “(iv) intended to detect an immediate
4 or delayed-type skin hypersensitivity reac-
5 tion to aid in the diagnosis of—

6 “(I) an allergy to an anti-
7 microbial agent;

8 “(II) an allergy that is not to an
9 antimicrobial agent, if the diagnostic
10 product was authorized for marketing
11 prior to October 1, 2022; or

12 “(III) infection with fungal or
13 mycobacterial pathogens; and

14 “(B) includes positive and negative con-
15 trols required to interpret the results of a prod-
16 uct described in subparagraph (A).”.

17 **SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.**

18 (a) TYPES OF FEES.—Section 736(a) of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(a)) is
20 amended—

21 (1) in the matter preceding paragraph (1), by
22 striking “2018” and inserting “2023”;

23 (2) in paragraph (1)—

1 (A) in subparagraph (A), by striking “sub-
2 section (c)(5)” each place it appears and insert-
3 ing “subsection (c)(6)”;

4 (B) in subparagraph (C), by inserting
5 “prior to approval” after “or was withdrawn”;
6 and

7 (C) by adding at the end the following:

8 “(H) EXCEPTION FOR SKIN-TEST DIAG-
9 NOSTIC PRODUCTS.—A human drug application
10 for a skin-test diagnostic product shall not be
11 subject to a fee under subparagraph (A).”; and
12 (3) in paragraph (2)—

13 (A) in subparagraph (A)—

14 (i) by striking “subsection (c)(5)” and
15 inserting “subsection (c)(6)”;

16 (ii) by striking “Except as provided”
17 and inserting the following:

18 “(i) PAYMENT OF FEES.—Except as
19 provided”; and

20 (iii) by adding at the end the fol-
21 lowing:

22 “(ii) PREVIOUSLY DISCONTINUED
23 DRUG PRODUCTS.—If a drug product that
24 is identified in a human drug application
25 approved as of October 1 of a fiscal year

1 is not a prescription drug product as of
2 that date because the drug product is in
3 the discontinued section of a list identified
4 in section 735(3), and on any subsequent
5 day during such fiscal year the drug prod-
6 uct is a prescription drug product, then ex-
7 cept as provided in subparagraphs (B) and
8 (C), each person who is named as the ap-
9 plicant in a human drug application with
10 respect to such product, and who, after
11 September 1, 1992, had pending before the
12 Secretary a human drug application or
13 supplement, shall pay the annual prescrip-
14 tion drug program fee established for a fis-
15 cal year under subsection (c)(6) for such
16 prescription drug product. Such fee shall
17 be due on the last business day of such fis-
18 cal year and shall be paid only once for
19 each product for a fiscal year in which the
20 fee is payable.”; and

21 (B) by amending subparagraph (B) to read
22 as follows:

23 “(B) EXCEPTION FOR CERTAIN PRESCRIP-
24 TION DRUG PRODUCTS.—A prescription drug
25 program fee shall not be assessed for a pre-

1 description drug product under subparagraph (A)
2 if such product is—

3 “(i) a large volume parenteral product
4 (a sterile aqueous drug product packaged
5 in a single-dose container with a volume
6 greater than or equal to 100 mL, not in-
7 cluding powders for reconstitution or phar-
8 macy bulk packages) identified on the list
9 compiled under section 505(j)(7);

10 “(ii) pharmaceutically equivalent (as
11 defined in section 314.3 of title 21, Code
12 of Federal Regulations (or any successor
13 regulations)), to another product on the
14 list of products compiled under section
15 505(j)(7) (not including the discontinued
16 section of such list); or

17 “(iii) a skin-test diagnostic product.”.

18 (b) FEE REVENUE AMOUNTS.—Section 736(b) of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
20 379h(b)) is amended—

21 (1) in paragraph (1)—

22 (A) in the matter preceding subparagraph
23 (A), by striking “2018 through 2022” and in-
24 serting “2023 through 2027”;

1 (B) by redesignating subparagraphs (C)
2 through (F) as subparagraphs (D) through (G),
3 respectively;

4 (C) by inserting after subparagraph (B)
5 the following:

6 “(C) The dollar amount equal to the stra-
7 tegic hiring and retention adjustment for the
8 fiscal year (as determined under subsection
9 (c)(2));”;

10 (D) in subparagraph (D), as so redesign-
11 ated, by striking “(c)(2)” and inserting
12 “(c)(3)”;

13 (E) in subparagraph (E), as so redesign-
14 ated, by striking “(c)(3)” and inserting
15 “(c)(4)”;

16 (F) in subparagraph (F), as so redesign-
17 ated, by striking “(c)(4)” and inserting
18 “(c)(5)”;

19 (G) in subparagraph (G), as so redesign-
20 ated, by striking clauses (i) through (v) and
21 inserting the following:

22 “(i) \$65,773,693 for fiscal year 2023.

23 “(ii) \$25,097,671 for fiscal year 2024.

24 “(iii) \$14,154,169 for fiscal year
25 2025.

1 “(iv) \$4,864,860 for fiscal year 2026.

2 “(v) \$1,314,620 for fiscal year
3 2027.”; and

4 (2) in paragraph (3)—

5 (A) in subparagraph (A), by striking
6 “2018, \$878,590,000” and inserting “2023,
7 \$1,151,522,958”; and

8 (B) in subparagraph (B)—

9 (i) by striking “2019 through 2022”
10 and inserting “2024 through 2027”; and

11 (ii) by striking “subsection (c)(3) or
12 (c)(4)” and inserting “subsection (c)(4) or
13 (c)(5)”.

14 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section
15 736(c) of the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 379h(c)) is amended—

17 (1) in paragraph (1)(B)(ii), by striking “Wash-
18 ington-Baltimore, DC–MD–VA–WV” and inserting
19 “Washington–Arlington–Alexandria, DC–VA–MD–
20 WV”;

21 (2) by redesignating paragraphs (2) through
22 (6) as paragraphs (3) through (7), respectively;

23 (3) by inserting after paragraph (1) the fol-
24 lowing:

1 “(2) STRATEGIC HIRING AND RETENTION AD-
2 JUSTMENT.—For each fiscal year, after the annual
3 base revenue established in subsection (b)(1)(A) is
4 adjusted for inflation in accordance with paragraph
5 (1), the Secretary shall further increase the fee rev-
6 enue and fees—

7 “(A) for fiscal year 2023, by \$9,000,000;

8 and

9 “(B) for fiscal year 2024 and each subse-
10 quent fiscal year, by \$4,000,000.”;

11 (4) in paragraph (3), as so redesignated—

12 (A) in subparagraph (A)—

13 (i) by striking “for inflation”; and

14 (ii) by striking “paragraph (1)” and
15 inserting “paragraphs (1) and (2)”;

16 (B) by amending subparagraph (B) to read
17 as follows:

18 “(B) METHODOLOGY.—For purposes of
19 this paragraph, the Secretary shall employ the
20 capacity planning methodology utilized by the
21 Secretary in setting fees for fiscal year 2021, as
22 described in the notice titled ‘Prescription Drug
23 User Fee Rates for Fiscal Year 2021’ (85 Fed.
24 Reg. 46651; August 3, 2020). The workload
25 categories used in forecasting shall include only

1 the activities described in such notice and, as
2 feasible, additional activities that are directly
3 related to the direct review of applications and
4 supplements, including additional formal meet-
5 ing types, the direct review of postmarketing
6 commitments and requirements, the direct re-
7 view of risk evaluation and mitigation strate-
8 gies, and the direct review of annual reports for
9 approved prescription drug products. Subject to
10 the exceptions in the preceding sentence, the
11 Secretary shall not include as workload cat-
12 egories in forecasting any non-core review ac-
13 tivities, including any activities that the Sec-
14 retary referenced for potential future use in
15 such notice but did not utilize in the setting
16 fees for fiscal year 2021.”;

17 (C) by striking subparagraph (C);

18 (D) by redesignating subparagraphs (D)
19 and (E) as subparagraphs (C) and (D), respec-
20 tively;

21 (E) in subparagraph (C), as so redesign-
22 ated—

23 (i) by striking “year) and” and insert-
24 ing “year),”; and

1 (ii) by inserting “, and subsection
2 (b)(1)(C) (the dollar amount of the stra-
3 tegic hiring and retention adjustment).”;

4 and

5 (F) in subparagraph (D), as so redesign-
6 nated, by striking “paragraph (5)” and insert-
7 ing “paragraph (6)”;

8 (5) in paragraph (4), as so redesignated—

9 (A) by amending subparagraph (A) to read
10 as follows:

11 “(A) INCREASE.—For fiscal year 2023 and
12 subsequent fiscal years, the Secretary shall, in
13 addition to adjustments under paragraphs (1),
14 (2), and (3), further increase the fee revenue
15 and fees if such an adjustment is necessary to
16 provide for at least the following amounts of op-
17 erating reserves of carryover user fees for the
18 process for the review of human drug applica-
19 tions for each fiscal year, as follows:

20 “(i) For fiscal year 2023, at least 8
21 weeks of operating reserves.

22 “(ii) For fiscal year 2024, at least 9
23 weeks of operating reserves.

1 “(iii) For fiscal year 2025 and subse-
2 quent fiscal years, at least 10 weeks of op-
3 erating reserves.”; and

4 (B) in subparagraph (C), by striking
5 “paragraph (5)” and inserting “paragraph
6 (6)”;

7 (6) by amending paragraph (5), as so redesign-
8 nated, to read as follows:

9 “(5) ADDITIONAL DIRECT COST ADJUST-
10 MENT.—The Secretary shall, in addition to adjust-
11 ments under paragraphs (1), (2), (3), and (4), fur-
12 ther increase the fee revenue and fees—

13 “(A) for fiscal year 2023, by \$44,386,150;
14 and

15 “(B) for fiscal years 2024 through 2027,
16 by the amount set forth in clauses (i) through
17 (iv), as applicable, multiplied by the Consumer
18 Price Index for urban consumers (Washington-
19 Arlington-Alexandria, DC-VA-MD-WV; Not
20 Seasonally Adjusted; All Items; Annual Index)
21 for the most recent year of available data, di-
22 vided by such Index for 2021—

23 “(i) for fiscal year 2024, \$60,967,993;

24 “(ii) for fiscal year 2025,
25 \$35,799,314;

1 “(iii) for fiscal year 2026,
2 \$35,799,314; and

3 “(iv) for fiscal year 2027,
4 \$35,799,314.”; and

5 (7) in paragraph (6), as so redesignated, by
6 striking “2017” and inserting “2022”.

7 (d) CREDITING AND AVAILABILITY OF FEES.—Sec-
8 tion 736(g)(3) of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 379h(g)(3)) is amended by striking “2018
10 through 2022” and inserting “2023 through 2027”.

11 (e) WRITTEN REQUESTS FOR WAIVERS, REDUC-
12 TIONS, AND REFUNDS.—Section 736(i) of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(i)) is
14 amended to read as follows:

15 “(i) WRITTEN REQUESTS FOR WAIVERS, REDUC-
16 TIONS, EXEMPTIONS, AND RETURNS; DISPUTES CON-
17 CERNING FEES.—To qualify for consideration for a waiver
18 or reduction under subsection (d), an exemption under
19 subsection (k), or the return of any fee paid under this
20 section, including if the fee is claimed to have been paid
21 in error, a person shall submit to the Secretary a written
22 request justifying such waiver, reduction, exemption, or
23 return not later than 180 days after such fee is due. A
24 request submitted under this paragraph shall include any
25 legal authorities under which the request is made.”.

1 (f) ORPHAN DRUGS.—Section 736(k) of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(k)) is
3 amended—

4 (1) in paragraph (1)(B), by striking “during
5 the previous year” and inserting “, as determined
6 under paragraph (2)”; and

7 (2) in paragraph (2), by striking “that its gross
8 annual revenues” and all that follows through the
9 period at the end and inserting “supported by tax
10 returns submitted to the Internal Revenue Service,
11 or, as necessary, by other appropriate financial in-
12 formation, that its gross annual revenues did not ex-
13 ceed \$50,000,000 for the last calendar year ending
14 prior to the fiscal year for which the exemption is
15 requested.”.

16 **SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENT.**

17 Section 736B of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 379h–2) is amended—

19 (1) by striking “2018” each place it appears
20 and inserting “2023”;

21 (2) by striking “Prescription Drug User Fee
22 Amendments of 2017” each place it appears and in-
23 serting “Prescription Drug User Fee Amendments
24 of 2022”;

1 (3) in subsection (a)(4), by striking “2020” and
2 inserting “2023”; and

3 (4) in subsection (f), by striking “2022” each
4 place it appears and inserting “2027”.

5 **SEC. 105. SUNSET DATES.**

6 (a) AUTHORIZATION.—Sections 735 and 736 of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;
8 379h) shall cease to be effective October 1, 2027.

9 (b) REPORTING REQUIREMENTS.—Section 736B of
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 379h–2) shall cease to be effective January 31, 2028.

12 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
13 ber 1, 2022, subsections (a) and (b) of section 104 of the
14 FDA Reauthorization Act of 2017 (Public Law 115–52)
15 are repealed.

16 **SEC. 106. EFFECTIVE DATE.**

17 The amendments made by this title shall take effect
18 on October 1, 2022, or the date of the enactment of this
19 Act, whichever is later, except that fees under part 2 of
20 subchapter C of chapter VII of the Federal Food, Drug,
21 and Cosmetic Act (21 U.S.C. 379g et seq.) shall be as-
22 sessed for all human drug applications received on or after
23 October 1, 2022, regardless of the date of the enactment
24 of this Act.

1 **SEC. 107. SAVINGS CLAUSE.**

2 Notwithstanding the amendments made by this title,
3 part 2 of subchapter C of chapter VII of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), as in
5 effect on the day before the date of the enactment of this
6 title, shall continue to be in effect with respect to human
7 drug applications and supplements (as defined in such
8 part as of such day) that were accepted by the Food and
9 Drug Administration for filing on or after October 1,
10 2017, but before October 1, 2022, with respect to assess-
11 ing and collecting any fee required by such part for a fiscal
12 year prior to fiscal year 2023.

13 **TITLE II—FEES RELATING TO**
14 **DEVICES**

15 **SEC. 201. SHORT TITLE; FINDING.**

16 (a) **SHORT TITLE.**—This title may be cited as the
17 “Medical Device User Fee Amendments of 2022”.

18 (b) **FINDING.**—Congress finds that the fees author-
19 ized under the amendments made by this title will be dedi-
20 cated toward expediting the process for the review of de-
21 vice applications and for assuring the safety and effective-
22 ness of devices, as set forth in the goals identified for pur-
23 poses of part 3 of subchapter C of chapter VII of the Fed-
24 eral Food, Drug, and Cosmetic Act in the letters from the
25 Secretary of Health and Human Services to the Chairman
26 of the Committee on Health, Education, Labor, and Pen-

1 sions of the Senate and the Chairman of the Committee
2 on Energy and Commerce of the House of Representa-
3 tives, as set forth in the Congressional Record.

4 **SEC. 202. DEFINITIONS.**

5 Section 737 of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 379i) is amended—

7 (1) in paragraph (9)—

8 (A) in the matter preceding subparagraph
9 (A), by striking “and premarket notification
10 submissions” and inserting “premarket notifica-
11 tion submissions, and de novo classification re-
12 quests”;

13 (B) in subparagraph (D), by striking “and
14 submissions” and inserting “submissions, and
15 de novo classification requests”;

16 (C) in subparagraph (F), by striking “and
17 premarket notification submissions” and insert-
18 ing “premarket notification submissions, and de
19 novo classification requests”;

20 (D) in subparagraphs (G) and (H), by
21 striking “or submissions” each place it appears
22 and inserting “submissions, or requests”; and

23 (E) in subparagraph (K), by striking “or
24 premarket notification submissions” and insert-

1 ing “premarket notification submissions, or de
2 novo classification requests”; and
3 (2) in paragraph (11), by striking “2016” and
4 inserting “2021”.

5 **SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.**

6 (a) TYPES OF FEES.—Section 738(a) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)) is
8 amended—

9 (1) in paragraph (1), by striking “2018” and
10 inserting “2023”; and

11 (2) in paragraph (2)—

12 (A) in subparagraph (A)—

13 (i) in the matter preceding clause (i),
14 by striking “2017” and inserting “2022”;

15 (ii) in clause (iii), by striking “75 per-
16 cent” and inserting “80 percent”; and

17 (iii) in clause (viii), by striking “3.4
18 percent” and inserting “4.5 percent”;

19 (B) in subparagraph (B)(iii), by striking
20 “or premarket notification submission” and in-
21 serting “premarket notification submission, or
22 de novo classification request”; and

23 (C) in subparagraph (C), by striking “or
24 periodic reporting concerning a class III device”
25 and inserting “periodic reporting concerning a

1 class III device, or de novo classification re-
 2 quest”.

3 (b) FEE AMOUNTS.—Section 738(b) of the Federal
 4 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(b)) is
 5 amended—

6 (1) in paragraph (1), by striking “2018
 7 through 2022” and inserting “2023 through 2027”;

8 (2) by amending the table in paragraph (2) to
 9 read as follows:

“Fee Type	Fiscal Year 2023	Fiscal Year 2024	Fiscal Year 2025	Fiscal Year 2026	Fiscal Year 2027
Premarket Ap- plication	\$425,000	\$435,000	\$445,000	\$455,000	\$470,000
Establishment Registration ..	\$6,250	\$6,875	\$7,100	\$7,575	\$8,465”;

10 and

11 (3) in paragraph (3), by amending subpara-
 12 graphs (A) through (E) to read as follows:

13 “(A) \$312,606,000 for fiscal year 2023.

14 “(B) \$335,750,000 for fiscal year 2024.

15 “(C) \$350,746,400 for fiscal year 2025.

16 “(D) \$366,486,300 for fiscal year 2026.

17 “(E) \$418,343,000 for fiscal year 2027.”.

18 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section
 19 738(c) of the Federal Food, Drug, and Cosmetic Act (21
 20 U.S.C. 379j(c)) is amended—

1 (1) in paragraph (1), by striking “2017” and
2 inserting “2022”;

3 (2) in paragraph (2)—

4 (A) by striking “2018” each place it ap-
5 pears and inserting “2023”;

6 (B) in subparagraph (B)(ii), by striking
7 “2016” and inserting “2022”;

8 (C) in subparagraph (C)(i)(II), by striking
9 “Washington-Baltimore, DC-MD-VA-WV”
10 and inserting “Washington-Arlington-Alexan-
11 dria, DC-VA-MD-WV”; and

12 (D) in subparagraph (D), by striking
13 “2022” and inserting “2027”;

14 (3) in paragraph (3), by striking “2018
15 through 2022” and inserting “2023 through 2027”;

16 (4) by redesignating paragraphs (4) and (5) as
17 paragraphs (7) and (8), respectively; and

18 (5) by inserting after paragraph (3) the fol-
19 lowing:

20 “(4) PERFORMANCE IMPROVEMENT ADJUST-
21 MENT.—

22 “(A) IN GENERAL.—For each of fiscal
23 years 2025 through 2027, after the adjustment
24 under paragraph (3), the base establishment
25 registration fee amounts for such fiscal year

1 shall be increased to reflect changes in the re-
2 source needs of the Secretary due to improved
3 review performance goals for the process for the
4 review of device applications identified in the
5 letters described in section 201(b) of the Med-
6 ical Device User Fee Amendments of 2022, as
7 the Secretary determines necessary to achieve
8 an increase in total fee collections for such fis-
9 cal year, equal to the following amounts, as ap-
10 plicable:

11 “(i) For fiscal year 2025, the product
12 of—

13 “(I) the amount determined
14 under subparagraph (B)(i)(I); and

15 “(II) the applicable inflation ad-
16 justment under paragraph (2)(B) for
17 such fiscal year.

18 “(ii) For fiscal year 2026, the product
19 of—

20 “(I) the sum of the amounts de-
21 termined under subparagraphs
22 (B)(i)(II), (B)(ii)(I), and (B)(iii)(I);
23 and

1 “(II) the applicable inflation ad-
2 justment under paragraph (2)(B) for
3 such fiscal year.

4 “(iii) For fiscal year 2027, the prod-
5 uct of—

6 “(I) the sum of the amounts de-
7 termined under subparagraphs
8 (B)(i)(III), (B)(ii)(II), and
9 (B)(iii)(II); and

10 “(II) the applicable inflation ad-
11 justment under paragraph (2)(B) for
12 such fiscal year.

13 “(B) AMOUNTS.—

14 “(i) PRESUBMISSION AMOUNT.—For
15 purposes of subparagraph (A), with respect
16 to the presubmission written feedback goal,
17 the amounts determined under this sub-
18 paragraph are as follows:

19 “(I) For fiscal year 2025,
20 \$15,396,600 if the goal for fiscal year
21 2023 is met.

22 “(II) For fiscal year 2026—

23 “(aa) \$15,396,600 if the
24 goal for fiscal year 2023 is met

1 and the goal for fiscal year 2024
2 is missed; or

3 “(bb) \$36,792,200 if the
4 goal for fiscal year 2024 is met.

5 “(III) For fiscal year 2027—

6 “(aa) \$15,396,600 if the
7 goal for fiscal year 2023 is met
8 and the goal for each of fiscal
9 years 2024 and 2025 is missed;

10 “(bb) \$36,792,200 if the
11 goal for fiscal year 2024 is met
12 and the goal for fiscal year 2025
13 is missed; or

14 “(cc) \$40,572,600 if the
15 goal for fiscal year 2025 is met.

16 “(ii) DE NOVO CLASSIFICATION RE-
17 QUEST AMOUNT.—For purposes of sub-
18 paragraph (A), with respect to the de novo
19 decision goal, the amounts determined
20 under this subparagraph are as follows:

21 “(I) For fiscal year 2026,
22 \$6,323,500 if the goal for fiscal year
23 2023 is met.

24 “(II) For fiscal year 2027—

1 “(aa) \$6,323,500 if the goal
2 for fiscal year 2023 is met and
3 the goal for fiscal year 2024 is
4 missed; or

5 “(bb) \$11,765,400 if the
6 goal for fiscal year 2024 is met.

7 “(iii) PREMARKET NOTIFICATION AND
8 PREMARKET APPROVAL AMOUNT.—For
9 purposes of subparagraph (A), with respect
10 to the 510(k) decision goal, 510(k) shared
11 outcome total time to decision goal, PMA
12 decision goal, and PMA shared outcome
13 total time to decision goal, the amounts de-
14 termined under this subparagraph are as
15 follows:

16 “(I) For fiscal year 2026,
17 \$1,020,000 if the 4 goals for fiscal
18 year 2023 are met.

19 “(II) For fiscal year 2027—

20 “(aa) \$1,020,000 if the 4
21 goals for fiscal year 2023 are met
22 and one or more of the 4 goals
23 for fiscal year 2024 is missed; or

1 “(bb) \$3,906,000 if the 4
2 goals for fiscal year 2024 are
3 met.

4 “(C) PERFORMANCE CALCULATION.—For
5 purposes of this paragraph, performance of the
6 following goals shall be determined as specified
7 in the letters described in section 201(b) of the
8 Medical Device User Fee Amendments of 2022
9 and based on data available as of the applicable
10 dates as follows:

11 “(i) The performance of the pre-
12 submission written feedback goal—

13 “(I) for fiscal year 2023, shall be
14 based on data available as of March
15 31, 2024;

16 “(II) for fiscal year 2024, shall
17 be based on data available as of
18 March 31, 2025; and

19 “(III) for fiscal year 2025, shall
20 be based on data available as of
21 March 31, 2026.

22 “(ii) The performance of the de novo
23 decision goal, 510(k) decision goal, 510(k)
24 shared outcome total time to decision goal,

1 PMA decision goal, and PMA shared out-
2 come total time to decision goal—

3 “(I) for fiscal year 2023, shall be
4 based on data available as of March
5 31, 2025; and

6 “(II) for fiscal year 2024, shall
7 be based on data available as of
8 March 31, 2026.

9 “(D) DEFINITIONS.—For purposes of this
10 paragraph, the terms ‘presubmission written
11 feedback goal’, ‘de novo decision goal’, ‘510(k)
12 decision goal’, ‘510(k) shared outcome total
13 time to decision goal’, ‘PMA decision goal’, and
14 ‘PMA shared outcome total time to decision
15 goal’ have the meanings given such terms in the
16 goals identified in the letters described in sec-
17 tion 201(b) of the Medical Device User Fee
18 Amendments of 2022.

19 “(5) HIRING ADJUSTMENT.—

20 “(A) IN GENERAL.—For each of fiscal
21 years 2025 through 2027, after the adjust-
22 ments under paragraphs (3) and (4), if applica-
23 ble, the base establishment registration fee
24 amounts shall be decreased as the Secretary de-
25 termines necessary to achieve a reduction in

1 total fee collections equal to the hiring adjust-
2 ment amount under subparagraph (B), if the
3 number of hires to support the process for the
4 review of device applications falls below the fol-
5 lowing thresholds for the applicable fiscal years:

6 “(i) For fiscal year 2025, 85 percent
7 of the hiring goal specified in subpara-
8 graph (C) for fiscal year 2023.

9 “(ii) For fiscal year 2026, 90 percent
10 of the hiring goal specified in subpara-
11 graph (C) for fiscal year 2024.

12 “(iii) For fiscal year 2027, 90 percent
13 of the hiring goal specified in subpara-
14 graph (C) for fiscal year 2025.

15 “(B) HIRING ADJUSTMENT AMOUNT.—The
16 hiring adjustment amount for fiscal year 2025
17 and each subsequent fiscal year is the product
18 of—

19 “(i) the number of hires by which the
20 hiring goal specified in subparagraph (C)
21 for the fiscal year before the prior fiscal
22 year was missed;

23 “(ii) \$72,877; and

1 “(iii) the applicable inflation adjust-
2 ment under paragraph (2)(B) for the fiscal
3 year for which the hiring goal was missed.

4 “(C) HIRING GOALS.—

5 “(i) IN GENERAL.—For purposes of
6 subparagraph (B), the hiring goals for
7 each of fiscal years 2023 through 2025 are
8 as follows:

9 “(I) For fiscal year 2023, 144
10 hires.

11 “(II) For fiscal year 2024, 42
12 hires.

13 “(III) For fiscal year 2025—

14 “(aa) 24 hires if the base es-
15 tablishment registration fees are
16 not increased by the amount de-
17 termined under paragraph
18 (4)(A)(i); or

19 “(bb) 83 hires if the base
20 establishment registration fees
21 are increased by the amount de-
22 termined under paragraph
23 (4)(A)(i).

24 “(ii) NUMBER OF HIRES.—For pur-
25 poses of this paragraph, the number of

1 hires for a fiscal year shall be determined
2 by the Secretary, as set forth in the letters
3 described in section 201(b) of the Medical
4 Device User Fee Amendments of 2022.

5 “(6) OPERATING RESERVE ADJUSTMENT.—

6 “(A) IN GENERAL.—For each of fiscal
7 years 2023 through 2027, after the adjust-
8 ments under paragraphs (3), (4), and (5), if ap-
9 plicable, if the Secretary has operating reserves
10 of carryover user fees for the process for the re-
11 view of device applications in excess of the des-
12 ignated amount in subparagraph (B), the Sec-
13 retary shall decrease the base establishment
14 registration fee amounts to provide for not
15 more than such designated amount of operating
16 reserves.

17 “(B) DESIGNATED AMOUNT.—Subject to
18 subparagraph (C), for each fiscal year, the des-
19 ignated amount in this subparagraph is equal
20 to the sum of—

21 “(i) 13 weeks of operating reserves of
22 carryover user fees; and

23 “(ii) the 1 month of operating re-
24 serves described in paragraph (8).

1 “(C) EXCLUDED AMOUNT.—For the period
2 of fiscal years 2023 through 2026, a total
3 amount equal to \$118,000,000 shall not be con-
4 sidered part of the designated amount under
5 subparagraph (B) and shall not be subject to
6 the decrease under subparagraph (A).”.

7 (d) SMALL BUSINESSES.—Section 738 of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-
9 ed—

10 (1) in subsection (d)(2)(B)(iii), by inserting “,
11 if extant,” after “national taxing authority”; and

12 (2) in subsection (e)(2)(B)(iii), by inserting “,
13 if extant,” after “national taxing authority”.

14 (e) CONDITIONS.—Section 738(g) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(g)) is
16 amended—

17 (1) in paragraph (1)(A), by striking
18 “\$320,825,000” and inserting “\$398,566,000”; and

19 (2) in paragraph (2), by inserting “de novo
20 classification requests,” after “class III device,”.

21 (f) AUTHORIZATION OF APPROPRIATIONS.—Section
22 738(h)(3) of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 379j(h)(3)) is amended to read as follows:

24 “(3) AUTHORIZATION OF APPROPRIATIONS.—

1 “(A) IN GENERAL.—For each of the fiscal
2 years 2023 through 2027, there is authorized to
3 be appropriated for fees under this section an
4 amount equal to the revenue amount deter-
5 mined in subparagraph (B), less the amount of
6 reductions determined in subparagraph (C).

7 “(B) REVENUE AMOUNT.—For purposes of
8 this paragraph, the revenue amount for each
9 fiscal year is the sum of—

10 “(i) the total revenue amount under
11 subsection (b)(3) for the fiscal year, as ad-
12 justed under subsection (c)(2); and

13 “(ii) the performance improvement
14 adjustment amount for the fiscal year
15 under subsection (c)(4)(A), if applicable.

16 “(C) AMOUNT OF REDUCTIONS.—For pur-
17 poses of this paragraph, the amount of reduc-
18 tions for each fiscal year is the sum of—

19 “(i) the hiring adjustment amount for
20 the fiscal year under subsection (c)(5), if
21 applicable; and

22 “(ii) the operating reserve adjustment
23 amount for the fiscal year under sub-
24 section (c)(6), if applicable.”.

1 **SEC. 204. ACCREDITATION PROGRAMS.**

2 (a) ACCREDITATION SCHEME FOR CONFORMITY AS-
3 SESSMENT.—Section 514(d) of the Federal Food, Drug,
4 and Cosmetic Act (21 U.S.C. 360d(d)) is amended—

5 (1) in the subsection heading, by striking
6 “PILOT”;

7 (2) in paragraph (1)—

8 (A) in the matter preceding subparagraph

9 (A), by striking “pilot”;

10 (B) in subparagraph (A)—

11 (i) by inserting “meeting criteria spec-
12 ified by the Secretary in guidance” after
13 “testing laboratories”;

14 (ii) by inserting “in guidance” after
15 “by the Secretary”; and

16 (iii) by striking “assess the conform-
17 ance of a device with” and inserting “con-
18 duct testing to support the assessment of
19 the conformance of a device to”; and

20 (C) in subparagraph (B)—

21 (i) by striking “determinations” and
22 inserting “results”;

23 (ii) by inserting “to support” after
24 “so accredited”; and

1 (iii) by striking “a particular such de-
2 termination” and inserting “particular
3 such results”;

4 (3) in paragraph (2)—

5 (A) in the paragraph heading, by striking
6 “DETERMINATIONS” and inserting “RESULTS”;

7 (B) in subparagraph (A)—

8 (i) by striking “determinations by
9 testing laboratories” and all that follows
10 through “such determinations or” and in-
11 sserting “results by testing laboratories ac-
12 credited pursuant to this subsection, in-
13 cluding by conducting periodic audits of
14 such results or of the”;

15 (ii) by inserting a comma after “or
16 testing laboratories”;

17 (iii) by inserting “or recognition of an
18 accreditation body” after “accreditation of
19 such testing laboratory”; and

20 (iv) by striking “such device” and in-
21 sserting “a device”; and

22 (C) in subparagraph (B)—

23 (i) by striking “by a testing labora-
24 tory so accredited” and inserting “under
25 this subsection”; and

1 (ii) by inserting “or recognition of an
2 accreditation body” before “under para-
3 graph (1)(A)”;

4 (4) in paragraph (3)(C)—

5 (A) in the subparagraph heading, by in-
6 serting “AND TRANSITION” after “INITIATION”;
7 and

8 (B) by adding at the end the following:
9 “After September 30, 2023, such pilot program
10 will be considered to be completed, and the Sec-
11 retary shall have the authority to continue oper-
12 ating a program consistent with this sub-
13 section.”; and

14 (5) by striking paragraph (4).

15 (b) ACCREDITED PERSONS.—Section 523(c) of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
17 360m(c)) is amended by striking “2022” and inserting
18 “2027”.

19 **SEC. 205. SUNSET DATES.**

20 (a) AUTHORIZATION.—Sections 737 and 738 of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i;
22 379fj) shall cease to be effective October 1, 2027.

23 (b) REPORTING REQUIREMENTS.—Section 738A of
24 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 379j–1) shall cease to be effective January 31, 2028.

1 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
2 ber 1, 2022, subsections (a) and (b) of section 210 of the
3 FDA Reauthorization Act of 2017 (Public Law 115–52)
4 are repealed.

5 **SEC. 206. EFFECTIVE DATE.**

6 The amendments made by this title shall take effect
7 on October 1, 2022, or the date of the enactment of this
8 Act, whichever is later, except that fees under part 3 of
9 subchapter C of chapter VII of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 379i et seq.) shall be as-
11 sessed for all submissions listed in section 738(a)(2)(A)
12 of such Act received on or after October 1, 2022, regard-
13 less of the date of the enactment of this Act.

14 **SEC. 207. SAVINGS CLAUSE.**

15 Notwithstanding the amendments made by this title,
16 part 3 of subchapter C of chapter VII of the Federal Food,
17 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in
18 effect on the day before the date of the enactment of this
19 title, shall continue to be in effect with respect to the sub-
20 missions listed in section 738(a)(2)(A) of such Act (as de-
21 fined in such part as of such day) that on or after October
22 1, 2017, but before October 1, 2022, were received by the
23 Food and Drug Administration with respect to assessing
24 and collecting any fee required by such part for a fiscal
25 year prior to fiscal year 2023.

1 **TITLE III—FEES RELATING TO**
2 **GENERIC DRUGS**

3 **SEC. 301. SHORT TITLE; FINDING.**

4 (a) **SHORT TITLE.**—This title may be cited as the
5 “Generic Drug User Fee Amendments of 2022”.

6 (b) **FINDING.**—The Congress finds that the fees au-
7 thorized by the amendments made in this title will be dedi-
8 cated to human generic drug activities, as set forth in the
9 goals identified for purposes of part 7 of subchapter C
10 of chapter VII of the Federal Food, Drug, and Cosmetic
11 Act, in the letters from the Secretary of Health and
12 Human Services to the Chairman of the Committee on
13 Health, Education, Labor, and Pensions of the Senate and
14 the Chairman of the Committee on Energy and Commerce
15 of the House of Representatives, as set forth in the Con-
16 gressional Record.

17 **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**
18 **NERIC DRUG FEES.**

19 (a) **TYPES OF FEES.**—Section 744B(a) of the Fed-
20 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
21 42(a)) is amended—

22 (1) in the matter preceding paragraph (1), by
23 striking “2018” and inserting “2023”;

1 (2) in paragraph (2)(C), by striking “fiscal
2 years 2018 through 2022” and inserting “fiscal
3 years 2023 through 2027”;

4 (3) in paragraph (3)(B), by striking “fiscal
5 years 2018 through 2022” and inserting “fiscal
6 years 2023 through 2027”;

7 (4) in paragraph (4)(D), by striking “fiscal
8 years 2018 through 2022” and inserting “fiscal
9 years 2023 through 2027”; and

10 (5) in paragraph (5)(D), by striking “fiscal
11 years 2018 through 2022” and inserting “fiscal
12 years 2023 through 2027”.

13 (b) FEE REVENUE AMOUNTS.—Section 744B(b) of
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 379j–42(b)) is amended—

16 (1) in paragraph (1)—

17 (A) in subparagraph (A)—

18 (i) in the heading, by striking “2018”
19 and inserting “2023”;

20 (ii) by striking “2018” and inserting
21 “2023”; and

22 (iii) by striking “\$493,600,000” and
23 inserting “\$582,500,000”; and

24 (B) in subparagraph (B)—

1 (i) in the heading, by striking “2019
2 THROUGH 2022” and inserting “2024
3 THROUGH 2027”;

4 (ii) by striking “For each” and insert-
5 ing the following:

6 “(i) IN GENERAL.—For each”;

7 (iii) by striking “2019 through 2022”
8 and inserting “2024 through 2027”;

9 (iv) by striking “\$493,600,000” and
10 inserting “the base revenue amount under
11 clause (ii)”;

12 (v) by adding at the end the following:

13 “(ii) BASE REVENUE AMOUNT.—The
14 base revenue amount for a fiscal year is
15 the total revenue amount established under
16 this paragraph for the previous fiscal year,
17 not including any adjustments made for
18 such previous fiscal year under subsection
19 (c)(3).”;

20 (2) in paragraph (2)—

21 (A) in subparagraph (C), by striking “one-
22 third the amount” and inserting “24 percent”;

23 (B) in subparagraph (D), by striking
24 “Seven” and inserting “Six”; and

1 (C) in subparagraph (E)(i), by striking
2 “Thirty-five” and inserting “Thirty-six”.

3 (c) ADJUSTMENTS.—Section 744B(c) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(c)) is
5 amended—

6 (1) in paragraph (1)—

7 (A) in the matter preceding subparagraph

8 (A)—

9 (i) by striking “2019” and inserting
10 “2024”; and

11 (ii) by striking “the product of the
12 total revenues established in such notice
13 for the prior fiscal year” and inserting
14 “the base revenue amount for the fiscal
15 year determined under subsection
16 (b)(1)(B)(ii)”; and

17 (B) in subparagraph (C), by striking
18 “Washington-Baltimore, DC–MD–VA–WV”
19 and inserting “Washington-Arlington-Alexan-
20 dria, DC–VA–MD–WV”; and

21 (2) by striking paragraph (2) and inserting the
22 following:

23 “(2) CAPACITY PLANNING ADJUSTMENT.—

24 “(A) IN GENERAL.—Beginning with fiscal
25 year 2024, the Secretary shall, in addition to

1 the adjustment under paragraph (1), further in-
2 crease the fee revenue and fees under this sec-
3 tion for a fiscal year, in accordance with this
4 paragraph, to reflect changes in the resource
5 capacity needs of the Secretary for human ge-
6 neric drug activities.

7 “(B) CAPACITY PLANNING METHOD-
8 OLOGY.—The Secretary shall establish a capac-
9 ity planning methodology for purposes of this
10 paragraph, which shall—

11 “(i) be derived from the methodology
12 and recommendations made in the report
13 titled ‘Independent Evaluation of the
14 GDUFA Resource Capacity Planning Ad-
15 justment Methodology: Evaluation and
16 Recommendations’ as announced in the
17 Federal Register on August 3, 2020 (85
18 Fed. Reg. 46658); and

19 “(ii) incorporate approaches and at-
20 tributes determined appropriate by the
21 Secretary, including those made in such re-
22 port recommendations, except the workload
23 categories used in forecasting resources
24 shall only be those specified in section
25 VIII.B.2.e. of the letters described in sec-

1 tion 301(b) of the Generic Drug User Fee
2 Amendments of 2022.

3 “(C) LIMITATIONS.—

4 “(i) IN GENERAL.—Under no cir-
5 cumstances shall an adjustment under this
6 paragraph result in fee revenue for a fiscal
7 year that is less than the sum of the
8 amounts under subsection (b)(1)(B)(ii)
9 (the base revenue amount for the fiscal
10 year) and paragraph (1) (the dollar
11 amount of the inflation adjustment for the
12 fiscal year).

13 “(ii) ADDITIONAL LIMITATION.—An
14 adjustment under this paragraph shall not
15 exceed 3 percent of the sum described in
16 clause (i) for the fiscal year, except that
17 such limitation shall be 4 percent if—

18 “(I) for purposes of an adjust-
19 ment for fiscal year 2024, the Sec-
20 retary determines that, during the pe-
21 riod from April 1, 2021, through
22 March 31, 2023—

23 “(aa) the total number of
24 abbreviated new drug applica-

1 tions submitted was greater than
2 or equal to 2,000; or

3 “(bb) thirty-five percent or
4 more of abbreviated new drug ap-
5 plications submitted related to
6 complex products (as that term is
7 defined in section XI of the let-
8 ters described in section 301(b)
9 of the Generic Drug User Fee
10 Amendments of 2022);

11 “(II) for purposes of an adjust-
12 ment for fiscal year 2025, the Sec-
13 retary determines that, during the pe-
14 riod from April 1, 2022, through
15 March 31, 2024—

16 “(aa) the total number of
17 abbreviated new drug applica-
18 tions submitted was greater than
19 or equal to 2,300; or

20 “(bb) thirty-five percent or
21 more of abbreviated new drug ap-
22 plications submitted related to
23 complex products (as so defined);

24 “(III) for purposes of an adjust-
25 ment for fiscal year 2026, the Sec-

1 retary determines that, during the pe-
2 riod from April 1, 2023, through
3 March 31, 2025—

4 “(aa) the total number of
5 abbreviated new drug applica-
6 tions submitted was greater than
7 or equal to 2,300; or

8 “(bb) thirty-five percent or
9 more of abbreviated new drug ap-
10 plications submitted related to
11 complex products (as so defined);
12 and

13 “(IV) for purposes of an adjust-
14 ment for fiscal year 2027, the Sec-
15 retary determines that, during the pe-
16 riod from April 1, 2024, through
17 March 31, 2026—

18 “(aa) the total number of
19 abbreviated new drug applica-
20 tions submitted was greater than
21 or equal to 2,300; or

22 “(bb) thirty-five percent or
23 more of abbreviated new drug ap-
24 plications submitted related to
25 complex products (as so defined).

1 “(D) PUBLICATION IN FEDERAL REG-
2 ISTER.—The Secretary shall publish in the Fed-
3 eral Register notice under subsection (a), the
4 fee revenue and fees resulting from the adjust-
5 ment and the methodology under this para-
6 graph.

7 “(3) OPERATING RESERVE ADJUSTMENT.—

8 “(A) IN GENERAL.—For fiscal year 2024
9 and subsequent fiscal years, the Secretary may,
10 in addition to adjustments under paragraphs
11 (1) and (2), further increase the fee revenue
12 and fees under this section if such an adjust-
13 ment is necessary to provide operating reserves
14 of carryover user fees for human generic drug
15 activities for not more than the number of
16 weeks specified in subparagraph (B).

17 “(B) NUMBER OF WEEKS.—The number of
18 weeks specified in this subparagraph is—

19 “(i) 8 weeks for fiscal year 2024;

20 “(ii) 9 weeks for fiscal year 2025; and

21 “(iii) 10 weeks for each of fiscal year
22 2026 and 2027.

23 “(C) DECREASE.—If the Secretary has
24 carryover balances for human generic drug ac-
25 tivities in excess of 12 weeks of the operating

1 reserves referred to in subparagraph (A), the
2 Secretary shall decrease the fee revenue and
3 fees referred to in such subparagraph to provide
4 for not more than 12 weeks of such operating
5 reserves.

6 “(D) RATIONALE FOR ADJUSTMENT.—If
7 an adjustment under this paragraph is made,
8 the rationale for the amount of the increase or
9 decrease (as applicable) in fee revenue and fees
10 shall be contained in the annual Federal Reg-
11 ister notice under subsection (a) publishing the
12 fee revenue and fees for the fiscal year in-
13 volved.”.

14 (d) ANNUAL FEE SETTING.—Section 744B(d)(1) of
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 379j–42(d)(1)) is amended—

17 (1) in the heading, by striking “2018 THROUGH
18 2022” and inserting “2023 THROUGH 2027”;

19 (2) by striking “more” and inserting “later”;
20 and

21 (3) by striking “2018 through 2022” and in-
22 serting “2023 through 2027”.

23 (e) EFFECT OF FAILURE TO PAY FEES.—The head-
24 ing of paragraph (3) of section 744B(g) of the Federal
25 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(g)) is

1 amended by striking “AND PRIOR APPROVAL SUPPLEMENT
2 FEE”.

3 (f) CREDITING AND AVAILABILITY OF FEES.—Sec-
4 tion 744B(i)(3) of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 379j–42(i)(3)) is amended by striking
6 “2018 through 2022” and inserting “2023 through
7 2027”.

8 **SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.**

9 Section 744C of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 379j–43) is amended—

11 (1) in subsection (a)—

12 (A) by striking “2018” each place it ap-
13 pears and inserting “2023”; and

14 (B) by striking “Generic Drug User Fee
15 Amendments of 2017” each place it appears
16 and inserting “Generic Drug User Fee Amend-
17 ments of 2022”;

18 (2) in subsection (b), by striking “2018” and
19 inserting “2023”;

20 (3) in subsection (c)—

21 (A) by striking “2018” and inserting
22 “2023”; and

23 (B) by striking “Generic Drug User Fee
24 Amendments of 2017” each place it appears

1 and inserting “Generic Drug User Fee Amend-
2 ments of 2022”; and

3 (4) in subsection (f)—

4 (A) in paragraph (1), by striking “2022”
5 and inserting “2027”; and

6 (B) in paragraph (5), by striking “January
7 15, 2022” and inserting “January 15, 2027”.

8 **SEC. 304. SUNSET DATES.**

9 (a) AUTHORIZATION.—Sections 744A and 744B of
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 379j–41; 379j–42) shall cease to be effective October 1,
12 2027.

13 (b) REPORTING REQUIREMENTS.—Section 744C of
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 379j–43) shall cease to be effective January 31, 2028.

16 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
17 ber 1, 2022, subsections (a) and (b) of section 305 of the
18 FDA Reauthorization Act of 2017 (Public Law 115–52)
19 are repealed.

20 **SEC. 305. EFFECTIVE DATE.**

21 The amendments made by this title shall take effect
22 on October 1, 2022, or the date of the enactment of this
23 Act, whichever is later, except that fees under part 7 of
24 subchapter C of chapter VII of the Federal Food, Drug,
25 and Cosmetic Act shall be assessed for all abbreviated new

1 drug applications received on or after October 1, 2022,
2 regardless of the date of the enactment of this Act.

3 **SEC. 306. SAVINGS CLAUSE.**

4 Notwithstanding the amendments made by this title,
5 part 7 of subchapter C of chapter VII of the Federal Food,
6 Drug, and Cosmetic Act, as in effect on the day before
7 the date of the enactment of this title, shall continue to
8 be in effect with respect to abbreviated new drug applica-
9 tions (as defined in such part as of such day) that were
10 received by the Food and Drug Administration within the
11 meaning of section 505(j)(5)(A) of such Act (21 U.S.C.
12 355(j)(5)(A)), prior approval supplements that were sub-
13 mitted, and drug master files for Type II active pharma-
14 ceutical ingredients that were first referenced on or after
15 October 1, 2017, but before October 1, 2022, with respect
16 to assessing and collecting any fee required by such part
17 for a fiscal year prior to fiscal year 2023.

18 **TITLE IV—FEES RELATING TO**
19 **BIOSIMILAR BIOLOGICAL**
20 **PRODUCTS**

21 **SEC. 401. SHORT TITLE; FINDING.**

22 (a) **SHORT TITLE.**—This title may be cited as the
23 “Biosimilar User Fee Amendments of 2022”.

24 (b) **FINDING.**—Congress finds that the fees author-
25 ized by the amendments made in this title will be dedi-

1 cated to expediting the process for the review of biosimilar
2 biological product applications, including postmarket safe-
3 ty activities, as set forth in the goals identified for pur-
4 poses of part 8 of subchapter C of chapter VII of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51
6 et seq.), in the letters from the Secretary of Health and
7 Human Services to the Chairman of the Committee on
8 Health, Education, Labor, and Pensions of the Senate and
9 the Chairman of the Committee on Energy and Commerce
10 of the House of Representatives, as set forth in the Con-
11 gressional Record.

12 **SEC. 402. DEFINITIONS.**

13 Section 744G of the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 379j–51) is amended—

15 (1) in paragraph (1)—

16 (A) by striking “Washington-Baltimore,
17 DC–MD–VA–WV” and inserting “Washington–
18 Arlington–Alexandria, DC–VA–MD–WV”;

19 (B) by striking “October of” and inserting
20 “September of”; and

21 (C) by striking “October 2011” and insert-
22 ing “September 2011”; and

23 (2) in paragraph (4)(B)(iii)—

24 (A) by striking subclause (II); and

1 (B) by redesignating subclauses (III) and
2 (IV) as subclauses (II) and (III), respectively.

3 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR BIO-**
4 **LOGICAL PRODUCT FEES.**

5 (a) TYPES OF FEES.—Section 744H(a) of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
7 52(a)) is amended—

8 (1) in the matter preceding paragraph (1), by
9 striking “2018” and inserting “2023”;

10 (2) in paragraph (1)—

11 (A) in subparagraph (A)—

12 (i) in clause (iv)(I), by striking “5
13 days” and inserting “7 days”; and

14 (ii) in clause (v)(II), by striking “5
15 days” and inserting “7 days”;

16 (B) in subparagraph (B)—

17 (i) in clause (i), by inserting “except
18 that, in the case that such product (includ-
19 ing, where applicable, ownership of the rel-
20 evant investigational new drug application)
21 is transferred to a licensee, assignee, or
22 successor of such person, and written no-
23 tice of such transfer is provided to the Sec-
24 retary, such licensee, assignee or successor
25 shall pay the annual biosimilar biological

1 product development fee” before the pe-
2 riod;

3 (ii) in clause (iii)—

4 (I) in subclause (I), by striking
5 “; or” and inserting a semicolon;

6 (II) in subclause (II), by striking
7 the period and inserting “; or”; and

8 (III) by adding at the end the
9 following:

10 “(III) been administratively re-
11 moved from the biosimilar biological
12 product development program for the
13 product under subparagraph (E)(v).”;
14 and

15 (iii) in clause (iv), by striking “accept-
16 ed for filing on or after October 1 of such
17 fiscal year” and inserting “subsequently
18 accepted for filing”;

19 (C) in subparagraph (D)—

20 (i) in clause (i)—

21 (I) in the matter preceding sub-
22 clause (I), by striking “shall, if the
23 person seeks to resume participation
24 in such program, pay” and inserting
25 “or who has been administratively re-

1 moved from such program for a prod-
2 uct under subparagraph (E)(v) shall,
3 if the person seeks to resume partici-
4 pation in such program, pay all an-
5 nual biosimilar biological product de-
6 velopment fees previously assessed for
7 such product and still owed and”;

8 (II) in subclause (I)—

9 (aa) by striking “5 days”
10 and inserting “7 days”; and

11 (bb) by inserting “or the
12 date of administrative removal,
13 as applicable” after “discon-
14 tinued”; and

15 (III) in subclause (II), by insert-
16 ing “or the date of administrative re-
17 moval, as applicable” after “discon-
18 tinued”; and

19 (ii) in clause (ii), by inserting “except
20 that, in the case that such product (includ-
21 ing, where applicable, ownership of the rel-
22 evant investigational new drug application)
23 is transferred to a licensee, assignee, or
24 successor of such person, and written no-
25 tice of such transfer is provided to the Sec-

1 retary, such licensee, assignee or successor
2 shall pay the annual biosimilar biological
3 product development fee” before the period
4 at the end; and

5 (D) in subparagraph (E), by adding at the
6 end the following:

7 “(v) ADMINISTRATIVE REMOVAL FROM
8 THE BIOSIMILAR BIOLOGICAL PRODUCT
9 DEVELOPMENT PROGRAM.—If a person has
10 failed to pay an annual biosimilar biological
11 product development fee for a product
12 as required under subparagraph (B) for a
13 period of 2 consecutive fiscal years, the
14 Secretary may administratively remove
15 such person from the biosimilar biological
16 product development program for the prod-
17 uct. At least 30 days prior to administra-
18 tively removing a person from the bio-
19 similar biological product development pro-
20 gram for a product under this clause, the
21 Secretary shall provide written notice to
22 such person of the intended administrative
23 removal.”;

24 (3) in paragraph (2)(D), by inserting “prior to
25 approval” after “withdrawn”;

1 (4) in paragraph (3)—

2 (A) in subparagraph (A)—

3 (i) in clause (i), by striking “; and”

4 and inserting a semicolon;

5 (ii) by redesignating clause (ii) as
6 clause (iii); and

7 (iii) by inserting the following after
8 clause (i):

9 “(ii) may be dispensed only under pre-
10 scription pursuant to section 503(b); and”;

11 and

12 (B) by adding at the end the following:

13 “(E) MOVEMENT TO DISCONTINUED
14 LIST.—

15 “(i) WRITTEN REQUEST TO PLACE ON
16 DISCONTINUED LIST.—

17 “(I) IN GENERAL.—If a written
18 request to place a product on the list
19 of discontinued biosimilar biological
20 products referred to in subparagraph
21 (A)(iii) is submitted to the Secretary
22 on behalf of an applicant, and the re-
23 quest identifies the date the product
24 is, or will be, withdrawn from sale,
25 then for purposes of assessing the bio-

1 similar biological product program fee,
2 the Secretary shall consider such
3 product to have been included on such
4 list on the later of—

5 “(aa) the date such request
6 was received; or

7 “(bb) if the product will be
8 withdrawn from sale on a future
9 date, such future date when the
10 product is withdrawn from sale.

11 “(II) WITHDRAWN FROM SALE
12 DEFINED.—For purposes of this
13 clause, a product shall be considered
14 withdrawn from sale once the appli-
15 cant has ceased its own distribution of
16 the product, whether or not the appli-
17 cant has ordered recall of all pre-
18 viously distributed lots of the product,
19 except that a routine, temporary
20 interruption in supply shall not render
21 a product withdrawn from sale.

22 “(ii) PRODUCTS REMOVED FROM DIS-
23 CONTINUED LIST.—If a biosimilar biologi-
24 cal product that is identified in a bio-
25 similar biological product application ap-

1 proved as of October 1 of a fiscal year ap-
2 pears, as of October 1 of such fiscal year,
3 on the list of discontinued biosimilar bio-
4 logical products referred to in subpara-
5 graph (A)(iii), and on any subsequent day
6 during such fiscal year the biosimilar bio-
7 logical product does not appear on such
8 list, except as provided in subparagraph
9 (D), each person who is named as the ap-
10 plicant in the biosimilar biological product
11 application shall pay the annual biosimilar
12 biological product program fee established
13 for a fiscal year under subsection (c)(5) for
14 such biosimilar biological product. Not-
15 withstanding subparagraph (B), such fee
16 shall be due on the last business day of
17 such fiscal year and shall be paid only once
18 for each product for each fiscal year.”; and

19 (5) by striking paragraph (4).

20 (b) FEE REVENUE AMOUNTS.—Section 744H(b) of
21 the Federal Food, Drug, and Cosmetic Act ((21 U.S.C.
22 379j–52(b)) is amended—

23 (1) by striking paragraph (1);

24 (2) by redesignating paragraphs (2) through

25 (4) as paragraphs (1) through (3), respectively;

1 (3) in paragraph (1), as so redesignated—

2 (A) in the paragraph heading, by striking
3 “SUBSEQUENT FISCAL YEARS” and inserting
4 “IN GENERAL”;

5 (B) in the matter preceding subparagraph
6 (A), by striking “2019 through 2022” and in-
7 serting “2023 through 2027”;

8 (C) in subparagraph (A), by striking
9 “paragraph (4)” and inserting “paragraph
10 (3)”;

11 (D) by redesignating subparagraphs (C)
12 and (D) as subparagraphs (D) and (E), respec-
13 tively;

14 (E) by inserting after subparagraph (B)
15 the following:

16 “(C) the dollar amount equal to the stra-
17 tegic hiring and retention adjustment (as deter-
18 mined under subsection (c)(2));”;

19 (F) in subparagraph (D), as so redesign-
20 ated, by striking “subsection (c)(2); and” and
21 inserting “subsection (c)(3));”;

22 (G) in subparagraph (E), as so redesign-
23 ated, by striking “subsection (c)(3).” and in-
24 serting “subsection (c)(4)); and”;

25 (H) by adding at the end the following:

1 “(F) for fiscal years 2023 and 2024, addi-
2 tional dollar amounts equal to—

3 “(i) \$4,428, 886 for fiscal year 2023;

4 and

5 “(ii) \$320,569 for fiscal year 2024.”;

6 (4) in paragraph (2), as so redesignated—

7 (A) in the paragraph heading, by striking

8 “; LIMITATIONS ON FEE AMOUNTS”;

9 (B) by striking subparagraph (B); and

10 (C) by redesignating subparagraphs (C)

11 and (D) as subparagraphs (B) and (C), respec-

12 tively; and

13 (5) by amending paragraph (3), as so redesign-

14 nated, to read as follows:

15 “(3) ANNUAL BASE REVENUE.—For purposes

16 of paragraph (1), the dollar amount of the annual

17 base revenue for a fiscal year shall be—

18 “(A) for fiscal year 2023, \$43,376,922;

19 and

20 “(B) for fiscal years 2024 through 2027,

21 the dollar amount of the total revenue amount

22 established under paragraph (1) for the pre-

23 vious fiscal year, excluding any adjustments to

24 such revenue amount under subsection (c)(4).”.

1 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section
2 744H(e) of the Federal Food, Drug, and Cosmetic Act
3 ((21 U.S.C. 379j–52(e)) is amended—

4 (1) in paragraph (1)—

5 (A) in subparagraph (A)—

6 (i) in the matter preceding clause (i),
7 by striking “subsection (b)(2)(B)” and in-
8 serting “subsection (b)(1)(B)”; and

9 (ii) in clause (i), by striking “sub-
10 section (b)” and inserting “subsection
11 (b)(1)(A)”; and

12 (B) in subparagraph (B)(ii), by striking
13 “Washington-Baltimore, DC–MD–VA–WV”
14 and inserting “Washington–Arlington–Alexan-
15 dria, DC–VA–MD–WV”;

16 (2) by striking paragraph (4);

17 (3) by redesignating paragraphs (2) and (3) as
18 paragraphs (3) and (4), respectively;

19 (4) by inserting after paragraph (1) the fol-
20 lowing:

21 “(2) STRATEGIC HIRING AND RETENTION AD-
22 JUSTMENT.—For each fiscal year beginning in fiscal
23 year 2023, after the annual base revenue under sub-
24 section (b)(1)(A) is adjusted for inflation in accord-

1 ance with paragraph (1), the Secretary shall further
2 increase the fee revenue and fees by \$150,000.”;

3 (5) in paragraph (3), as so redesignated—

4 (A) in subparagraph (A)—

5 (i) by striking “Beginning with the
6 fiscal year described in subparagraph
7 (B)(ii)(II)” and inserting “For each fiscal
8 year”; and

9 (ii) by striking “adjustment under
10 paragraph (1), further increase” and in-
11 serting “adjustments under paragraphs (1)
12 and (2), further adjust”; and

13 (B) by amending subparagraph (B) to read
14 as follows:

15 “(B) METHODOLOGY.—For purposes of
16 this paragraph, the Secretary shall employ the
17 capacity planning methodology utilized by the
18 Secretary in setting fees for fiscal year 2021, as
19 described in the notice titled ‘Biosimilar User
20 Fee Rates for Fiscal Year 2021’ (85 Fed. Reg.
21 47220; August 4, 2020). The workload cat-
22 egories used in forecasting shall include only
23 the activities described in such notice and, as
24 feasible, additional activities that are also di-
25 rectly related to the direct review of biosimilar

1 biological product applications and supplements,
2 including additional formal meeting types and
3 the direct review of postmarketing commitments
4 and requirements, the direct review of risk eval-
5 uation and mitigation strategies, and the direct
6 review of annual reports for approved biosimilar
7 biological products. Subject to the exceptions in
8 the preceding sentence, the Secretary shall not
9 include as workload categories in forecasting
10 any non-core review activities, including any ac-
11 tivities that the Secretary referenced for poten-
12 tial future use in such notice but did not utilize
13 in setting fees for fiscal year 2021.”; and

14 (C) in subparagraph (C)—

15 (i) by striking “subsections (b)(2)(A)”
16 and inserting “subsections (b)(1)(A)”;

17 (ii) by striking “and (b)(2)(B)” and
18 inserting “, (b)(1)(B)”;

19 (iii) by inserting “, and (b)(1)(C) (the
20 dollar amount of the strategic hiring and
21 retention adjustment)” before the period at
22 the end;

23 (6) by amending paragraph (4), as so redesign-
24 nated, to read as follows:

25 “(4) OPERATING RESERVE ADJUSTMENT.—

1 “(A) INCREASE.—For fiscal year 2023 and
2 subsequent fiscal years, the Secretary shall, in
3 addition to adjustments under paragraphs (1),
4 (2), and (3), further increase the fee revenue
5 and fees if such an adjustment is necessary to
6 provide for at least 10 weeks of operating re-
7 serves of carryover user fees for the process for
8 the review of biosimilar biological product appli-
9 cations.

10 “(B) DECREASE.—

11 “(i) FISCAL YEAR 2023.—For fiscal
12 year 2023, if the Secretary has carryover
13 balances for the process for the review of
14 biosimilar biological product applications in
15 excess of 33 weeks of such operating re-
16 serves, the Secretary shall decrease such
17 fee revenue and fees to provide for not
18 more than 33 weeks of such operating re-
19 serves.

20 “(ii) FISCAL YEAR 2024.—For fiscal
21 year 2024, if the Secretary has carryover
22 balances for the process for the review of
23 biosimilar biological product applications in
24 excess of 27 weeks of such operating re-
25 serves, the Secretary shall decrease such

1 fee revenue and fees to provide for not
2 more than 27 weeks of such operating re-
3 serves.

4 “(iii) FISCAL YEAR 2025 AND SUBSE-
5 QUENT FISCAL YEARS.—For fiscal year
6 2025 and subsequent fiscal years, if the
7 Secretary has carryover balances for the
8 process for the review of biosimilar biologi-
9 cal product applications in excess of 21
10 weeks of such operating reserves, the Sec-
11 retary shall decrease such fee revenue and
12 fees to provide for not more than 21 weeks
13 of such operating reserves.

14 “(C) FEDERAL REGISTER NOTICE.—If an
15 adjustment under subparagraph (A) or (B) is
16 made, the rationale for the amount of the in-
17 crease or decrease (as applicable) in fee revenue
18 and fees shall be contained in the annual Fed-
19 eral Register notice under paragraph (5)(B) es-
20 tablishing fee revenue and fees for the fiscal
21 year involved.”; and

22 (7) in paragraph (5), in the matter preceding
23 subparagraph (A), by striking “2018” and inserting
24 “2023”.

1 (d) CREDITING AND AVAILABILITY OF FEES.—Sec-
2 tion 744H(f)(3) of the Federal Food, Drug, and Cosmetic
3 Act ((21 U.S.C. 379j–52(f)(3)) is amended by striking
4 “2018 through 2022” and inserting “2023 through
5 2027”.

6 (e) WRITTEN REQUESTS FOR WAIVERS AND RE-
7 FUNDS.—Subsection (h) of section 744H of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52) is
9 amended to read as follows:

10 “(h) WRITTEN REQUESTS FOR WAIVERS AND RE-
11 TURNS; DISPUTES CONCERNING FEES.—To qualify for
12 consideration for a waiver under subsection (d), or the re-
13 turn of any fee paid under this section, including if the
14 fee is claimed to have been paid in error, a person shall
15 submit to the Secretary a written request justifying such
16 waiver or return and, except as otherwise specified in this
17 section, such written request shall be submitted to the Sec-
18 retary not later than 180 days after such fee is due. A
19 request submitted under this paragraph shall include any
20 legal authorities under which the request is made.”.

21 **SEC. 404. REAUTHORIZATION; REPORTING REQUIREMENTS.**

22 Section 744I of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 379j–53) is amended—

24 (1) by striking “2018” each place it appears
25 and inserting “2023”;

1 (2) by striking “Biosimilar User Fee Amend-
2 ments of 2017” each place it appears and inserting
3 “Biosimilar User Fee Amendments of 2022”;

4 (3) in subsection (a)(4), by striking “2020” and
5 inserting “2023”; and

6 (4) in subsection (f), by striking “2022” each
7 place it appears and inserting “2027”.

8 **SEC. 405. SUNSET DATES.**

9 (a) AUTHORIZATION.—Sections 744G and 744H of
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 379j–51, 379j–52) shall cease to be effective October 1,
12 2027.

13 (b) REPORTING REQUIREMENTS.—Section 744I of
14 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
15 379j–53) shall cease to be effective January 31, 2028.

16 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-
17 ber 1, 2022, subsections (a) and (b) of section 405 of the
18 FDA Reauthorization Act of 2017 (Public Law 115–52)
19 are repealed.

20 **SEC. 406. EFFECTIVE DATE.**

21 The amendments made by this title shall take effect
22 on October 1, 2022, or the date of the enactment of this
23 Act, whichever is later, except that fees under part 8 of
24 subchapter C of chapter VII of the Federal Food, Drug,
25 and Cosmetic Act (21 U.S.C. 379j–51 et seq.) shall be

1 assessed for all biosimilar biological product applications
2 received on or after October 1, 2022, regardless of the
3 date of the enactment of this Act.

4 **SEC. 407. SAVINGS CLAUSE.**

5 Notwithstanding the amendments made by this title,
6 part 8 of subchapter C of chapter VII of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.), as
8 in effect on the day before the date of the enactment of
9 this title, shall continue to be in effect with respect to bio-
10 similar biological product applications and supplements
11 (as defined in such part as of such day) that were accepted
12 by the Food and Drug Administration for filing on or after
13 October 1, 2017, but before October 1, 2022, with respect
14 to assessing and collecting any fee required by such part
15 for a fiscal year prior to fiscal year 2023.

16 **TITLE V—IMPROVING REGULA-**
17 **TION OF DRUGS AND BIO-**
18 **LOGICAL PRODUCTS**

19 **SEC. 501. ALTERNATIVES TO ANIMAL TESTING.**

20 (a) IN GENERAL.—Section 505 of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

22 (1) in subsection (i)—

23 (A) in paragraph (1)(A), by striking “pre-
24 clinical tests (including tests on animals)” and
25 inserting “nonclinical tests”; and

1 (B) in paragraph (2)(B), by striking “ani-
2 mal” and inserting “nonclinical tests”; and
3 (2) after subsection (y), by inserting the fol-
4 lowing:

5 “(z) NONCLINICAL TEST DEFINED.—For purposes
6 of this section, the term ‘nonclinical test’ means a test con-
7 ducted in vitro, in silico, or in chemico, or a non-human
8 in vivo test that occurs before or during the clinical trial
9 phase of the investigation of the safety and effectiveness
10 of a drug, and may include animal tests, or non-animal
11 or human biology-based test methods, such as cell-based
12 assays, microphysiological systems, or computer models.”.

13 (b) BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-
14 TIONS.—Item (bb) of section 351(k)(2)(A)(i)(I) of the
15 Public Health Service Act (42 U.S.C. 262(k)(2)(A)(i)(I))
16 is amended to read as follows:

17 “(bb) an assessment of tox-
18 icity (which may rely on, or con-
19 sist of, a study or studies de-
20 scribed in item (aa) or (cc));
21 and”.

22 **SEC. 502. SAFER DISPOSAL OF OPIOIDS.**

23 Section 505–1(e)(4)(B) of the Federal Food, Drug,
24 and Cosmetic Act (21 U.S.C. 355–1(e)(4)(B)) is amended
25 by striking “for purposes of rendering drugs nonretriev-

1 able (as defined in section 1300.05 of title 21, Code of
2 Federal Regulations (or any successor regulation))”.

3 **SEC. 503. CLARIFICATIONS TO EXCLUSIVITY PROVISIONS**
4 **FOR FIRST INTERCHANGEABLE BIOSIMILAR**
5 **BIOLOGICAL PRODUCTS.**

6 Section 351(k)(6) of the Public Health Service Act
7 (42 U.S.C. 262(k)(6)) is amended—

8 (1) in the matter preceding subparagraph (A)—

9 (A) by striking “Upon review of” and in-
10 sserting “The Secretary shall not make licensure
11 as an interchangeable biological product effec-
12 tive with respect to”;

13 (B) by striking “relying on” and inserting
14 “that relies on”; and

15 (C) by striking “the Secretary shall not
16 make a determination under paragraph (4) that
17 the second or subsequent biological product is
18 interchangeable for any condition of use”; and

19 (2) in the flush text that follows subparagraph
20 (C), by striking the period and inserting “, and the
21 term ‘first interchangeable biosimilar biological prod-
22 uct’ means any interchangeable biosimilar biological
23 product that is approved on the first day on which
24 such a product is approved as interchangeable with
25 the reference product.”.

1 **SEC. 504. IMPROVEMENTS TO THE PURPLE BOOK.**

2 (a) IN GENERAL.—Section 506I of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 356i) is amended—

4 (1) in subsection (a)—

5 (A) by striking “The holder of an applica-
6 tion approved under subsection (c) or (j) of sec-
7 tion 505” and inserting “The holder of an ap-
8 plication approved under subsection (c) or (j) of
9 section 505 of this Act or subsection (a) or (k)
10 of section 351 of the Public Health Service
11 Act”;

12 (B) in paragraph (2), by inserting “(in the
13 case of a biological product, the proper name)”
14 after “established name”; and

15 (C) in paragraph (3), by striking “or ab-
16 breviated application number” and inserting “,
17 abbreviated application number, or biologics li-
18 cense application number”; and

19 (2) in subsection (b)—

20 (A) in the matter preceding paragraph (1),
21 by striking “The holder of an application ap-
22 proved under subsection (c) or (j)” and insert-
23 ing “The holder of an application approved
24 under subsection (c) or (j) of section 505 of
25 this Act or subsection (a) or (k) of section 351
26 of the Public Health Service Act”;

1 (B) in paragraph (1), by inserting “(in the
2 case of a biological product, the proper name)”
3 after “established name”; and

4 (C) in paragraph (2), by striking “or ab-
5 breviated application number” and inserting “,
6 abbreviated application number, or biologics li-
7 cense application number”.

8 (b) ADDITIONAL ONE-TIME REPORT.—Subsection
9 (c) of section 506I of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 356i) is amended to read as follows:

11 “(c) ADDITIONAL ONE-TIME REPORT.—Within 180
12 days of the date of enactment of the Food and Drug Ad-
13 ministration Safety and Landmark Advancements Act of
14 2022, all holders of applications approved under sub-
15 section (a) or (k) of section 351 of the Public Health Serv-
16 ice Act shall review the information in the list published
17 under section 351(k)(9)(A) and shall submit a written no-
18 tice to the Secretary—

19 “(1) stating that all of the application holder’s
20 biological products in the list published under sec-
21 tion 351(k)(9)(A) that are not listed as discontinued
22 are available for sale; or

23 “(2) including the information required pursu-
24 ant to subsection (a) or (b), as applicable, for each
25 of the application holder’s biological products that

1 are in the list published under section 351(k)(9)(A)
2 and not listed as discontinued, but have been discon-
3 tinued from sale or never have been available for
4 sale.”.

5 (c) PURPLE BOOK.—Section 506I of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 356i) is amend-
7 ed—

8 (1) in subsection (d)—

9 (A) by striking “or (c), the Secretary” and
10 inserting “or (c)—

11 “(1) the Secretary”;

12 (B) by striking the period at the end, and
13 inserting “; and”; and

14 (C) by adding at the end the following:

15 “(2) the Secretary may identify the application
16 holder’s biological products as discontinued in the
17 list published under section 351(k)(9)(A) of the
18 Public Health Service Act, except that the Secretary
19 shall remove from the list in accordance with section
20 351(k)(9)(B) of such Act any biological product for
21 which a license has been revoked or suspended for
22 reasons of safety, purity, or potency.”; and

23 (2) in subsection (e)—

24 (A) by inserting after the first sentence the
25 following: “The Secretary shall update the list

1 published under section 351(k)(9)(A) of the
2 Public Health Service Act based on information
3 provided under subsections (a), (b), and (c) by
4 identifying as discontinued biological products
5 that are not available for sale, except that any
6 biological product for which the license has been
7 revoked or suspended for reasons of safety, pu-
8 rity, or potency shall be removed from the list
9 in accordance with section 351(k)(9)(B) of the
10 Public Health Service Act.”; and

11 (B) in the last sentence—

12 (i) by striking “updates to the list”
13 and inserting “updates to the lists pub-
14 lished under section 505(j)(7)(A) of this
15 Act and section 351(k)(9)(A) of the Public
16 Health Service Act”; and

17 (ii) by striking “update the list” and
18 inserting “update such lists”.

19 **SEC. 505. THERAPEUTIC EQUIVALENCE EVALUATIONS.**

20 Section 505(j)(7)(A) of the Federal Food, Drug, and
21 Cosmetic Act (21 U.S.C. 355(j)(7)(A)) is amended by
22 adding at the end the following:

23 “(v)(I) With respect to an application submitted pur-
24 suant to subsection (b)(2) for a drug that is subject to
25 section 503(b) for which the sole difference from a listed

1 drug relied upon in the application is a difference in inac-
2 tive ingredients not permitted under clause (iii) or (iv) of
3 section 314.94(a)(9) of title 21, Code of Federal Regula-
4 tions (or successor regulations), the Secretary shall make
5 an evaluation with respect to whether such drug is a thera-
6 peutic equivalent (as defined in section 314.3 of title 21,
7 Code of Federal Regulations (or any successor regula-
8 tions)) to another approved drug product in the prescrip-
9 tion drug product section of the list under this paragraph
10 as follows:

11 “(aa) With respect to such an application sub-
12 mitted after the date of enactment of the Food and
13 Drug Administration Safety and Landmark Ad-
14 vancements Act of 2022, the evaluation shall be
15 made with respect to a listed drug relied upon in the
16 application under subsection (b)(2) that is a phar-
17 maceutical equivalent (as defined in section 314.3 of
18 title 21, Code of Federal Regulations (or any suc-
19 cessor regulations)) to the drug in the application
20 under subsection (b)(2) at the time of approval of
21 such application or not later than 180 days after the
22 date of such approval, provided that the request for
23 such a determination is made in the original applica-
24 tion (or in a resubmission to a complete response
25 letter), and all necessary data and information are

1 submitted in the original application (or in a resub-
2 mission in response to a complete response letter)
3 for the therapeutic equivalence evaluation, including
4 information to demonstrate bioequivalence, in a form
5 and manner prescribed by the Secretary.

6 “(bb) With respect to such an application sub-
7 mitted prior to the date of enactment of the Food
8 and Drug Administration Safety and Landmark Ad-
9 vancements Act of 2022, with respect to an applica-
10 tion approved on or after the date of enactment of
11 such Act, the evaluation shall be made not later
12 than 180 days after receipt of a request for a thera-
13 peutic equivalence evaluation submitted as part of a
14 supplement to such application; or with respect to an
15 application that was not approved as of the date of
16 enactment of such Act, the evaluation shall be made
17 not later than 180 days after the date of approval
18 of such application if a request for such evaluation
19 is submitted to the application, provided that—

20 “(AA) such request for a therapeutic
21 equivalent evaluation is being sought with re-
22 spect to a listed drug relied upon in the applica-
23 tion, and the relied upon listed drug is in the
24 prescription drug product section of the list
25 under this paragraph and is a pharmaceutical

1 equivalent (as defined in section 314.3 of title
2 21, Code of Federal Regulations (or any suc-
3 cessor regulations)) to the drug for which a
4 therapeutic equivalence evaluation is sought;
5 and

6 “(BB) the initial submission containing
7 such request, or the relevant application, in-
8 cludes all necessary data and information for
9 the therapeutic equivalence evaluation, includ-
10 ing information to demonstrate bioequivalence,
11 in a form and manner prescribed by the Sec-
12 retary.

13 “(II) When the Secretary makes an evaluation under
14 subclause (I), the Secretary shall, in revisions made to the
15 list pursuant to clause (ii), include such information for
16 such drug.”.

17 **SEC. 506. MODERNIZING ACCELERATED APPROVAL.**

18 (a) IN GENERAL.—Section 506(c) of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 356(c)) is
20 amended—

21 (1) in paragraph (2)—

22 (A) by redesignating subparagraphs (A)
23 and (B) as clauses (i) and (ii), respectively, and
24 adjusting the margins accordingly;

1 (B) by striking “Approval of a product”
2 and inserting the following:

3 “(A) IN GENERAL.—Approval of a prod-
4 uct”;

5 (C) in clause (i) of such subparagraph (A),
6 as so redesignated, by striking “appropriate
7 postapproval studies” and inserting “an appro-
8 priate postapproval study or studies (which may
9 be augmented or supported by real world evi-
10 dence)”; and

11 (D) by adding at the end the following:

12 “(B) STUDIES NOT REQUIRED.—If the
13 Secretary does not require that the sponsor of
14 a product approved under accelerated approval
15 conduct a postapproval study under this para-
16 graph, the Secretary shall publish on the
17 website of the Food and Drug Administration
18 the rationale for why such study is not appro-
19 priate or necessary.

20 “(C) POSTAPPROVAL STUDY CONDI-
21 TIONS.—Not later than the time of approval of
22 a product under accelerated approval, the Sec-
23 retary shall specify the conditions for a post-
24 approval study or studies required to be con-
25 ducted under this paragraph with respect to

1 such product, which may include enrollment
2 targets, the study protocol, and milestones, in-
3 cluding the target date of study completion.

4 “(D) STUDIES BEGUN BEFORE AP-
5 PROVAL.—The Secretary may require such
6 study or studies to be underway prior to ap-
7 proval.”; and

8 (2) in paragraph (3)—

9 (A) by redesignating subparagraphs (A)
10 through (D) as clauses (i) through (iv), respec-
11 tively and adjusting the margins accordingly;

12 (B) by striking “The Secretary may” and
13 inserting the following:

14 “(A) IN GENERAL.—The Secretary may”;

15 (C) in clause (i) of such subparagraph (A),
16 as so redesignated, by striking “drug with due
17 diligence” and inserting “product with due dili-
18 gence, including with respect to conditions spec-
19 ified by the Secretary under paragraph (2)(C)”;

20 (D) in clause (iii) of such subparagraph
21 (A), as so redesignated, by inserting “shown to
22 be” after “product is not”; and

23 (E) by adding at the end the following:

24 “(B) EXPEDITED PROCEDURES DE-
25 SCRIBED.—Expedited procedures described in

1 this subparagraph shall consist of, prior to the
2 withdrawal of accelerated approval—

3 “(i) providing the sponsor with—

4 “(I) due notice;

5 “(II) an explanation for the pro-
6 posed withdrawal;

7 “(III) an opportunity for a meet-
8 ing with the Commissioner or the
9 Commissioner’s designee; and

10 “(IV) an opportunity for written
11 appeal to—

12 “(aa) the Commissioner; or

13 “(bb) a designee of the
14 Commissioner who has not par-
15 ticipated in the proposal with-
16 drawal of approval (other than a
17 meeting pursuant to subclause
18 (III)) and is not subordinate of
19 an individual (other than the
20 Commissioner) who participated
21 in such proposed withdrawal;

22 “(ii) providing an opportunity for
23 public comment on the proposing to with-
24 drawal approval;

1 “(iii) the publication of a summary of
2 the public comments received, and the Sec-
3 retary’s response to such comments, on the
4 website of the Food and Drug Administra-
5 tion; and

6 “(iv) convening and consulting an ad-
7 visory committee on issues related to the
8 proposed withdrawal, if requested by the
9 sponsor and if no such advisory committee
10 has previously advised the Secretary on
11 such issues with respect to the withdrawal
12 of the product prior to the sponsor’s re-
13 quest.”.

14 (b) REPORTS OF POSTMARKETING STUDIES.—Sec-
15 tion 506B of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 356b(a)) is amended—

17 (1) by redesignating paragraph (2) as para-
18 graph (3); and

19 (2) by inserting after paragraph (1) the fol-
20 lowing:

21 “(2) ACCELERATED APPROVAL.—Notwith-
22 standing paragraph (1), a sponsor of a drug ap-
23 proved under accelerated approval shall submit to
24 the Secretary a report of the progress of any study
25 required under section 506(c), including progress to-

1 ward enrollment targets, milestones, and other infor-
2 mation as required by the Secretary, not later than
3 180 days after the approval of such drug and not
4 less frequently than every 180 days thereafter, until
5 the study is completed or terminated.”.

6 (c) ENFORCEMENT.—Section 301 of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 331), as
8 amended by section 824, is further amended by adding
9 at the end the following:

10 “(l) The failure of a sponsor of a product approved
11 under accelerated approval pursuant to section 506(c)—

12 “(1) to conduct with due diligence any post-
13 approval study required under section 506(c) with
14 respect to such product; or

15 “(2) to submit timely reports with respect to
16 such product in accordance with section
17 506B(a)(2).”.

18 (d) GUIDANCE.—

19 (1) IN GENERAL.—The Secretary of Health and
20 Human Services shall issue guidance describing—

21 (A) how sponsor questions related to the
22 identification of novel surrogate or intermediate
23 clinical endpoints may be addressed in early-
24 stage development meetings with the Food and
25 Drug Administration;

1 (B) the use of novel clinical trial designs
2 that may be used to conduct appropriate post-
3 approval studies as may be required under sec-
4 tion 506(c)(2)(A) of the Federal Food, Drug,
5 and Cosmetic Act, as amended by subsection
6 (a);

7 (C) the expedited procedures described in
8 section 506(e)(3)(B) of the Federal Food,
9 Drug, and Cosmetic Act; and

10 (D) considerations related to the use of
11 surrogate or intermediate clinical endpoints
12 that may support the accelerated approval of an
13 application under 506(e)(1)(A), including con-
14 siderations in evaluating the evidence related to
15 any such endpoints.

16 (2) FINAL GUIDANCE.—The Secretary shall
17 issue—

18 (A) a draft guidance under paragraph (1)
19 not later than 18 months after the date of en-
20 actment of this Act; and

21 (B) final guidance not later than 1 year
22 after the close of the public comment period on
23 such draft guidance.

24 (e) RARE DISEASE ENDPOINT ADVANCEMENT
25 PILOT.—

1 (1) IN GENERAL.—The Secretary of Health and
2 Human Services shall establish a pilot program
3 under which the Secretary will establish procedures
4 to provide increased interaction with sponsors of
5 rare disease drug development programs for pur-
6 poses of advancing the development of efficacy
7 endpoints, including surrogate and intermediate
8 endpoints, for drugs intended to treat rare diseases,
9 including through—

10 (A) determining eligibility of participants
11 for such program; and

12 (B) developing and implementing a process
13 for applying to, and participating in, such a
14 program.

15 (2) PUBLIC WORKSHOPS.—The Secretary shall
16 conduct up to 3 public workshops, which shall be
17 completed not later than September 30, 2026, to
18 discuss topics relevant to the development of
19 endpoints for rare diseases, which may include dis-
20 cussions about—

21 (A) novel endpoints developed through the
22 pilot program established under this subsection;
23 and

24 (B) as appropriate, the use of real world
25 evidence and real work data to support the vali-

1 dation of efficacy endpoints, including surrogate
2 and intermediate endpoints, for rare diseases.

3 (3) REPORT.—Not later than September 30,
4 2027, the Secretary shall submit to the Committee
5 on Energy and Commerce of the House of Rep-
6 resentatives and the Committee on Health, Edu-
7 cation, Labor, and Pensions of the Senate a report
8 describing the outcomes of the pilot program estab-
9 lished under this subsection.

10 (4) GUIDANCE.—Not later than September 30,
11 2027, the Secretary shall issue guidance describing
12 best practices and strategies for development of effi-
13 cacy endpoints, including surrogate and intermediate
14 endpoints, for rare diseases.

15 (5) SUNSET.—The Secretary may not accept
16 any new application or request to participate in the
17 program established by this subsection on or after
18 October 1, 2027.

19 (f) ACCELERATED APPROVAL COUNCIL.—

20 (1) GENERAL.—Not later than 180 days after
21 the date of enactment of this Act, the Secretary of
22 Health and Human Services shall establish an intra-
23 agency coordinating council within the Food and
24 Drug Administration to ensure the consistent and
25 appropriate use of accelerated approval across the

1 Food and Drug Administration, pursuant to section
2 506(c) of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 356(c)).

4 (2) MEMBERSHIP.—The members of the Coun-
5 cil shall consist of the following senior officials, or
6 a designee of such official, from the Food and Drug
7 Administration and relevant Centers:

8 (A) The Director of the Center for Drug
9 Evaluation and Research.

10 (B) The Director of the Center for Bio-
11 logics Evaluation and Research.

12 (C) The Director of the Oncology Center
13 of Excellence.

14 (D) The Director of the Office of New
15 Drugs.

16 (E) The Director of the Office of Orphan
17 Products Development.

18 (F) The Director of the Office of Tissues
19 and Advanced Therapies.

20 (G) The Director of the Office of Medical
21 Policy.

22 (H) At least 3 directors of review division
23 overseeing products approved under accelerated
24 approval, including at least one director of a re-
25 view division within the Office of Neuroscience.

1 (3) DUTIES OF THE COUNCIL.—

2 (A) MEETINGS.—The Council shall con-
3 vene not fewer than 3 times per calendar year
4 to discuss issues related to accelerated approval,
5 including any relevant cross-disciplinary ap-
6 proaches related to product review with respect
7 to accelerated approval.

8 (B) POLICY DEVELOPMENT.—The Council
9 shall directly engage with product review teams
10 to support the consistent and appropriate use of
11 accelerated approval across the Food and Drug
12 Administration. Such activities may include—

13 (i) developing guidance for Food and
14 Drug Administration staff and best prac-
15 tices for, and across, product review teams,
16 including with respect to communication
17 between sponsors and the Food and Drug
18 Administration and the review of products
19 under accelerated approval;

20 (ii) providing training for product re-
21 view teams; and

22 (iii) advising review divisions on prod-
23 uct-specific development, review, and with-
24 drawal of products under accelerated ap-
25 proval.

1 (4) PUBLICATION OF A REPORT.—Not later
 2 than 1 year after the date of enactment of this Act,
 3 and annually thereafter, the council shall publish on
 4 the public website of the Food and Drug Adminis-
 5 tration a report on the activities of the council.

6 (g) RULE OF CONSTRUCTION.—Nothing in this sec-
 7 tion (including the amendments made by this section)
 8 shall be construed to affect products approved under
 9 506(c) of the Federal Food, Drug, and Cosmetic Act (21
 10 U.S.C. 356(c)) prior to the date of enactment of this Act.

11 **TITLE VI—OTHER** 12 **REAUTHORIZATIONS**

13 **SEC. 601. REAUTHORIZATION OF THE CRITICAL PATH PUB-** 14 **LIC-PRIVATE PARTNERSHIP.**

15 Section 566(f) of the Federal Food, Drug, and Cos-
 16 metic Act (21 U.S.C. 360bbb–5(f)) is amended by striking
 17 “2018 through 2022” and inserting “2023 through
 18 2027”.

19 **SEC. 602. REAUTHORIZATION OF THE BEST PHARMA-** 20 **CEUTICALS FOR CHILDREN PROGRAM.**

21 Section 409I(d)(1) of the Public Health Service Act
 22 (42 U.S.C. 284m(d)(1)) is amended by striking “2018
 23 through 2022” and inserting “2023 through 2027”.

1 **SEC. 603. REAUTHORIZATION OF THE HUMANITARIAN DE-**
2 **VICE EXEMPTION INCENTIVE.**

3 Section 520(m)(6)(A)(iv) of the Federal Food, Drug,
4 and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is
5 amended by striking “2022” and inserting “2027”.

6 **SEC. 604. REAUTHORIZATION OF THE PEDIATRIC DEVICE**
7 **CONSORTIA PROGRAM.**

8 Section 305(e) of the Food and Drug Administration
9 Amendments Act of 2007 (Public Law 110–85; 42 U.S.C.
10 282 note) is amended by striking “\$5,250,000 for each
11 of fiscal years 2018 through 2022” and inserting
12 “\$7,000,000 for each of fiscal years 2023 through 2027”.

13 **SEC. 605. REAUTHORIZATION OF PROVISION PERTAINING**
14 **TO DRUGS CONTAINING SINGLE**
15 **ENANTIOMERS.**

16 Section 505(u) of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 355(u)) is amended by—

18 (1) in paragraph (1)(A)(ii)(II), by adding
19 “(other than bioavailability studies)” after “any clin-
20 ical investigations”; and

21 (2) in paragraph (4), by striking “October 1,
22 2022” and inserting “October 1, 2027”.

23 **SEC. 606. REAUTHORIZATION OF ORPHAN DRUG GRANTS.**

24 Section 5(c) of the Orphan Drug Act (21 U.S.C.
25 360ee(c)) is amended by striking “2018 through 2022”
26 and inserting “2023 through 2027”.

1 **SEC. 607. REAUTHORIZATION OF CERTAIN DEVICE INSPEC-**
 2 **TIONS.**

3 Section 704(g)(11) of the Federal Food, Drug, and
 4 Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by strik-
 5 ing “2022” and inserting “2027”.

6 **TITLE VII—ENHANCING FDA**
 7 **HIRING AUTHORITIES**

8 **SEC. 701. ENHANCING FDA HIRING AUTHORITY FOR SCI-**
 9 **ENTIFIC, TECHNICAL, AND PROFESSIONAL**
 10 **PERSONNEL.**

11 Section 714A of the Federal Food, Drug, and Cos-
 12 metic Act (21 U.S.C. 379d–3a) is amended—

13 (1) in subsection (a)—

14 (A) by inserting “, including cross-cutting
 15 operational positions,” after “professional posi-
 16 tions”; and

17 (B) by inserting “and the regulation of
 18 food” after “medical products”; and

19 (2) in subsection (d)(1)—

20 (A) in the matter preceding subparagraph

21 (A)—

22 (i) by striking “the 21st Century
 23 Cures Act” and inserting “the Food and
 24 Drug Administration Safety and Land-
 25 mark Advancements Act of 2022”; and

1 (ii) by striking “that examines the ex-
2 tent” and all that follows through “, in-
3 cluding” and inserting “that addresses”;

4 (B) in subparagraph (A)—

5 (i) by inserting “updated” before
6 “analysis”; and

7 (ii) by striking “; and” and inserting
8 a semicolon;

9 (C) by redesignating subparagraph (B) as
10 subparagraph (C);

11 (D) by inserting after subparagraph (A)
12 the following:

13 “(B) an analysis of how the Secretary has
14 used the authorities provided under this section,
15 and a plan for how the Secretary will use the
16 authority under this section, and other applica-
17 ble hiring authorities, for employees of the
18 Food and Drug Administration; and”;

19 (E) in subparagraph (C), as so redesign-
20 ated, by striking “a recruitment” and insert-
21 ing “an updated recruitment”.

22 **SEC. 702. STRATEGIC WORKFORCE PLAN AND REPORT.**

23 Chapter VII of the Federal Food, Drug, and Cos-
24 metic Act (21 U.S.C. 371 et seq.) is amended by inserting
25 after section 714A the following:

1 **“SEC. 714B. STRATEGIC WORKFORCE PLAN AND REPORT.**

2 “(a) IN GENERAL.—Not later than September 30,
3 2023, and at least every 4 years thereafter, the Secretary
4 shall develop and submit to the appropriate committees
5 of Congress and post on the website of the Food and Drug
6 Administration, a coordinated strategy and report to pro-
7 vide direction for the activities and programs of the Sec-
8 retary to recruit, hire, train, develop, and retain the work-
9 force needed to fulfill the public health mission of the
10 Food and Drug Administration, including to facilitate col-
11 laboration across centers, to keep pace with new bio-
12 medical, technological, and scientific advancements, and
13 support the development, review, and regulation of med-
14 ical products. Each such report shall be known as the
15 ‘Food and Drug Administration Strategic Workforce
16 Plan’.

17 “(b) USE OF THE FOOD AND DRUG ADMINISTRATION
18 STRATEGIC WORKFORCE PLAN.—Each center within the
19 Food and Drug Administration shall develop and update,
20 as appropriate, a strategic plan that will be informed by
21 the Food and Drug Administration Strategic Workforce
22 Plan developed and updated under this subsection.

23 “(c) CONTENTS OF THE FOOD AND DRUG ADMINIS-
24 TRATION STRATEGIC WORKFORCE PLAN.—Each Food
25 and Drug Administration Strategic Workforce Plan under
26 subsection (a) shall—

1 “(1) include agency-wide strategic goals and
2 priorities for recruiting, hiring, training, developing,
3 and retaining a qualified workforce for the Food and
4 Drug Administration;

5 “(2) establish specific activities the Secretary
6 will take to achieve its strategic goals and priorities
7 and address the workforce needs of the Food and
8 Drug Administration in the forthcoming fiscal years;

9 “(3) identify challenges and risks the Secretary
10 will face in meeting its strategic goals and priorities,
11 and the activities the Secretary will undertake to
12 overcome those challenges and mitigate those risks;

13 “(4) establish metrics and milestones that the
14 Secretary will use to measure progress in achieving
15 its strategic goals and priorities; and

16 “(5) define functions, capabilities, and gaps in
17 such workforce and identify strategies to recruit,
18 hire, train, develop, and retain such workforce.

19 “(d) CONSIDERATIONS.—In developing each Food
20 and Drug Administration Strategic Workforce Plan under
21 subsection (a), the Secretary shall consider—

22 “(1) the number of employees, employee exper-
23 tise, and employing center of employees, including
24 senior leadership and non-senior leadership employ-
25 ees, eligible for retirement;

1 “(2) the vacancy and turnover rates for employ-
2 ees with different types of expertise and from dif-
3 ferent centers, including any changes or trends re-
4 lated to such rates;

5 “(3) the results of the Federal Employee View-
6 point Survey for employees of the Food and Drug
7 Administration, including any changes or trends re-
8 lated to such results;

9 “(4) rates of pay for different types of posi-
10 tions, including rates for different types of expertise
11 within the same field (such as differences in pay be-
12 tween different medical specialists), and how such
13 rates of pay impact the ability of the Secretary to
14 achieve strategic goals and priorities; and

15 “(5) the statutory hiring authorities used to
16 hire Food and Drug Administration employees, and
17 the time to hire across different hiring authorities.

18 “(e) EVALUATION OF PROGRESS.—Each Food and
19 Drug Administration Strategic Workforce Plan issued
20 pursuant to subsection (a), with the exception of the first
21 such Food and Drug Administration Strategic Workforce
22 Plan, shall include an evaluation of the progress the Sec-
23 retary has made, based on the metrics, benchmarks, and
24 other milestones that measure successful recruitment, hir-
25 ing, training, development, and retention activities; and

1 whether such actions improved the capacity of the Food
2 and Drug Administration to achieve the strategic goals
3 and priorities set forth in the previous Food and Drug
4 Administration Strategic Workforce Plan.

5 “(f) ADDITIONAL CONSIDERATIONS.—The Food and
6 Drug Administration Strategic Workforce Plan issued in
7 fiscal year 2023 shall address the effect of the COVID–
8 19 pandemic on hiring, retention, and other workforce
9 challenges for the Food and Drug Administration, includ-
10 ing protecting such workforce during public health emer-
11 gencies.”.

12 **TITLE VIII—ADVANCING REGU-**
13 **LATION OF COSMETICS, DIE-**
14 **TARY SUPPLEMENTS, AND**
15 **LABORATORY DEVELOPED**
16 **TESTS**

17 **Subtitle A—Cosmetics**

18 **SEC. 801. SHORT TITLE.**

19 This subtitle may be cited as the “Modernization of
20 Cosmetics Regulation Act of 2022”.

21 **SEC. 802. AMENDMENTS TO COSMETIC REQUIREMENTS.**

22 Chapter VI of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 361 et seq.) is amended by adding at the
24 end the following:

1 **“SEC. 604. DEFINITIONS.**

2 “In this chapter:

3 “(1) ADVERSE EVENT.—The term ‘adverse
4 event’ means any health-related event associated
5 with the use of a cosmetic product that is adverse.

6 “(2) COSMETIC PRODUCT.—The term ‘cosmetic
7 product’ means a preparation of cosmetic ingredi-
8 ents with a qualitatively and quantitatively set com-
9 position for use in a finished product.

10 “(3) FACILITY.—

11 “(A) IN GENERAL.—The term ‘facility’ in-
12 cludes any establishment (including an estab-
13 lishment of an importer) that manufactures or
14 processes cosmetic products distributed in the
15 United States.

16 “(B) Such term does not include any of
17 the following:

18 “(i) Beauty shops and salons, unless
19 such establishment manufactures or proc-
20 esses cosmetic products at that location.

21 “(ii) Cosmetic product retailers, in-
22 cluding individual sales representatives, di-
23 rect sellers, retail distribution facilities,
24 and pharmacies, unless such establishment
25 manufactures or processes cosmetic prod-

1 ucts that are not sold directly to con-
2 sumers at that location.

3 “(iii) Hospitals, physicians’ offices,
4 and health care clinics.

5 “(iv) Public health agencies and other
6 nonprofit entities that provide cosmetic
7 products directly to the consumer.

8 “(v) Entities (such as hotels and air-
9 lines) that provide complimentary cosmetic
10 products to customers incidental to other
11 services.

12 “(vi) Trade shows and other venues
13 where cosmetic product samples are pro-
14 vided free of charge.

15 “(vii) An establishment that manufac-
16 tures or processes cosmetic products that
17 are solely for use in research or evaluation,
18 including for production testing and not of-
19 fered for retail sale.

20 “(viii) An establishment that solely
21 performs one or more of the following with
22 respect to cosmetic products:

23 “(I) Labeling.

24 “(II) Relabeling.

25 “(III) Packaging.

1 “(IV) Repackaging.

2 “(V) Holding.

3 “(VI) Distributing.

4 “(C) CLARIFICATION.—For the purposes
5 of subparagraph (B)(viii), the terms ‘packaging’
6 and ‘repackaging’ do not include filling a prod-
7 uct container with a cosmetic product.

8 “(4) RESPONSIBLE PERSON.—The term ‘re-
9 sponsible person’ means the manufacturer, packer,
10 or distributor of a cosmetic product whose name ap-
11 pears on the label of such cosmetic product in ac-
12 cordance with section 609(a) of this Act or section
13 4(a) of the Fair Packaging and Labeling Act.

14 “(5) SERIOUS ADVERSE EVENT.—The term ‘se-
15 rious adverse event’ means an adverse event that—

16 “(A) results in—

17 “(i) death;

18 “(ii) a life-threatening experience;

19 “(iii) inpatient hospitalization;

20 “(iv) a persistent or significant dis-
21 ability or incapacity;

22 “(v) a congenital anomaly or birth de-
23 fect; or

24 “(vi) significant disfigurement (includ-
25 ing serious and persistent rashes or infec-

1 tions, second- or third-degree burns, sig-
2 nificant hair loss, or permanent or signifi-
3 cant alteration of appearance), other than
4 as intended, under conditions of use that
5 are customary or usual; or

6 “(B) requires, based on reasonable medical
7 judgment, a medical or surgical intervention to
8 prevent an outcome described in subparagraph
9 (A).

10 **“SEC. 605. ADVERSE EVENTS.**

11 “(a) SERIOUS ADVERSE EVENT REPORTING RE-
12 QUIREMENTS.—The responsible person shall submit to the
13 Secretary any report received of a serious adverse event
14 associated with the use, in the United States, of a cosmetic
15 product manufactured, packed, or distributed by such per-
16 son.

17 “(b) SUBMISSION OF REPORTS.—

18 “(1) SERIOUS ADVERSE EVENT REPORT.—The
19 responsible person shall submit to the Secretary a
20 serious adverse event report accompanied by a copy
21 of the label on or within the retail packaging of such
22 cosmetic product no later than 15 business days
23 after the report is received by the responsible per-
24 son.

1 “(2) NEW MEDICAL INFORMATION.—The re-
2 sponsible person shall submit to the Secretary any
3 new and material medical information, related to a
4 serious adverse event report submitted to the Sec-
5 retary in accordance with paragraph (1), that is re-
6 ceived by the responsible person within 1 year of the
7 initial report to the Secretary, no later than 15 busi-
8 ness days after such information is received by such
9 responsible person.

10 “(3) CONSOLIDATION OF REPORTS.—The Sec-
11 retary shall develop systems to enable responsible
12 persons to submit a single report that includes du-
13 plicate reports of, or new medical information re-
14 lated to, a serious adverse event.

15 “(c) EXEMPTIONS.—The Secretary may establish by
16 regulation an exemption to any of the requirements of this
17 section if the Secretary determines that such exemption
18 would have no significant adverse effect on public health.

19 “(d) CONTACT INFORMATION.—The responsible per-
20 son shall receive reports of adverse events through the do-
21 mestic address, domestic telephone number, or electronic
22 contact information included on the label in accordance
23 with section 609(a).

24 “(e) MAINTENANCE AND INSPECTION OF ADVERSE
25 EVENT RECORDS.—

1 “(1) MAINTENANCE.—The responsible person
2 shall maintain records related to each report of an
3 adverse event associated with the use, in the United
4 States, of a cosmetic product manufactured or dis-
5 tributed by such person received by such person, for
6 a period of 6 years.

7 “(2) INSPECTION.—

8 “(A) IN GENERAL.— The responsible per-
9 son shall permit an authorized person to have
10 access to records required to be maintained
11 under this section during an inspection pursu-
12 ant to section 704.

13 “(B) AUTHORIZED PERSON.—For pur-
14 poses of this paragraph, the term ‘authorized
15 person’ means an officer or employee of the De-
16 partment of Health and Human Services who
17 has—

18 “(i) appropriate credentials, as deter-
19 mined by the Secretary; and

20 “(ii) been duly designated by the Sec-
21 retary to have access to the records re-
22 quired under this section.

23 “(f) FRAGRANCE AND FLAVOR INGREDIENTS.—If
24 the Secretary has reasonable grounds to believe that an
25 ingredient or combination of ingredients in a fragrance or

1 flavor has caused or contributed to a serious adverse event
2 required to be reported under this section, the Secretary
3 may request in writing a complete list of ingredients in
4 the specific fragrances or flavors in the cosmetic product,
5 from the responsible person. The responsible person shall
6 ensure that the requested information is submitted to the
7 Secretary within 30 days of such request. Information
8 submitted to the Secretary under this subsection that is
9 confidential commercial or trade secret information shall
10 be exempt from disclosure under section 552 of title 5,
11 United States Code.

12 “(g) PROTECTED INFORMATION.—A serious adverse
13 event report submitted to the Secretary under this section,
14 including any new medical information submitted under
15 subsection (a)(2), or an adverse event report, or any new
16 information, voluntarily submitted to the Secretary shall
17 be considered to be—

18 “(1) a safety report under section 756 and may
19 be accompanied by a statement, which shall be a
20 part of any report that is released for public disclo-
21 sure, that denies that the report or the records con-
22 stitute an admission that the product involved
23 caused or contributed to the adverse event; and

24 “(2) a record about an individual under section
25 552a of title 5, United States Code (commonly re-

1 ferred to as the ‘Privacy Act of 1974’) and a med-
2 ical or similar file the disclosure of which would con-
3 stitute a violation of section 552 of such title 5
4 (commonly referred to as the ‘Freedom of Informa-
5 tion Act’), and shall not be publicly disclosed unless
6 all personally identifiable information is redacted.

7 “(h) EFFECT OF SECTION.—

8 “(1) IN GENERAL.—Nothing in this section
9 shall affect the authority of the Secretary to provide
10 adverse event reports and information to any health,
11 food, or drug officer or employee of any State, terri-
12 tory, or political subdivision of a State or territory,
13 under a memorandum of understanding between the
14 Secretary and such State, territory, or political sub-
15 division.

16 “(2) PERSONALLY IDENTIFIABLE INFORMA-
17 TION.—Notwithstanding any other provision of law,
18 personally identifiable information in adverse event
19 reports provided by the Secretary to any health,
20 food, or drug officer or employee of any State, terri-
21 tory, or political subdivision of a State or territory,
22 shall not—

23 “(A) be made publicly available pursuant
24 to any State or other law requiring disclosure
25 of information or records; or

1 “(B) otherwise be disclosed or distributed
2 to any party without the written consent of the
3 Secretary and the person submitting such infor-
4 mation to the Secretary.

5 “(3) USE OF REPORTS.—Nothing in this sec-
6 tion shall permit a State, territory, or political sub-
7 division of a State or territory, to use any safety re-
8 port received from the Secretary in a manner incon-
9 sistent with this section.

10 “(4) RULE OF CONSTRUCTION.—The submis-
11 sion of any report in compliance with this section
12 shall not be construed as an admission that the cos-
13 metic product involved caused or contributed to the
14 relevant adverse event.

15 **“SEC. 606. GOOD MANUFACTURING PRACTICE.**

16 “(a) IN GENERAL.—The Secretary shall by regula-
17 tion establish good manufacturing practices for facilities
18 that are consistent, to the extent practicable, and appro-
19 priate, with national and international standards, in ac-
20 cordance with section 601. Any such regulations shall be
21 intended to protect the public health and ensure that cos-
22 metic products are not adulterated. Such regulations may
23 allow for the Secretary to inspect records necessary to
24 demonstrate compliance with good manufacturing prac-

1 tices prescribed by the Secretary under this paragraph
2 during an inspection conducted under section 704.

3 “(b) CONSIDERATIONS.—In establishing regulations
4 for good manufacturing practices under this section, the
5 Secretary shall take into account the size and scope of the
6 businesses engaged in the manufacture of cosmetics, and
7 the risks to public health posed by such cosmetics, and
8 provide sufficient flexibility to be practicable for all sizes
9 and types of facilities to which such regulations will apply.
10 Such regulations shall include simplified good manufac-
11 turing practice requirements for smaller businesses, as ap-
12 propriate, to ensure that such regulations do not impose
13 undue economic hardship for smaller businesses, and may
14 include longer compliance times for smaller businesses.
15 Before issuing regulations to implement subsection (a),
16 the Secretary shall consult with cosmetics manufacturers,
17 including smaller businesses, consumer organizations, and
18 other experts selected by the Secretary.

19 “(c) TIMEFRAME.—The Secretary shall publish a no-
20 tice of proposed rulemaking not later than 2 years after
21 the date of enactment of the Modernization of Cosmetics
22 Regulation Act of 2022 and shall publish a final such rule
23 not later than 3 years after such date of enactment.

24 **“SEC. 607. REGISTRATION AND PRODUCT LISTING.**

25 “(a) SUBMISSION OF REGISTRATION.—

1 “(1) INITIAL REGISTRATION.—

2 “(A) EXISTING FACILITIES.—Every person
3 that, on the date of enactment of the Mod-
4 ernization of Cosmetics Regulation Act of 2022,
5 owns or operates a facility that engages in the
6 manufacturing or processing of a cosmetic
7 product for distribution in the United States
8 shall register each facility with the Secretary
9 not later than 1 year after date of enactment
10 of such Act.

11 “(B) NEW FACILITIES.—Every person that
12 owns or operates a facility that first engages,
13 after the date of enactment of the Moderniza-
14 tion of Cosmetics Regulation Act of 2022, in
15 manufacturing or processing of a cosmetic
16 product for distribution in the United States,
17 shall register with the Secretary such facility
18 within 60 days of first engaging in such activity
19 or 60 days after the deadline for registration
20 under subparagraph (A), whichever is later.

21 “(2) BIENNIAL RENEWAL OF REGISTRATION.—

22 A person required to register a facility under para-
23 graph (1) shall renew such registrations with the
24 Secretary biennially.

1 “(3) CONTRACT MANUFACTURERS.—If a facility
2 manufactures or processes cosmetic products on be-
3 half of a responsible person, the Secretary shall re-
4 quire only a single registration for such facility even
5 if such facility is manufacturing or processing its
6 own cosmetic products or cosmetic products on be-
7 half of more than one responsible person. Such sin-
8 gle registration may be submitted to the Secretary
9 by such facility or any responsible person whose
10 products are manufactured or processed at such fa-
11 cility.

12 “(4) UPDATES TO CONTENT.—A person that is
13 required to register under subsection (a)(1) shall no-
14 tify the Secretary within 60 days of any changes to
15 information required under subsection (b)(2).

16 “(5) ABBREVIATED RENEWAL REGISTRA-
17 TIONS.—The Secretary shall provide for an abbrevi-
18 ated registration renewal process for any person
19 that owns or operates a facility that has not been re-
20 quired to submit updates under paragraph (4) for a
21 registered facility since submission of the most re-
22 cent registration of such facility under paragraph
23 (1) or (2).

24 “(b) FORMAT; CONTENTS OF REGISTRATION.—

1 “(1) IN GENERAL.—Registration information
2 under this section may be submitted at such time
3 and in such manner as the Secretary may prescribe.

4 “(2) CONTENTS.—The registration under sub-
5 section (a) shall contain—

6 “(A) the facility’s name, physical address,
7 email address, and telephone number;

8 “(B) with respect to any foreign facility,
9 the contact for the United States agent of the
10 facility, and, if available, the electronic contact
11 information;

12 “(C) the facility registration number, if
13 any, previously assigned by the Secretary under
14 subsection (d);

15 “(D) all brand names under which cos-
16 metic products manufactured or processed in
17 the facility are sold; and

18 “(E) the product category or categories
19 and responsible person for each cosmetic prod-
20 uct manufactured or processed at the facility.

21 “(c) COSMETIC PRODUCT LISTING.—

22 “(1) IN GENERAL.—For each cosmetic product,
23 the responsible person shall submit, or ensure is sub-
24 mitted, to the Secretary a cosmetic product listing,

1 at such time and in such manner as the Secretary
2 may prescribe.

3 “(2) COSMETIC PRODUCT LISTING.—The re-
4 sponsible person of a cosmetic product that is mar-
5 keted on the date of enactment of the Modernization
6 of Cosmetics Regulation Act of 2022 shall submit to
7 the Secretary a cosmetic product listing not later
8 than 1 year after the date of enactment of the Mod-
9 ernization of Cosmetics Regulation Act of 2022, or
10 for a cosmetic product that is first marketed after
11 the date of enactment of such Act, within 120 days
12 of marketing such product in interstate commerce.
13 Thereafter, any updates to such listing shall be
14 made annually, consistent with paragraphs (4) and
15 (5).

16 “(3) ABBREVIATED RENEWAL.—The Secretary
17 shall provide for an abbreviated process for the re-
18 newal of any cosmetic product listing under this sub-
19 section with respect to which there has been no
20 change since the responsible person submitted the
21 previous listing.

22 “(4) CONTENTS OF LISTING.—

23 “(A) IN GENERAL.—Each such cosmetic
24 product listing shall include—

1 “(i) the facility registration number of
2 each facility where the cosmetic product is
3 manufactured or processed;

4 “(ii) the name and contact number of
5 the responsible person and the name for
6 the cosmetic product, as such name ap-
7 pears on the label;

8 “(iii) the applicable cosmetic category
9 or categories for the cosmetic product;

10 “(iv) a list of ingredients in the cos-
11 metic product, including any fragrances,
12 flavors, or colors, with each ingredient
13 identified by the name adopted in regula-
14 tions promulgated by the Secretary, if any,
15 or by the common or usual name of the in-
16 gredient; and

17 “(v) the product listing number, if
18 any previously assigned by the Secretary
19 under subsection (d).

20 “(B) FLEXIBLE LISTINGS.—A single list-
21 ing submission for a cosmetic product may in-
22 clude multiple cosmetic products with identical
23 formulations, or formulations that differ only
24 with respect to colors, fragrances or flavors, or
25 quantity of contents.

1 “(5) UPDATES TO CONTENT.—A responsible
2 person that is required to submit a cosmetic product
3 listing shall submit any updates to such cosmetic
4 product listing annually.

5 “(6) SUBMISSION.—A responsible person may
6 submit product listing information as part of a facil-
7 ity registration or separately.

8 “(d) FACILITY REGISTRATION AND PRODUCT LIST-
9 ING NUMBERS.—At the time of the initial registration of
10 any facility under subsection (a)(1) or initial listing of any
11 cosmetic product under (c)(1), the Secretary shall assign
12 a facility registration number to the facility and a product
13 listing number to each cosmetic product. The Secretary
14 shall not make such product listing number publicly avail-
15 able.

16 “(e) CONFIDENTIALITY.—Information submitted to
17 the Secretary under this section that is confidential com-
18 mercial or trade secret information shall be exempt from
19 disclosure under section 552 of title 5, United States
20 Code, including all information submitted under sub-
21 section (b)(2)(D) or (c)(4)(A)(i).

22 “(f) SUSPENSIONS.—

23 “(1) SUSPENSION OF REGISTRATION OF A FA-
24 CILITY.—The Secretary may suspend the registra-
25 tion of a facility if the Secretary determines that a

1 cosmetic product manufactured or processed by a
2 registered facility and distributed in the United
3 States has a reasonable probability of causing seri-
4 ous adverse health consequences or death to humans
5 and the Secretary has a reasonable belief that other
6 products manufactured or processed by the facility
7 may be similarly affected because of a failure that
8 cannot be isolated to a product or products, or is
9 sufficiently pervasive to raise concerns about other
10 products manufactured in the facility.

11 “(2) NOTICE OF SUSPENSION.—Before sus-
12 pending a facility registration under this section, the
13 Secretary shall provide—

14 “(A) notice to the facility registrant of the
15 cosmetic product or other responsible person, as
16 appropriate, of the intent to suspend the facility
17 registration, which shall specify the basis of the
18 determination by the Secretary that the facility
19 should be suspended; and

20 “(B) an opportunity, within 5 business
21 days of the notice provided under subparagraph
22 (A), for the responsible person to provide a plan
23 for addressing the reasons for possible suspen-
24 sion of the facility registration.

1 “(3) HEARING ON SUSPENSION.—The Secretary
2 shall provide the registrant subject to an order
3 under paragraph (1) or (2) with an opportunity for
4 an informal hearing, to be held as soon as possible
5 but not later than 5 business days after the issuance
6 of the order, or such other time period agreed upon
7 by the Secretary and the registrant, on the actions
8 required for reinstatement of registration and why
9 the registration that is subject to the suspension
10 should be reinstated. The Secretary shall reinstate a
11 registration if the Secretary determines, based on
12 evidence presented, that adequate grounds do not
13 exist to continue the suspension of the registration.

14 “(4) POST-HEARING CORRECTIVE ACTION
15 PLAN.—If, after providing opportunity for an infor-
16 mal hearing under paragraph (3), the Secretary de-
17 termines that the suspension of registration remains
18 necessary, the Secretary shall require the registrant
19 to submit a corrective action plan to demonstrate
20 how the registrant plans to correct the conditions
21 found by the Secretary. The Secretary shall review
22 such plan not later than 14 business days after the
23 submission of the corrective action plan or such
24 other time period as determined by the Secretary, in
25 consultation with the registrant.

1 “(5) VACATING OF ORDER; REINSTATEMENT.—
2 Upon a determination by the Secretary that ade-
3 quate grounds do not exist to continue the suspen-
4 sion actions, the Secretary shall promptly vacate the
5 suspension and reinstate the registration of the facil-
6 ity.

7 “(6) EFFECT OF SUSPENSION.—If the registra-
8 tion of the facility is suspended under this section,
9 no person shall introduce or deliver for introduction
10 into commerce in the United States cosmetic prod-
11 ucts from such facility.

12 “(7) NO DELEGATION.—The authority con-
13 ferred by this section to issue an order to suspend
14 a registration or vacate an order of suspension shall
15 not be delegated to any officer or employee other
16 than the Commissioner.

17 **“SEC. 608. SAFETY SUBSTANTIATION.**

18 “(a) SUBSTANTIATION OF SAFETY.—A responsible
19 person for a cosmetic product shall ensure, and maintain
20 records supporting, that there is adequate substantiation
21 of safety of such cosmetic product.

22 “(b) COAL-TAR HAIR DYE.—Subsection (a) shall not
23 apply to coal-tar hair dye that otherwise complies with the
24 requirements of section 601(a). A responsible person for

1 a coal-tar hair dye shall maintain records related to the
2 safety of such product.

3 “(c) DEFINITIONS.—For purposes of this section:

4 “(1) ADEQUATE SUBSTANTIATION OF SAFE-
5 TY.—The term ‘adequate substantiation of safety’
6 means tests or studies, research, analyses, or other
7 evidence or information that is considered, among
8 experts qualified by scientific training and experi-
9 ence to evaluate the safety of cosmetic products and
10 their ingredients, sufficient to support a reasonable
11 certainty that a cosmetic product is safe.

12 “(2) SAFE.—The term ‘safe’ means that the
13 cosmetic product, including any ingredient thereof,
14 is not injurious to users under the conditions of use
15 prescribed in the labeling thereof, or under such con-
16 ditions of use as are customary or usual. The Sec-
17 retary shall not consider a cosmetic ingredient or
18 cosmetic product injurious to users solely because it
19 can cause minor and transient reactions or minor
20 and transient skin irritations in some users. In de-
21 termining for purposes of this section whether a cos-
22 metic product is safe, the Secretary may consider, as
23 appropriate and available, the cumulative or other
24 relevant exposure to the cosmetic product, including
25 any ingredient thereof.

1 **“SEC. 609. LABELING.**

2 “(a) GENERAL REQUIREMENT.—Each cosmetic prod-
3 uct shall bear a label that includes a domestic address,
4 domestic phone number, or electronic contact information,
5 which may include a website, through which the respon-
6 sible person can receive adverse event reports with respect
7 to such cosmetic product.

8 “(b) FRAGRANCE ALLERGENS.—The responsible per-
9 son shall identify on the label of a cosmetic product each
10 fragrance allergen included in such cosmetic product. Sub-
11 stances that are fragrance allergens for purposes of this
12 subsection shall be determined by the Secretary by regula-
13 tion. The Secretary shall issue a notice of proposed rule-
14 making promulgating the regulation implementing this re-
15 quirement not later than 18 months after the date of en-
16 actment of the Modernization of Cosmetics Regulation Act
17 of 2022, and not later than 180 days after the date on
18 which the public comment period on the proposed rule-
19 making closes, shall issue a final rulemaking. In promul-
20 gating regulations implementing this subsection, the Sec-
21 retary shall consider international, State, and local re-
22 quirements for allergen disclosure, including the substance
23 and format of requirements in the European Union, and
24 may establish threshold levels of amounts of substances
25 subject to disclosure pursuant to such regulations.

1 “(c) COSMETIC PRODUCTS FOR PROFESSIONAL
2 USE.—

3 “(1) DEFINITION OF PROFESSIONAL.—For pur-
4 poses of this subsection, the term ‘professional’
5 means an individual who is licensed by an official
6 State authority to practice in the field of cosme-
7 tology, nail care, barbering, or esthetics.

8 “(2) PROFESSIONAL USE LABELING.—A cos-
9 metic product introduced into interstate commerce
10 and intended to be used only by a professional shall
11 bear a label that—

12 “(A) contains a clear and prominent state-
13 ment that the product shall be administered or
14 used only by licensed professionals; and

15 “(B) is in conformity with the require-
16 ments of the Secretary for cosmetics labeling
17 under this Act and section 4(a) of the Fair
18 Packaging and Labeling Act.

19 **“SEC. 610. RECORDS.**

20 “(a) IN GENERAL.—If the Secretary has a reasonable
21 belief that a cosmetic product, including an ingredient in
22 such cosmetic product, and any other cosmetic product
23 that the Secretary reasonably believes is likely to be af-
24 fected in a similar manner, is likely to be adulterated such
25 that the use or exposure to such product presents a threat

1 of serious adverse health consequences or death to hu-
2 mans, each responsible person and facility shall, at the re-
3 quest of an officer or employee duly designated by the Sec-
4 retary, permit such officer or employee, upon presentation
5 of appropriate credentials and a written notice to such
6 person, at reasonable times and within reasonable limits
7 and in a reasonable manner, to have access to and copy
8 all records relating to such cosmetic product, and to any
9 other cosmetic product that the Secretary reasonably be-
10 lieves is likely to be affected in a similar manner, that
11 are needed to assist the Secretary in determining whether
12 the cosmetic product is adulterated and presents a threat
13 of serious adverse health consequences or death to hu-
14 mans. This subsection shall not be construed to extend
15 to recipes or formulas for cosmetics, financial data, pricing
16 data, personnel data (other than data as to qualification
17 of technical and professional personnel performing func-
18 tions subject to this Act), research data (other than safety
19 substantiation data for cosmetic products and their ingre-
20 dients), or sales data (other than shipment data regarding
21 sales).

22 “(b) PROTECTION OF SENSITIVE INFORMATION.—
23 The Secretary shall take appropriate measures to ensure
24 that there are in effect effective procedures to prevent the
25 unauthorized disclosure of any trade secret or confidential

1 information that is obtained by the Secretary pursuant to
2 this section.

3 “(c) **RULE OF CONSTRUCTION.**—Nothing in this sec-
4 tion shall be construed to limit the authority of the Sec-
5 retary to inspect records or require establishment and
6 maintenance of records under any other provision of this
7 Act, including section 605 or 606.

8 **“SEC. 611. MANDATORY RECALL AUTHORITY.**

9 “(a) **IN GENERAL.**—If the Secretary determines that
10 there is a reasonable probability that a cosmetic is adulter-
11 ated under section 601 or misbranded under section 602
12 and the use of or exposure to such cosmetic will cause
13 serious adverse health consequences or death, the Sec-
14 retary shall provide the responsible person with an oppor-
15 tunity to voluntarily cease distribution and recall such ar-
16 ticle. If the responsible person refuses to or does not vol-
17 untarily cease distribution or recall such cosmetic within
18 the time and manner prescribed by the Secretary (if so
19 prescribed), the Secretary may, by order, require, as the
20 Secretary deems necessary, such person to immediately
21 cease distribution of such article.

22 “(b) **HEARING.**—The Secretary shall provide the re-
23 sponsible person who is subject to an order under sub-
24 section (a) with an opportunity for an informal hearing,
25 to be held not later than 10 days after the date of issuance

1 of the order, on whether adequate evidence exists to justify
2 the order.

3 “(c) ORDER RESOLUTION.—After an order is issued
4 according to the process under subsections (a) and (b),
5 the Secretary shall, except as provided in subsection (d)—

6 “(1) vacate the order, if the Secretary deter-
7 mines that inadequate grounds exist to support the
8 actions required by the order;

9 “(2) continue the order ceasing distribution of
10 the cosmetic until a date specified in such order; or

11 “(3) amend the order to require a recall of the
12 cosmetic, including any requirements to notify ap-
13 propriate persons, a timetable for the recall to occur,
14 and a schedule for updates to be provided to the
15 Secretary regarding such recall.

16 “(d) ACTION FOLLOWING ORDER.—Any person who
17 is subject to an order pursuant to paragraph (2) or (3)
18 of subsection (c) shall immediately cease distribution of
19 or recall, as applicable, the cosmetic and provide notifica-
20 tion as required by such order.

21 “(e) NOTICE TO PERSONS AFFECTED.—If the Sec-
22 retary determines necessary, the Secretary may require
23 the person subject to an order pursuant to subsection (a)
24 or an amended order pursuant to paragraph (2) or (3)
25 of subsection (c) to provide either a notice of a recall order

1 for, or an order to cease distribution of, such cosmetic,
2 as applicable, under this section to appropriate persons,
3 including persons who manufacture, distribute, import, or
4 offer for sale such product that is the subject of an order
5 and to the public.

6 “(f) PUBLIC NOTIFICATION.—In conducting a recall
7 under this section, the Secretary shall—

8 “(1) ensure that a press release is published re-
9 garding the recall, and that alerts and public notices
10 are issued, as appropriate, in order to provide notifi-
11 cation—

12 “(A) of the recall to consumers and retail-
13 ers to whom such cosmetic was, or may have
14 been, distributed; and

15 “(B) that includes, at a minimum—

16 “(i) the name of the cosmetic subject
17 to the recall;

18 “(ii) a description of the risk associ-
19 ated with such article; and

20 “(iii) to the extent practicable, infor-
21 mation for consumers about similar cos-
22 metics that are not affected by the recall;
23 and

24 “(2) ensure publication, as appropriate, on the
25 website of the Food and Drug Administration of an

1 image of the cosmetic that is the subject of the press
2 release described in paragraph (1), if available.

3 “(g) NO DELEGATION.—The authority conferred by
4 this section to order a recall or vacate a recall order shall
5 not be delegated to any officer or employee other than the
6 Commissioner.

7 “(h) EFFECT.—Nothing in this section shall affect
8 the authority of the Secretary to request or participate
9 in a voluntary recall, or to issue an order to cease distribu-
10 tion or to recall under any other provision of this chapter.

11 **“SEC. 612. SMALL BUSINESSES.**

12 “(a) IN GENERAL.—Responsible persons, and owners
13 and operators of facilities, whose average gross annual
14 sales in the United States of cosmetic products for the
15 previous 3-year period is less than \$1,000,000, adjusted
16 for inflation, and who do not engage in the manufacturing
17 or processing of the cosmetic products described in sub-
18 section (b), shall be considered small businesses and not
19 subject to the requirements of section 606 or 607.

20 “(b) REQUIREMENTS APPLICABLE TO ALL MANU-
21 FACTURERS AND PROCESSORS OF COSMETICS.—The ex-
22 emptions under subsection (a) shall not apply to any re-
23 sponsible person or facility engaged in the manufacturing
24 or processing of any of the following products:

1 “(1) Cosmetic products that regularly come into
2 contact with mucus membrane of the eye under con-
3 ditions of use that are customary or usual.

4 “(2) Cosmetic products that are injected.

5 “(3) Cosmetic products that are intended for
6 internal use.

7 “(4) Cosmetic products that are intended to
8 alter appearance for more than 24 hours under con-
9 ditions of use that are customary or usual and re-
10 moval by the consumer is not part of such conditions
11 of use that are customary or usual.

12 **“SEC. 613. EXEMPTION FOR CERTAIN PRODUCTS AND FA-**
13 **CILITIES.**

14 “(a) IN GENERAL.—Notwithstanding any other pro-
15 vision of law, except as provided in subsection (b), a cos-
16 metic product or facility that is also subject to the require-
17 ments of chapter V shall be exempt from the requirements
18 of sections 605, 606, 607, 608, 609(a), 610, and 611.

19 “(b) EXCEPTION.—A facility described in subsection
20 (a) that also manufactures or processes cosmetic products
21 that are not subject to the requirements of chapter V shall
22 not be exempt from the requirements of sections 605, 606,
23 607, 608, 609(a), 610, and 611, with respect to such cos-
24 metic products.

1 **“SEC. 614. PREEMPTION.**

2 “(a) IN GENERAL.—No State or political subdivision
3 of a State may establish or continue in effect any law,
4 regulation, order, or other requirement for cosmetics that
5 is different from or in addition to, or otherwise not iden-
6 tical with, any requirement applicable under this chapter
7 with respect to registration and product listing, good man-
8 ufacturing practice, recordkeeping, recalls, adverse event
9 reporting, or safety substantiation.

10 “(b) LIMITATION.—Nothing in the amendments to
11 this Act made by the Modernization of Cosmetics Regula-
12 tion Act of 2022 shall be construed to preempt any State
13 statute, public initiative, referendum, regulation, or other
14 State action, except as expressly provided in subsection
15 (a). Notwithstanding subsection (a), nothing in this sec-
16 tion shall be construed to prevent any State from prohib-
17 iting the use or limiting the amount of an ingredient in
18 a cosmetic product, or from continuing in effect a require-
19 ment of any State that is in effect at the time of enact-
20 ment of the Modernization of Cosmetics Regulation Act
21 of 2022 for the reporting to the State of an ingredient
22 in an cosmetic product.

23 “(c) SAVINGS.—Nothing in the amendments to this
24 Act made by the Modernization of Cosmetics Regulation
25 Act of 2022, nor any standard, rule, requirement, regula-
26 tion, or adverse event report shall be construed to modify,

1 preempt, or displace any action for damages or the liabil-
 2 ity of any person under the law of any State, whether stat-
 3 utory or based in common law.

4 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
 5 tion shall be construed to amend, expand, or limit the pro-
 6 visions under section 752.”.

7 **SEC. 803. ENFORCEMENT AND CONFORMING AMEND-**
 8 **MENTS.**

9 (a) IN GENERAL.—

10 (1) PROHIBITED ACTS.—Section 301 of the
 11 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 12 331) is amended—

13 (A) by adding at the end the following:

14 “(fff) The failure to register or submit listing infor-
 15 mation in accordance with section 607.

16 “(ggg) The refusal or failure to follow an order under
 17 section 611.”; and

18 (B) in paragraph (d), by striking “or 564”
 19 and inserting “, 564, or 607”.

20 (2) ADULTERATED PRODUCTS.—Section 601 of
 21 the Federal Food, Drug, and Cosmetic Act (21
 22 U.S.C. 361) is amended by adding at the end the
 23 following:

24 “(f) If it has been manufactured or processed under
 25 conditions that do not meet good manufacturing practice

1 regulations, as prescribed by the Food and Drug Adminis-
2 tration in accordance with section 606.

3 “(g) If it is a cosmetic product, and the cosmetic
4 product, including each ingredient in the cosmetic product,
5 does not have adequate substantiation for safety, as de-
6 fined in section 608(e).”.

7 (3) MISBRANDED COSMETICS.—Section 602(b)
8 of the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 362(b)) is amended—

10 (A) by striking “and (2)” and inserting
11 “(2)”; and

12 (B) by inserting after “numerical count”
13 the following: “; and (3) the information re-
14 quired under section 609”.

15 (4) ADVERSE EVENT REPORTING.—The Federal
16 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
17 seq.) is amended—

18 (A) in section 301(e) (21 U.S.C. 331(e))—

19 (i) by striking “564, 703” and insert-
20 ing “564, 605, 703”; and

21 (ii) by striking “564, 760” and insert-
22 ing “564, 605, 611, 760”;

23 (B) in section 301(ii) (21 U.S.C.
24 331(ii))—

1 (i) by striking “760 or 761) or” and
2 inserting “604, 760, or 761) or”; and

3 (ii) by inserting “or required under
4 section 605(a)” after “report (as defined
5 under section 760 or 761”;

6 (C) in section 801(a) (21 U.S.C. 381(a))—

7 (i) by striking “under section 760 or
8 761” and inserting “under section 605,
9 760, or 761”;

10 (ii) by striking “defined in such sec-
11 tion 760 or 761” and inserting “defined in
12 section 604, 760, or 761”;

13 (iii) by striking “of such section 760
14 or 761” and inserting “of such section
15 605, 760, or 761”; and

16 (iv) by striking “described in such
17 section 760 or 761” and inserting “de-
18 scribed in such section 605, 760, or 761”;

19 and

20 (D) in section 801(b) (21 U.S.C.
21 381(b))—

22 (i) by striking “requirements of sec-
23 tions 760 or 761,” and inserting “require-
24 ments of section 605, 760, or 761”;

1 (ii) by striking “as defined in section
2 760 or 761” and inserting “as defined in
3 section 604, 760, or 761”; and

4 (iii) by striking “with section 760 or
5 761” and inserting “with section 605, 760,
6 or 761”.

7 (b) EFFECTIVE DATE.—The amendments made by
8 subsection (a) shall take effect on the date that is 1 year
9 after the date of enactment of this Act.

10 **SEC. 804. RECORDS INSPECTION.**

11 Section 704(a)(1) of the Federal Food, Drug, and
12 Cosmetic Act (21 U.S.C. 374(a)(1)) is amended by insert-
13 ing after the second sentence the following: “In the case
14 of a facility (as defined in section 604) that manufactures
15 or processes cosmetic products, the inspection shall extend
16 to all records and other information described in sections
17 605, 606, and 610, when the standard for records inspec-
18 tion under such section applies.”.

19 **SEC. 805. TALC-CONTAINING COSMETICS.**

20 The Secretary of Health and Human Services—

21 (1) not later than one year after the date of en-
22 actment of this Act, shall promulgate proposed regu-
23 lations to establish and require standardized testing
24 methods for detecting and identifying asbestos in
25 talc-containing cosmetic products; and

1 (2) not later than 180 days after the date on
2 which the public comment period on the proposed
3 regulations closes, shall issue such final regulations.

4 **SEC. 806. PFAS IN COSMETICS.**

5 (a) IN GENERAL.—The Secretary of Health and
6 Human Services (referred to in this section as the “Sec-
7 retary”) shall assess the use of perfluoroalkyl and
8 polyfluoroalkyl substances in cosmetic products and the
9 scientific evidence regarding the safety of such use in cos-
10 metic products, including any risks associated with such
11 use. In conducting such assessment, the Secretary may,
12 as appropriate, consult with the National Center for Toxi-
13 cological Research.

14 (b) REPORT.—Not later than 2 years after enactment
15 of this Act, the Secretary shall publish on the website of
16 the Food and Drug Administration a report summarizing
17 the results of the assessment conducted under subsection
18 (a).

19 **SEC. 807. FUNDING.**

20 There is authorized to be appropriated \$14,200,000
21 for fiscal year 2023, \$25,960,000 for fiscal year 2024, and
22 \$41,890,000 for each of the fiscal years 2025 through
23 2027, for purposes of conducting the activities under this
24 subtitle (including the amendments made by this subtitle)

1 and hiring personnel required to carry out this subtitle
2 (including the amendments made by this subtitle).

3 **Subtitle B—Dietary Supplements**

4 **SEC. 811. REGULATION OF DIETARY SUPPLEMENTS.**

5 (a) IN GENERAL.—Chapter IV of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
7 ed by adding after section 403C of such Act (21 U.S.C.
8 343–3) the following:

9 **“SEC. 403D. DIETARY SUPPLEMENT LISTING REQUIRE-** 10 **MENT.**

11 “(a) IN GENERAL.—Beginning on the date specified
12 in subsection (b)(4), each dietary supplement shall be list-
13 ed with the Secretary in accordance with this section.
14 Each such listing shall include, with respect to the dietary
15 supplement, the information specified in subsection (b)(1).

16 “(b) REQUIREMENTS.—

17 “(1) IN GENERAL.—The manufacturer, packer,
18 or distributor of a dietary supplement whose name
19 (pursuant to section 403(e)(1)) appears on the label
20 of a dietary supplement marketed in the United
21 States (referred to in this section as the ‘responsible
22 person’), or if the responsible person is a foreign en-
23 tity, the United States agent of such person, shall
24 submit to the Secretary in accordance with this sec-

1 tion the following information for a dietary supple-
2 ment that is marketed:

3 “(A) Any name of the dietary supplement
4 and the statement of identity, including brand
5 name and specified flavors, if applicable.

6 “(B) The name and address of the respon-
7 sible person and the name and email address of
8 the owner, operator, or agent in charge of the
9 responsible person.

10 “(C) The name, domestic address, and
11 email address for the United States agent, if
12 the responsible person is a foreign entity.

13 “(D) The business name and mailing ad-
14 dress of all locations at which the responsible
15 person manufactures, packages, labels, or holds
16 the dietary supplement.

17 “(E) A list of all ingredients in each such
18 dietary supplement required under sections
19 101.4 and 101.36, title 21, Code of Federal
20 Regulations (or any successor regulations) to
21 appear on the label of a dietary supplement, in-
22 cluding—

23 “(i) where applicable, ingredients in a
24 proprietary blend as described in section

1 101.36(c) of title 21, Code of Federal Reg-
2 ulations (or any successor regulations);

3 “(ii) the amount per serving of each
4 listed dietary ingredient;

5 “(iii) if required by section 101.36 of
6 title 21, Code of Federal Regulations (or
7 any successor regulations), the percent of
8 the daily value of each listed dietary ingre-
9 dient; and

10 “(iv) the amount per serving of die-
11 tary ingredients within a proprietary blend.

12 “(F) The number of servings per container
13 for each container size of the identical formula-
14 tion.

15 “(G) The directions for use.

16 “(H) Warnings, notice, and safe handling
17 statements, as required by section 101.17 of
18 title 21, Code of Federal Regulations (or any
19 successor regulations).

20 “(I) Allergen statements for major food al-
21 lergens (pursuant to sections 403(w) and
22 403(x)).

23 “(J) The form of the dietary supplement
24 (such as tablets, capsules).

1 “(K) Any health claims or structure or
2 function claims.

3 “(L) The dietary supplement product list-
4 ing number for the product provided by the
5 Secretary in accordance with subsection (c) for
6 that product.

7 “(2) FORMAT.—The Secretary may require that
8 a listing submitted under paragraph (1) be sub-
9 mitted in an electronic format. Upon receipt of a
10 complete listing under paragraph (1), the Secretary
11 shall promptly notify the responsible person of the
12 receipt of such listing.

13 “(3) LISTING CONTENT.—A single listing sub-
14 mission for a dietary supplement under paragraph
15 (1) may include multiple dietary supplements with
16 identical formulations, or formulations that differ
17 only with respect to color, additives, or flavorings,
18 whether offered in a single package size or in mul-
19 tiple package sizes.

20 “(4) TIMING.—

21 “(A) IN GENERAL.—

22 “(i) DIETARY SUPPLEMENTS ON THE
23 MARKET.—In the case of a dietary supple-
24 ment that is being offered in interstate
25 commerce on or before January 1, 2024, a

1 listing for each such dietary supplement in-
2 troduced or delivered for introduction into
3 interstate commerce shall be submitted by
4 the responsible person to the Secretary
5 under this subsection not later than 18
6 months after the date of enactment of the
7 Food and Drug Administration Safety and
8 Landmark Advancements Act of 2022.

9 “(ii) NEW DIETARY SUPPLEMENTS.—

10 In the case of a dietary supplement that is
11 not being offered in interstate commerce
12 on or before January 1, 2024, a listing for
13 each such dietary supplement introduced
14 or delivered for introduction into interstate
15 commerce that has not been included in
16 any listing previously submitted by the re-
17 sponsible person to the Secretary under
18 this subsection shall be submitted to the
19 Secretary at the time of introduction into
20 interstate commerce.

21 “(B) DISCONTINUED DIETARY SUPPLE-
22 MENTS.—The responsible person shall notify
23 the Secretary within one year of the date of dis-
24 continuance of a dietary supplement required to
25 be listed with the Secretary under paragraph

1 (1) for which the responsible person has discon-
2 tinued commercial marketing.

3 “(C) CHANGES TO EXISTING LISTINGS.—

4 The responsible person shall submit to the Sec-
5 retary a change or modification to listing infor-
6 mation submitted under paragraph (1) included
7 on the label for a dietary supplement at the
8 time the dietary supplement with the change or
9 modification is introduced into interstate com-
10 merce.

11 “(5) ADDITIONAL INFORMATION.—The respon-
12 sible person shall provide upon request from the Sec-
13 retary, within 10 calendar days of such request, the
14 full business name and physical and mailing address
15 from which the responsible person receives a dietary
16 ingredient or combination of dietary ingredients that
17 the responsible person uses in the manufacture of
18 the dietary supplement or, if applicable, from which
19 the responsible person receives the dietary supple-
20 ment.

21 “(c) PRODUCT LISTING NUMBER AND DIETARY SUP-
22 PLEMENT ELECTRONIC DATABASE.—

23 “(1) DIETARY SUPPLEMENT PRODUCT LISTING
24 NUMBER.—The Secretary shall provide each dietary
25 supplement listed in accordance with subsection

1 (b)(1) a dietary supplement product listing number,
2 which may apply to multiple dietary supplements
3 with identical formulations, or formulations that dif-
4 fer only with respect to color, additives, or
5 flavorings, including dietary supplements offered in
6 a single package size or in multiple package sizes.
7 The Secretary shall provide a process for a respon-
8 sible person to reserve dietary supplement listing
9 numbers in advance of listing under subsection
10 (b)(1).

11 “(2) ELECTRONIC DATABASE.—Not later than
12 2 years after the date of enactment of the Food and
13 Drug Administration Safety and Landmark Ad-
14 vancements Act of 2022, the Secretary shall estab-
15 lish and maintain an electronic database that is pub-
16 licly available and contains information submitted
17 under subsection (b)(1) (except for the information
18 submitted under subparagraphs (D) and (E)(iv) of
19 such subsection). The Secretary shall make such in-
20 formation maintained in the electronic database pub-
21 licly searchable, including by dietary supplement
22 product listing number, and by any field of informa-
23 tion or combination of fields of information provided
24 under subsection (b)(1).

1 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
2 tion shall be construed—

3 “(1) to limit the authority of the Secretary to
4 inspect or copy records or to require the establish-
5 ment and maintenance of records under any other
6 provision of this Act; or

7 “(2) to authorize the disclosure of trade secret
8 or confidential commercial information subject to
9 section 552(b)(4) of title 5, United States Code, as
10 prohibited under section 301(j) of this Act or section
11 1905 of title 18, United States Code, including in-
12 formation provided to the Secretary under sub-
13 section (b)(1)(D) or (b)(1)(E)(iv).

14 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
15 is authorized to be appropriated \$7,498,080 for fiscal year
16 2023, and \$6,300,000 for each of fiscal years 2024
17 through 2027, for purposes of conducting the activities
18 under this section and hiring personnel required to carry
19 out this section.”.

20 (b) GUIDANCE.—Not later than 18 months after the
21 date of enactment of this Act, the Secretary of Health and
22 Human Services shall publish final guidance related to the
23 draft guidance titled, “Dietary Supplements: New Dietary
24 Ingredient Notifications and Related Issues; Revised
25 Draft Guidance for Industry; Availability” (81 Fed. Reg.

1 53486; August 12, 2016), consistent with section 403D
2 of the Federal Food, Drug, and Cosmetic Act, as added
3 by subsection (a).

4 (c) INSPECTIONS FOR CERTAIN DIETARY SUPPLE-
5 MENTS.—The Secretary of Health and Human Services
6 shall direct resources to inspections of facilities, suppliers,
7 and dietary supplement types that present a high risk to
8 public health (as identified by the Secretary).

9 (d) MISBRANDING.—Section 403 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amend-
11 ed by adding at the end the following:

12 “(z) If it is a dietary supplement for which a respon-
13 sible person is required under section 403D to file a list-
14 ing, file a change to an existing listing, or provide addi-
15 tional information to the Secretary, and such person has
16 failed to comply with any such requirements under section
17 403D with respect to such dietary supplement.”.

18 (e) NEW PROHIBITED ACT.—Section 301 of the Fed-
19 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331), as
20 amended by section 803(a), is further amended by adding
21 at the end the following:

22 “(hhh) The introduction or delivery for introduction
23 into interstate commerce of any product marketed as a
24 dietary supplement that does not meet the definition of
25 a dietary supplement under section 201(ff).

1 “(iii) The introduction or delivery for introduction
 2 into interstate commerce of a dietary supplement that has
 3 been prepared, packed, or held using the assistance of, or
 4 at the direction of, a person debarred under section 306.”.

5 **Subtitle C—In Vitro Clinical Tests**

6 **SEC. 821. SHORT TITLE; TABLE OF CONTENTS.**

7 (a) **SHORT TITLE.**—This subtitle may be cited as the
 8 “Food and Drug Administration Safety and Landmark
 9 Advancements Act of 2022” or the “VALID Act of 2022”.

10 (b) **TABLE OF CONTENTS.**—The table of contents of
 11 this subtitle is as follows:

SUBCHAPTER C—IN VITRO CLINICAL TESTS

- Sec. 821. Short title; table of contents.
- Sec. 822. Definitions.
- Sec. 823. Regulation of in vitro clinical tests.

“SUBCHAPTER J—IN VITRO CLINICAL TESTS

- “SUBCHAPTER J. In Vitro Clinical Tests
- “Sec. 587. Definitions.
- “Sec. 587A. Regulation of in vitro clinical tests.
- “Sec. 587B. Premarket review.
- “Sec. 587C. Exemptions.
- “Sec. 587D. Technology certification.
- “Sec. 587E. Mitigating measures.
- “Sec. 587F. Regulatory pathway designation.
- “Sec. 587G. Grandfathered in vitro clinical tests.
- “Sec. 587H. Advisory committees.
- “Sec. 587I. Breakthrough in vitro clinical tests.
- “Sec. 587J. Registration and listing.
- “Sec. 587K. Test design and quality requirements.
- “Sec. 587L. Labeling requirements.
- “Sec. 587M. Adverse event reporting.
- “Sec. 587N. Corrections and removals.
- “Sec. 587O. Restricted in vitro clinical tests.
- “Sec. 587P. Appeals.
- “Sec. 587Q. Accredited persons.
- “Sec. 587R. Recognized standards.
- “Sec. 587S. Investigational use.
- “Sec. 587T. Collaborative communities for in vitro clinical tests.
- “Sec. 587U. Comprehensive test information system.
- “Sec. 587V. Preemption.

“Sec. 587W. Adulteration.

“Sec. 587X. Misbranding.

“Sec. 587Y. Postmarket surveillance.

“Sec. 587Z. Electronic format for submissions.

“Sec. 587AA. Postmarket remedies.

“Sec. 587BB. Applicability.

“Sec. 587CC. Judicial review.

Sec. 824. Enforcement and other provisions.

Sec. 825. Transition.

Sec. 826. Emergency use authorization.

Sec. 827. Antimicrobial susceptibility tests.

Sec. 828. Combination products.

Sec. 829. Resources.

1 **SEC. 822. DEFINITIONS.**

2 (a) IN GENERAL.—Section 201 of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

4 (1) by adding at the end the following:

5 “(ss)(1) The term ‘in vitro clinical test’ means an ar-
6 ticle specified in subparagraph (2) that is intended by its
7 developer (as defined in section 587) to be used in the
8 collection, preparation, analysis, or in vitro clinical exam-
9 ination of specimens taken or derived from the human
10 body for the purpose of—

11 “(A) identifying or diagnosing a disease or con-
12 dition;

13 “(B) providing information for diagnosing,
14 screening, measuring, detecting, predicting,
15 prognosing, analyzing, or monitoring a disease or
16 condition, including by making a determination of
17 an individual’s state of health; or

18 “(C) selecting, monitoring, or informing ther-
19 apy or treatment for a disease or condition.

- 1 “(2) An article specified in this subparagraph is—
- 2 “(A) a test kit;
- 3 “(B) a test system;
- 4 “(C) a test protocol or laboratory test protocol;
- 5 “(D) an instrument (as defined in section
- 6 587(11));
- 7 “(E) a specimen receptacle (as defined in sec-
- 8 tion 587(17));
- 9 “(F) software, excluding software that is ex-
- 10 cluded by section 520(o) from the definition of a de-
- 11 vice under section 201(h), that—
- 12 “(i) is a component or part of another in
- 13 vitro clinical test or analyzes, processes, or in-
- 14 terprets a signal or pattern from another in
- 15 vitro clinical test; and
- 16 “(ii) does not analyze, process, or interpret
- 17 a signal, pattern, or medical image from a de-
- 18 vice; and
- 19 “(G) subject to subparagraph (3), a component
- 20 or part of a test, a test protocol, an instrument, an
- 21 article, or software described in any of clauses (A)
- 22 through (D) of such subparagraph, whether alone or
- 23 in combination, including reagents, calibrators, and
- 24 controls.

1 “(3) Notwithstanding subparagraph (2)(G), an arti-
2 cle intended to be used as a component or part of an in
3 vitro clinical test described in subparagraph (1) is ex-
4 cluded from the definition in subparagraph (1) if the arti-
5 cle consists of any of the following:

6 “(A) Blood, blood components, or human cells
7 or tissues, from the time of acquisition, donation, or
8 recovery of such article, including determination of
9 donor eligibility, as applicable, until such time as the
10 article is released as a component or part of an in
11 vitro clinical test by the establishment that collected
12 such article.

13 “(B) An article used for invasive sampling, a
14 needle, or a lancet, except to the extent such article,
15 needle, or lancet is an integral component of an arti-
16 cle for holding, storing, or transporting a specimen.

17 “(C) General purpose laboratory equipment, in-
18 cluding certain pre-analytical equipment, as deter-
19 mined by the Secretary.

20 “(D) An article used solely for personal protec-
21 tion during the administering, conducting, or other-
22 wise performing of test activities.”;

23 (2) by adding at the end of section 201(g) the
24 following:

1 “(3) The term ‘drug’ does not include an in vitro clin-
2 ical test.”; and

3 (3) in section 201(h)(1), in the matter following
4 clause (C), by striking “section 520(o)” and insert-
5 ing “section 520(o) or an in vitro clinical test”.

6 (b) EXCLUSION FROM DEFINITION OF BIOLOGICAL
7 PRODUCT.—Section 351(i)(1) of the Public Health Serv-
8 ice Act (42 U.S.C. 262(i)(1)) is amended—

9 (1) by striking “(1) The term ‘biological prod-
10 uct’ means” and inserting “(1)(A) The term ‘biologi-
11 cal product’ means”; and

12 (2) by adding at the end the following:

13 “(B) The term ‘biological product’ does not in-
14 clude an in vitro clinical test as defined in section
15 201(ss) of the Federal Food, Drug, and Cosmetic
16 Act.”.

17 (c) IN VITRO CLINICAL TEST DEFINITION.—In this
18 Act, the term “in vitro clinical test” has the meaning given
19 such term in section 201(ss) of the Federal Food, Drug,
20 and Cosmetic Act, as added by subsection (a).

21 **SEC. 823. REGULATION OF IN VITRO CLINICAL TESTS.**

22 The Federal Food, Drug, and Cosmetic Act (21
23 U.S.C. 301 et seq.) is amended—

1 (1) by amending the heading of chapter V to
2 read as follows: “**DRUGS, DEVICES, AND IN**
3 **VITRO CLINICAL TESTS**”; and

4 (2) by adding at the end of chapter V the fol-
5 lowing:

6 **“Subchapter J—In Vitro Clinical Tests**

7 **“SEC. 587. DEFINITIONS.**

8 “In this subchapter:

9 “(1) ANALYTICAL VALIDITY.—The term ‘ana-
10 lytical validity’ means, with respect to an in vitro
11 clinical test, the ability of the in vitro clinical test,
12 to identify, measure, detect, calculate, or analyze (or
13 assist in such identification, measurement, detection,
14 calculation, or analysis of) one or more analytes, bio-
15 markers, substances, or other targets intended to be
16 identified, measured, detected, calculated, or ana-
17 lyzed by the test.

18 “(2) APPLICABLE STANDARD.—The term ‘ap-
19 plicable standard’, with respect to an in vitro clinical
20 test, means a reasonable assurance of analytical and
21 clinical validity for its indications for use, and a rea-
22 sonable assurance of safety for individuals who come
23 into contact with such in vitro clinical test, except
24 that such term, with respect to specimen receptacles
25 and test instruments, means a reasonable assurance

1 of analytical validity for its indications for use and
2 safety for individuals who come into contact with
3 such specimen receptacle or test instrument.

4 “(3) CLINICAL USE.—The term ‘clinical use’
5 means the operation, application, or functioning of
6 an in vitro clinical test for the purpose for which it
7 is intended as described in section 201(ss)(1).

8 “(4) CLINICAL VALIDITY.—The term ‘clinical
9 validity’ means the ability of an in vitro clinical test
10 to achieve the purpose for which it is intended as de-
11 scribed in section 201(ss)(1).

12 “(5) COMPONENT OR PART.—The term ‘compo-
13 nent or part’ means a substance, piece, part, raw
14 material, software, firmware, labeling, or assembly,
15 including reagents, that is intended by the developer
16 to be included as an aspect of an in vitro clinical test
17 described in section 201(ss)(1).

18 “(6) DEVELOP.—The term ‘develop’, with re-
19 spect to an in vitro clinical test, means—

20 “(A) designing, validating, producing,
21 manufacturing, remanufacturing, labeling, ad-
22 vertising, propagating, or assembling an in vitro
23 clinical test;

24 “(B) modifying an in vitro clinical test, in-
25 cluding modifying the indications for use of the

1 in vitro clinical test, or modifying an article to
2 be in an in vitro clinical test; or

3 “(C) establishing a test system as de-
4 scribed or included in a test protocol developed
5 by another entity unless such test protocol is
6 listed as an in vitro clinical test in the com-
7 prehensive test information system established
8 under section 587T by that other entity.

9 “(7) DEVELOPER.—The term ‘developer’ means
10 a person who engages in development as described in
11 paragraph (6), except the term does not include a
12 laboratory that—

13 “(A) is certified by the Secretary under
14 section 353 of the Public Health Service Act;
15 and

16 “(B) assembles for use solely within that
17 laboratory, without otherwise developing, an in
18 vitro clinical test appropriately listed in the
19 comprehensive test information system estab-
20 lished under section 587T by a different person.

21 “(8) FIRST-OF-A-KIND.—The term ‘first-of-a-
22 kind’, with respect to an in vitro clinical test, means
23 that such test has any novel combination of the ele-
24 ments specified in paragraph (10) that differs from
25 in vitro clinical tests that already are legally avail-

1 able in the United States, except for such tests of-
2 fered under section 587C(a)(3), 587C(a)(4), or
3 587G.

4 “(9) HIGH-RISK.—The term ‘high-risk’, with
5 respect to an in vitro clinical test or category of in
6 vitro clinical tests, means that an undetected inac-
7 curate result from such test, or such category of
8 tests, when used as intended—

9 “(A)(i) has the substantial likelihood to re-
10 sult in serious or irreversible harm or death to
11 a patient or patients, or would otherwise cause
12 serious harm to the public health; or

13 “(ii) is reasonably likely to result in the
14 absence, significant delay, or discontinuation of
15 life-supporting or life-sustaining medical treat-
16 ment; and

17 “(B) sufficient mitigating measures are
18 not able to be established and applied to pre-
19 vent, mitigate, or detect the inaccurate result,
20 or otherwise mitigate the risk resulting from an
21 undetected inaccurate result described in sub-
22 paragraph (A), such that the test would be
23 moderate-risk or low-risk.

1 “(10) INDICATIONS FOR USE.—The term ‘indi-
2 cations for use’, with respect to an in vitro clinical
3 test, means the following elements:

4 “(A) Substance or substances measured by
5 the in vitro clinical test, such as an analyte,
6 protein, or pathogen.

7 “(B) Test method.

8 “(C) Test purpose or purposes, as de-
9 scribed in section 201(ss)(1).

10 “(D) Diseases or conditions for which the
11 in vitro clinical test is intended for use, includ-
12 ing intended patient populations.

13 “(E) Context of use, such as in a clinical
14 laboratory, in a health care facility, prescription
15 home use, over-the-counter use, or direct-to-
16 consumer testing.

17 “(11) INSTRUMENT.—

18 “(A) IN GENERAL.—The term ‘instrument’
19 means an analytical or pre-analytical instru-
20 ment.

21 “(B) ANALYTIC INSTRUMENT.—The term
22 ‘analytic instrument’ means an in vitro clinical
23 test that is hardware intended by the hardware
24 developer to be used with one or more other in
25 vitro clinical tests to generate a clinical test re-

1 sult, including software used to effectuate the
2 functionality of the hardware.

3 “(C) PRE-ANALYTICAL INSTRUMENT.—The
4 term ‘pre-analytical instrument’ means an in
5 vitro clinical test that is hardware intended by
6 the hardware’s developer solely to generate an
7 output for use exclusively with one or more ana-
8 lytical instruments as defined in subparagraph
9 (B) and which does not itself generate a clinical
10 test result. Such term may include software
11 used to effectuate the hardware’s functionality.

12 “(12) INSTRUMENT FAMILY.—The term ‘instru-
13 ment family’ means more than one instrument devel-
14 oped by the same developer for which the developer
15 demonstrates and documents, with respect to all
16 such instruments, that all—

17 “(A) have the same basic architecture, de-
18 sign, and performance characteristics;

19 “(B) have the same indications for use and
20 capabilities;

21 “(C) share the same measurement prin-
22 ciples, detection methods, and reaction condi-
23 tions, as applicable; and

1 “(D) produce the same or similar analyt-
2 ical results from samples of the same specimen
3 type or types.

4 “(13) LOW-RISK.—The term ‘low-risk’, with re-
5 spect to an in vitro clinical test or category of in
6 vitro clinical tests, means that an undetected inac-
7 curate result from such in vitro clinical test, or such
8 category of in vitro clinical tests, when used as in-
9 tended—

10 “(A) would cause only minimal or imme-
11 diately reversible harm, and would lead to only
12 a remote risk of adverse patient impact or ad-
13 verse public health impact; or

14 “(B) sufficient mitigating measures are
15 able to be established and applied such that the
16 in vitro clinical test meets the standard de-
17 scribed in subparagraph (A).

18 “(14) MITIGATING MEASURES.—The term
19 ‘mitigating measures’—

20 “(A) means controls, standards, and other
21 requirements that the Secretary determines,
22 based on evidence, are necessary—

23 “(i) for an in vitro clinical test, or a
24 category of in vitro clinical tests, to meet
25 the applicable standard; or

1 “(ii) to mitigate the risk of harm en-
2 suing from an undetected inaccurate result
3 or misinterpretation of a result; and

4 “(B) may include, as required by the Sec-
5 retary, as appropriate, applicable requirements
6 regarding labeling, conformance to performance
7 standards and consensus standards, perform-
8 ance testing, submission of clinical data, adver-
9 tising, website posting of information, clinical
10 studies, postmarket surveillance, user com-
11 prehension studies, training, and confirmatory
12 laboratory, clinical findings, or testing.

13 “(15) MODERATE-RISK.—The term ‘moderate-
14 risk’, with respect to an in vitro clinical test or cat-
15 egory of in vitro clinical tests, means that, when
16 used as intended, such test or category of tests—

17 “(A) meets the criteria specified in para-
18 graph (9) for classification as high-risk, but one
19 or more mitigating measures are able to be es-
20 tablished and applied to prevent or detect an in-
21 accurate result or otherwise sufficiently miti-
22 gate such risk, but are not sufficient such that
23 the test is low-risk; or

24 “(B)(i) an undetected inaccurate result for
25 the intended use of the test would cause only

1 non-life-threatening harm, harm that is medi-
2 cally reversible, or the absence, significant
3 delay, or discontinuation of necessary treatment
4 that is not life-supporting or life-sustaining;
5 and

6 “(ii) mitigating measures are not able to
7 be established and applied to prevent or detect
8 such inaccurate result or otherwise sufficiently
9 mitigate the risk of such inaccurate result such
10 that the test would be low-risk.

11 “(16) SPECIMEN RECEPTACLE.—The term
12 ‘specimen receptacle’ means an in vitro clinical test
13 intended for taking, collecting, holding, storing, or
14 transporting of specimens derived from the human
15 body or for in vitro examination for purposes de-
16 scribed in subparagraph (A) or (B) of section
17 201(ss)(1).

18 “(17) TECHNOLOGY.—The term ‘technology’—

19 “(A) means a set of control mechanisms,
20 energy sources, or operating principles—

21 “(i) that do not differ significantly
22 among multiple in vitro clinical tests; and

23 “(ii) for which design and develop-
24 ment (including analytical and clinical vali-
25 dation, as applicable) of the tests would be

1 addressed in a similar manner or through
2 similar procedures; and

3 “(B) may include clot detection, colorimetric (non-immunoassay), electrochemical
4 (non-immunoassay), enzymatic (non-immunoassay), flow cytometry, fluorometry
5 (non-immunoassay), immunoassay, mass spectrometry or chromatography, microbial culture,
6 next generation sequencing, nephelometric or turbidimetric (non-immunoassay), singleplex or
7 multiplex non-NGS nucleic acid analysis, slide-based technology, spectroscopy, and any other
8 technology, as the Secretary determines appropriate.
9
10
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14

15 “(18) TEST.—The term ‘test’, unless otherwise
16 provided, means an in vitro clinical test.

17 “(19) VALID SCIENTIFIC EVIDENCE.—The term
18 ‘valid scientific evidence’—

19 “(A) means, with respect to an in vitro
20 clinical test, evidence that—

21 “(i) has been generated and evaluated
22 by persons qualified by training or experience to do so, using procedures generally
23 accepted by other persons so qualified; and
24

1 “(ii) forms an appropriate basis for
2 concluding by qualified experts whether the
3 applicable standard has been met by the in
4 vitro clinical test; and

5 “(B) may include evidence described in
6 subparagraph (A) consisting of—

7 “(i) peer-reviewed literature;
8 “(ii) clinical guidelines;
9 “(iii) reports of significant human ex-
10 perience with an in vitro clinical test;

11 “(iv) bench studies;

12 “(v) case studies or histories;

13 “(vi) clinical data;

14 “(vii) consensus standards;

15 “(viii) reference standards;

16 “(ix) data registries;

17 “(x) postmarket data;

18 “(xi) real world data;

19 “(xii) clinical trials; and

20 “(xiii) data collected in countries
21 other than the United States if such data
22 are demonstrated to be appropriate for the
23 purpose of making a regulatory determina-
24 tion under this subchapter.

1 **“SEC. 587A. REGULATION OF IN VITRO CLINICAL TESTS.**

2 “(a) IN GENERAL.—No person shall introduce or de-
3 liver for introduction into interstate commerce any in vitro
4 clinical test, unless—

5 “(1) an approval of an application filed pursu-
6 ant to subsection (a) or (b) of section 587B is effec-
7 tive with respect to such in vitro clinical test;

8 “(2) a technology certification order is in effect
9 under section 587D; or

10 “(3) the test is exempt under sections 587C or
11 587G from the requirements of section 587B.

12 “(b) TRANSFER OR SALE OF IN VITRO CLINICAL
13 TESTS.—

14 “(1) TRANSFER AND ASSUMPTION OF REGU-
15 LATORY OBLIGATIONS.—If ownership of an in vitro
16 clinical test is sold or transferred in such manner
17 that the developer transfers the regulatory submis-
18 sions and obligations applicable under this sub-
19 chapter with respect to the test, the transferee or
20 purchaser becomes the developer of the test and
21 shall have all regulatory obligations applicable to
22 such a test under this subchapter. The transferee or
23 purchaser shall update the registration and listing
24 information under section 587J for the in vitro clin-
25 ical test.

1 “(2) TRANSFER OR SALE OF PREMARKET AP-
2 PROVAL.—

3 “(A) NOTICE REQUIRED.—If a developer
4 of an in vitro clinical test transfers or sells the
5 approval of the in vitro clinical test, the trans-
6 feror or seller shall—

7 “(i) submit a notice of the transfer or
8 sale to the Secretary and update the reg-
9 istration and listing information under sec-
10 tion 587J for the in vitro clinical test; and

11 “(ii) submit a supplement to an appli-
12 cation if required under section 587B(h).

13 “(B) EFFECTIVE DATE OF APPROVAL
14 TRANSFER.—A transfer or sale described in
15 subparagraph (A) shall become effective upon
16 completion of a transfer or sale described in
17 paragraph (1) or the approval of a supplement
18 to an application under section 587B(h) if re-
19 quired, whichever is later. The transferee or
20 purchaser shall update the registration and list-
21 ing information under section 587J for the in
22 vitro clinical test within 15 calendar days of the
23 effective date of the transfer or sale.

24 “(3) TRANSFER OR SALE OF TECHNOLOGY CER-
25 TIFICATION.—

1 “(A) REQUIREMENTS FOR TRANSFER OR
2 SALE OF TECHNOLOGY CERTIFICATION.—An
3 unexpired technology certification can be trans-
4 ferred or sold if the transferee or purchaser—

5 “(i) is an eligible person under section
6 587D(a)(2); and

7 “(ii) maintains, upon such transfer or
8 sale, test design and quality requirements,
9 processes and procedures under the scope
10 of technology certification, and scope of the
11 technology certification identified in the
12 applicable technology certification order.

13 “(B) NOTICE REQUIRED.—If a developer
14 of an in vitro clinical test transfers or sells a
15 technology certification order that has not ex-
16 pired, the transferor or seller shall submit a no-
17 tice of the transfer or sale to the Secretary and
18 shall update the registration and listing infor-
19 mation under section 587J for all in vitro clin-
20 ical tests covered by the technology certifi-
21 cation.

22 “(C) EFFECTIVE DATE OF TECHNOLOGY
23 CERTIFICATION TRANSFER.—The transfer of a
24 technology certification shall become effective
25 upon completion of a transfer or sale described

1 in subparagraph (A). The transferee or pur-
2 chaser shall update the registration and listing
3 information under section 587J for the in vitro
4 clinical test within 30 calendar days of the ef-
5 fective date of the technology certification
6 transfer.

7 “(D) NEW TECHNOLOGY CERTIFICATION
8 REQUIRED.—If the requirements of subpara-
9 graph (A)(ii) are not met, the technology cer-
10 tification order may not be transferred and the
11 transferee or purchaser of an in vitro clinical
12 test is required to submit an application for
13 technology certification and obtain a technology
14 certification order prior to offering the test for
15 clinical use.

16 “(c) REGULATIONS.—The Secretary may issue regu-
17 lations to implement this subchapter.

18 **“SEC. 587B. PREMARKET REVIEW.**

19 “(a) APPLICATION.—

20 “(1) FILING.—Any developer may file with the
21 Secretary an application for premarket approval of
22 an in vitro clinical test under this subsection.

23 “(2) TRANSPARENCY AND PREDICTABILITY.—If
24 a developer files a premarket application under this
25 section and provides any additional documentation

1 required under section 587D, the in vitro clinical
2 test that is the subject of the premarket application
3 may be utilized as the representative in vitro clinical
4 test reviewed by the Secretary to support a tech-
5 nology certification order under section 587D.

6 “(3) APPLICATION CONTENT.—An application
7 submitted under paragraph (1) shall include the fol-
8 lowing, in such format as the Secretary specifies:

9 “(A) General information regarding the in
10 vitro clinical test, including—

11 “(i) the name and address of the ap-
12 plicant;

13 “(ii) the table of contents for the ap-
14 plication and the identification of the infor-
15 mation the applicant claims as trade secret
16 or confidential commercial or financial in-
17 formation;

18 “(iii) a description of the test’s design
19 and intended use, including the indications
20 for use; and

21 “(iv) a description regarding test
22 function and performance characteristics.

23 “(B) A summary of the data and informa-
24 tion in the application for the in vitro clinical
25 test, including—

1 “(i) a brief description of the foreign
2 and domestic marketing history of the test,
3 if any, including a list of all countries in
4 which the test has been marketed and a
5 list of all countries in which the test has
6 been withdrawn from marketing for any
7 reason related to the ability of the in vitro
8 clinical test to meet the applicable stand-
9 ard, if known by the applicant;

10 “(ii) a description of benefit and risk
11 considerations related to the in vitro clin-
12 ical test, including a description of any ap-
13 plicable adverse effects of the test on
14 health and how such adverse effects have
15 been, or will be, mitigated;

16 “(iii) a risk assessment of the test;
17 and

18 “(iv) a description of how the data
19 and information in the application con-
20 stitute valid scientific evidence and support
21 a showing that the test meets the applica-
22 ble standard under section 587(2).

23 “(C) The signature of the developer filing
24 the premarket application or an authorized rep-
25 resentative.

1 “(D) A bibliography of applicable pub-
2 lished reports relied upon by the applicant and
3 a description of any studies conducted, includ-
4 ing any unpublished studies related to such
5 test, that are known or that should reasonably
6 be known to the applicant, and a description of
7 data and information relevant to the evaluation
8 of whether the test meets the applicable stand-
9 ard.

10 “(E) Applicable information regarding the
11 methods used in, and the facilities or controls
12 used for, the development of the test to dem-
13 onstrate compliance with the applicable quality
14 requirements under section 587K.

15 “(F) Information demonstrating compli-
16 ance with any relevant and applicable—

17 “(i) mitigating measures under sec-
18 tion 587E; and

19 “(ii) standards established or recog-
20 nized under section 514 prior to the date
21 of enactment of the VALID Act of 2022,
22 or, after applicable standards are estab-
23 lished or recognized under section 587Q,
24 with such standards.

1 “(G) Valid scientific evidence to support
2 that the test meets the applicable standard,
3 which shall include—

4 “(i) summary information for all sup-
5 porting validation studies performed, in-
6 cluding a description of the objective of the
7 study, a description of the experimental de-
8 sign of the study, a description of any limi-
9 tations of the study, a brief description of
10 how the data were collected and analyzed,
11 a brief description of the results of each
12 study, and conclusions drawn from each
13 study;

14 “(ii) new raw data for each study,
15 which may include, as applicable, tabula-
16 tions of data and results as required under
17 section 814.20(b)(6)(ii) of title 21, Code of
18 Federal Regulations (or any successor reg-
19 ulations); and

20 “(iii) for nonclinical laboratory studies
21 involving the test, if applicable, a state-
22 ment that studies were conducted in com-
23 pliance with applicable good laboratory
24 practices.

1 “(H) To the extent the application seeks
2 authorization to make modifications to the test
3 within the scope of the approval that are not
4 otherwise permitted without premarket review
5 under this subchapter, a proposed change pro-
6 tocol that includes validation procedures and
7 acceptance criteria for anticipated modifications
8 that could be made to the test within the scope
9 of the approval.

10 “(I) Proposed labeling, in accordance with
11 the requirements of section 587L.

12 “(J) Such other data or information as the
13 Secretary may require in accordance with the
14 least burdensome requirements under section
15 587AA(c).

16 “(4) GUIDANCE FOR PREMARKET AND ABBRE-
17 VIATED PREMARKET APPLICATIONS.—In accordance
18 with section 825 of the VALID Act of 2022, the
19 Secretary shall issue draft guidance detailing the in-
20 formation to be provided in a premarket application
21 and abbreviated premarket application under this
22 section. The Secretary shall issue final guidance de-
23 tailing the information to be provided in a pre-
24 market application and abbreviated premarket appli-

1 cation under this section not later than 1 year prior
2 to the effective date of such Act.

3 “(5) REFUSE TO FILE A PREMARKET OR AB-
4 BREVIATED PREMARKET APPLICATION.—The Sec-
5 retary may refuse to file an application under this
6 section only for lack of completeness or legibility of
7 the application. If, after receipt of an application
8 under this section, the Secretary refuses to file such
9 an application, the Secretary shall provide to the de-
10 veloper, within 60 calendar days of receipt of such
11 application, a description of the reason for such re-
12 fusals, and identify the information required, if any,
13 to allow for the filing of the application.

14 “(6) SUBSTANTIVE REVIEW FOR DEFICIENT AP-
15 PPLICATION.—If, after receipt of an application under
16 this section, the Secretary determines that any por-
17 tion of such application is materially deficient, the
18 Secretary shall provide to the applicant a description
19 of such material deficiencies and the information re-
20 quired to resolve such deficiencies.

21 “(7) INSPECTIONS.—With respect to an appli-
22 cation under paragraph (1), preapproval inspections
23 authorized by an employee of the Food and Drug
24 Administration or a person accredited under section

1 587Q need not occur unless requested by the Sec-
2 retary.

3 “(b) ABBREVIATED PREMARKET REVIEW.—

4 “(1) IN GENERAL.—Any developer may file
5 with the Secretary an application for abbreviated
6 premarket approval for—

7 “(A) an instrument;

8 “(B) a specimen receptacle;

9 “(C) an in vitro clinical test that is mod-
10 erate-risk; or

11 “(D) an in vitro clinical test that is deter-
12 mined by the Secretary to be eligible for abbrevi-
13 ated premarket review under section
14 587F(a)(1)(B).

15 “(2) APPLICATION CONTENT.—An application
16 under paragraph (1) shall include—

17 “(A) the information required for applica-
18 tions submitted under subsection (a)(2), except
19 that applications under paragraph (1) need not
20 include—

21 “(i) quality requirement information;

22 or

23 “(ii) raw data, unless explicitly re-
24 quested by the Secretary; and

1 “(B) data, as applicable, to support soft-
2 ware validation, electromagnetic compatibility,
3 and electrical safety, and information dem-
4 onstrating compliance with maintaining quality
5 systems documentation.

6 “(3) SAFETY INFORMATION.—The developer of
7 an in vitro clinical test specimen receptacle reviewed
8 under this subsection shall maintain safety informa-
9 tion for such specimen receptacle.

10 “(4) INSPECTIONS.—With respect to an appli-
11 cation under paragraph (1), preapproval inspections
12 authorized by an employee of the Food and Drug
13 Administration or a person accredited under section
14 587Q need not occur unless requested by the Sec-
15 retary.

16 “(c) INSTRUMENTS AND INSTRUMENT FAMILIES.—

17 “(1) IN GENERAL.—A developer of an instru-
18 ment family shall file with the Secretary an applica-
19 tion for premarket approval of one version of an in-
20 strument under this subsection. Any modified
21 versions of the instrument that generate a new in-
22 strument within the same instrument family shall be
23 exempt from premarket review requirements of this
24 section, provided that the developer of such instru-
25 ment or instrument family—

1 “(A) maintains documentation that the
2 new instrument is part of the instrument fam-
3 ily, as defined in section 587;

4 “(B) performs, documents, and maintains
5 a risk assessment (as described in subsection
6 (a)(2)(B)(iv)) of the new instrument compared
7 to the instrument approved under subsection
8 (b) and no new risks are identified;

9 “(C) performs, documents, and maintains
10 validation and verification activities for the new
11 instrument;

12 “(D) makes such documentation available
13 to the Secretary upon request; and

14 “(E) registers and lists the new instrument
15 in accordance with section 587J.

16 “(2) TEST KITS AND TEST PROTOCOLS.—A test
17 kit or test protocol that is approved under this sec-
18 tion for use on an approved instrument or an instru-
19 ment exempt from premarket review, including an
20 instrument within an instrument family under this
21 section, a submission under this section shall not be
22 required for such test kit or test protocol in order
23 for it to be used on a new instrument within its in-
24 strument family, provided that—

1 “(A) use of the test kit or test protocol
2 with the new instrument does not—

3 “(i) change the claims for the test kit
4 or test protocol, except as applicable,
5 claims regarding an instrument or instru-
6 ments that can be used with such test kit
7 or test protocol;

8 “(ii) adversely affect performance of
9 the test kit or test protocol; or

10 “(iii) cause the test kit or test pro-
11 tocol to no longer conform with perform-
12 ance standards required under section
13 587R or comply with any applicable miti-
14 gating measures under section 587E, con-
15 ditions of approval under subsection
16 (e)(2)(B), or restrictions under section
17 587O;

18 “(B) the test developer does not identify
19 any new risks for the test kit or test protocol
20 when using the new instrument;

21 “(C) the test developer validates the use of
22 the new instrument with the test kit or test
23 protocol and maintains validation documenta-
24 tion;

1 “(D) the test kit or test protocol is not in-
2 tended for use—

3 “(i) at the point of care setting or in
4 settings for which a certificate of waiver is
5 in effect under section 353 of the Public
6 Health Service Act;

7 “(ii) without a prescription;

8 “(iii) at home; or

9 “(iv) in testing donors, donations, and
10 recipients of blood, blood components,
11 human cells, tissues, cellular-based prod-
12 ucts, or tissue-based products;

13 “(E) the test developer makes the docu-
14 mentation described under subparagraph (C)
15 available to the Secretary upon request; and

16 “(F) the test developer updates the listing
17 information for the test kit or test protocol, as
18 applicable.

19 “(d) AMENDMENTS TO AN APPLICATION.—An appli-
20 cant shall amend an application submitted under sub-
21 section (a), (b), or (f) if the applicant becomes aware of
22 information that could reasonably affect an evaluation
23 under subsection (e) of whether the approval standard has
24 been met.

1 “(e) ACTION ON AN APPLICATION FOR PREMARKET
2 APPROVAL.—

3 “(1) REVIEW.—

4 “(A) DISPOSITION.—As promptly as possible,
5 but not later than 90 calendar days after
6 an application under subsection (a) is accepted
7 for submission (unless the Secretary determines
8 that an extension is necessary to review one or
9 more major amendments to the application), or
10 not later than 60 calendar days after an appli-
11 cation under subsection (b) is accepted for sub-
12 mission or a supplemental application under
13 subsection (f) is accepted for submission, the
14 Secretary, after considering any applicable re-
15 port and recommendations pursuant to advisory
16 committees under section 587H, shall issue an
17 order approving the application, unless the Sec-
18 retary finds that the grounds for approval in
19 paragraph (2) are not met.

20 “(B) RELIANCE ON PROPOSED LABEL-
21 ING.—In determining whether to approve or
22 deny an application under paragraph (1), the
23 Secretary shall rely on the indications for use
24 included in the proposed labeling, provided that

1 such labeling is not false or misleading based on
2 a fair evaluation of all material facts.

3 “(2) APPROVAL OF AN APPLICATION.—

4 “(A) IN GENERAL.—The Secretary shall
5 approve an application submitted under sub-
6 section (a) or (b) with respect to an in vitro
7 clinical test if the Secretary finds that the ap-
8 plicable standard is met, and—

9 “(i) the applicant is in compliance
10 with applicable quality requirements in sec-
11 tion 587K;

12 “(ii) the application does not contain
13 a false statement or misrepresentation of
14 material fact;

15 “(iii) based on a fair evaluation of all
16 material facts, the proposed labeling is
17 truthful and non-misleading and complies
18 with the requirements of section 587L;

19 “(iv) the applicant permits, if re-
20 quested, authorized employees of the Food
21 and Drug Administration and persons ac-
22 credited under section 587Q an oppor-
23 tunity to inspect pursuant to section 704;

24 “(v) the test conforms with any appli-
25 cable performance standards required

1 under section 587R and any applicable
2 mitigating measures under section 587E;

3 “(vi) all nonclinical laboratory studies
4 and clinical investigations involving human
5 subjects that are described in the applica-
6 tion were conducted in a manner that
7 meets the applicable requirements of this
8 subchapter; and

9 “(vii) other data and information the
10 Secretary may require under subsection
11 (a)(2)(K) support approval.

12 “(B) CONDITIONS OF APPROVAL.—An
13 order approving an application pursuant to this
14 section may require reasonable conditions of ap-
15 proval for the in vitro clinical test, which may
16 include conformance with applicable mitigating
17 measures under section 587E, restrictions
18 under section 587O, and performance standards
19 under section 587R.

20 “(C) PUBLICATION.—The Secretary shall
21 publish an order for each application approved
22 pursuant to this paragraph on the public
23 website of the Food and Drug Administration
24 and make publicly available a summary of the
25 data used to approve such application, except to

1 the extent the Secretary determines that such
2 order—

3 “(i) contains commercially confidential
4 or trade secret information; or

5 “(ii) if published, would present a risk
6 to national security.

7 “(3) REVIEW OF DENIALS.—An applicant
8 whose application submitted under this section has
9 been denied approval under this subsection may, by
10 petition filed not more than 60 calendar days after
11 the date on which the applicant receives notice of
12 such denial, obtain review of the denial in accord-
13 ance with section 587P.

14 “(f) SUPPLEMENTS TO AN APPROVED APPLICA-
15 TION.—

16 “(1) RISK ANALYSIS.—Prior to implementing
17 any modification to an in vitro clinical test, the hold-
18 er of the application approved under subsection (a)
19 or (b) for such test shall perform risk analyses in ac-
20 cordance with this subsection, unless such modifica-
21 tion is included in the change protocol submitted by
22 the applicant and approved under this section or ex-
23 empt under section 587C.

24 “(2) SUPPLEMENT REQUIREMENT.—

1 “(A) IN GENERAL.—If the holder of an ap-
2 plication of an approved in vitro clinical test
3 makes a modification to such in vitro clinical
4 test, except as provided in subparagraph (C), or
5 otherwise specified by the Secretary, the holder
6 of the application approved under subsection (e)
7 for an in vitro clinical test shall submit a sup-
8 plemental application to the Secretary. The
9 holder of the application may not implement
10 such modification to the in vitro clinical test
11 until such supplemental application is approved.
12 The information required in a supplemental ap-
13 plication is limited to what is needed to support
14 the change.

15 “(B) ADJUSTMENTS TO CHANGE PRO-
16 TOCOL.—The holder of an approved application
17 may submit under this paragraph a supple-
18 mental application to modify the change pro-
19 tocol of the test at any time after the applica-
20 tion is submitted under subsection (a) or (b).

21 “(C) EXCEPTIONS.—Notwithstanding sub-
22 paragraphs (A) and (B), and so long as the
23 holder of an approved application submitted
24 under subsection (a) or (b) for an in vitro clin-
25 ical test does not add a manufacturing site, or

1 change activities at an existing manufacturing
2 site, with respect to the test, the holder of an
3 approved application may, without submission
4 of a supplemental application, implement the
5 following modifications to the test:

6 “(i) Modifications in accordance with
7 an approved change protocol under sub-
8 section (a)(3)(H).

9 “(ii) Modifications that are exempt
10 under section 587C(b).

11 “(iii) Labeling changes that are ap-
12 propriate to address a safety concern, ex-
13 cept such labeling changes that include any
14 of the following, remain subject to sub-
15 paragraph (A):

16 “(I) A change to the indications
17 for use of the test.

18 “(II) A change to the perform-
19 ance claims made with respect to the
20 test.

21 “(III) A change that adversely
22 affects performance of the test.

23 “(D) REPORTING FOR CERTAIN MODIFICA-
24 TIONS MADE PURSUANT TO A CHANGE PRO-
25 TOCOL.—The holder of an application approved

1 under subsection (e), with an approved change
2 protocol under subsection (a)(2)(H) for such in
3 vitro clinical test shall—

4 “(i) report any modification to such
5 test made pursuant to such change pro-
6 tocol approved under subsection (a)(2)(H)
7 in a submission under section
8 587J(c)(2)(B); and

9 “(ii) include in such report—

10 “(I) a description of the modi-
11 fication;

12 “(II) the rationale for imple-
13 menting such modification; and

14 “(III) as applicable, a summary
15 of the evidence supporting that the
16 test, as modified, meets the applicable
17 standard, complies with performance
18 standards required under section
19 587Q, and complies with any miti-
20 gating measures established under
21 section 587E and any restrictions
22 under section 587O.

23 “(E) REPORTING FOR CERTAIN SAFETY
24 RELATED LABELING CHANGES.—The holder of
25 the application for an in vitro clinical test ap-

1 proved under subsection (a) or (b) pursuant to
2 subsection (e) shall—

3 “(i) report to the Secretary any modi-
4 fication to the test described in subpara-
5 graph (C)(iii) not more than 30 days after
6 the date on which the test, with the modi-
7 fications, is introduced into interstate com-
8 merce; and

9 “(ii) include in the report—

10 “(I) a description of the change
11 or changes;

12 “(II) the rationale for imple-
13 menting such change or changes; and

14 “(III) a description of how the
15 change or changes were evaluated.

16 “(3) CONTENTS OF SUPPLEMENT.—Unless oth-
17 erwise specified by the Secretary, a supplement
18 under this subsection shall include—

19 “(A) for modifications other than manufac-
20 turing site changes requiring a supplement—

21 “(i) a description of the modification;

22 “(ii) data relevant to the modification
23 to demonstrate that the applicable stand-
24 ard is met, not to exceed data require-
25 ments for the original submission;

1 “(iii) acceptance criteria; and

2 “(iv) any revised labeling; and

3 “(B) for manufacturing site changes—

4 “(i) the information listed in subpara-
5 graph (A); and

6 “(ii) information regarding the meth-
7 ods used in, or the facilities or controls
8 used for, the development of the test to
9 demonstrate compliance with the applicable
10 quality requirements under section 587K.

11 “(4) ADDITIONAL DATA.—The Secretary may
12 require, when necessary, data to evaluate a modifica-
13 tion to an in vitro clinical test that is in addition to
14 the data otherwise required under the preceding
15 paragraphs if the data request is in accordance with
16 the least burdensome requirements under section
17 587AA(c).

18 “(5) CONDITIONS OF APPROVAL.—In an order
19 approving a supplement under this subsection, the
20 Secretary may require conditions of approval for the
21 in vitro clinical test, including compliance with re-
22 strictions under section 587O and conformance to
23 performance standards under section 587R.

24 “(6) APPROVAL.—The Secretary shall approve
25 a supplement under this subsection if—

1 “(A) the data demonstrate that the modi-
2 fied in vitro clinical test meets the applicable
3 standard; and

4 “(B) the holder of the application approved
5 under subsection (e) for the test has dem-
6 onstrated compliance with applicable quality
7 and inspection requirements, as applicable and
8 appropriate.

9 “(7) PUBLICATION.—The Secretary shall pub-
10 lish on the public website of the Food and Drug Ad-
11 ministration notice of any order approving a supple-
12 ment under this subsection, except that such publi-
13 cation shall exclude—

14 “(A) commercial confidential or trade se-
15 cret information; and

16 “(B) any other information that the Sec-
17 retary determines to relate to national security
18 or countermeasures or to be restricted from dis-
19 closure pursuant to another provision of law.

20 “(8) REVIEW OF DENIAL.—An applicant whose
21 supplement under this subsection has been denied
22 approval may, by petition filed on or before the 60th
23 calendar day after the date upon which the applicant
24 receives notice of such denial, obtain review of the
25 denial in accordance with section 587P.

1 “(g) WITHDRAWAL AND TEMPORARY SUSPENSION
2 OF APPROVAL.—

3 “(1) ORDER WITHDRAWING APPROVAL.—

4 “(A) IN GENERAL.—The Secretary may,
5 after providing due notice and an opportunity
6 for an informal hearing to the holder of an ap-
7 proved application for an in vitro clinical test
8 under this section, issue an order withdrawing
9 approval of the application if the Secretary
10 finds that—

11 “(i) the grounds for approval under
12 subsection (e) are no longer met;

13 “(ii) there is a reasonable likelihood
14 that the test would cause death or serious
15 adverse health consequences, including by
16 causing the absence, significant delay, or
17 discontinuation of life-saving or life sus-
18 taining medical treatment;

19 “(iii) the holder of the approved appli-
20 cation—

21 “(I) has failed to, or repeatedly
22 or deliberately failed to, maintain
23 records to make reports, as required
24 under section 587M;

1 “(II) has refused to permit ac-
2 cess to, or copying or verification of
3 such records, as required under sec-
4 tion 704;

5 “(III) has not complied with the
6 requirements of section 587K; or

7 “(IV) has not complied with any
8 mitigating measure required under
9 section 587E or restriction under sec-
10 tion 587O; or

11 “(iv) the labeling of such in vitro clin-
12 ical test, based on a fair evaluation of all
13 material facts, is false or misleading in any
14 particular and was not corrected within a
15 reasonable time after receipt of written no-
16 tice from the Secretary of such fact.

17 “(B) CONTENT.—An order under subpara-
18 graph (A) withdrawing approval of an applica-
19 tion shall state each ground for withdrawal and
20 shall notify the holder of such application 60
21 calendar days prior to issuing such order.

22 “(C) PUBLICATION.—The Secretary shall
23 publish any order under subparagraph (A) on
24 the public website of the Food and Drug Ad-

1 ministration, except that such publication shall
2 exclude—

3 “(i) commercial confidential or trade
4 secret information; and

5 “(ii) any other information that the
6 Secretary determines, if published, would
7 present a risk to national security.

8 “(2) ORDER OF TEMPORARY SUSPENSION.—If,
9 after providing due notice and an opportunity for an
10 informal hearing to the holder of an approved appli-
11 cation for an in vitro clinical test under this section,
12 the Secretary determines, based on scientific evi-
13 dence, that there is a reasonable likelihood that the
14 in vitro clinical test would cause death or serious ad-
15 verse health consequences, such as by causing the
16 absence, significant delay, or discontinuation of life-
17 saving or life-sustaining medical treatment, the Sec-
18 retary shall, by order, temporarily suspend the ap-
19 proval of the application. If the Secretary issues
20 such an order, the Secretary shall proceed expedi-
21 tiously under paragraph (1) to withdraw approval of
22 such application.

23 “(3) APPEAL WITHDRAWING APPROVAL AND
24 ORDERS OF TEMPORARY SUSPENSIONS.—An order of

1 withdrawal or an order of temporary suspension may
2 be appealed under 587P.

3 **“SEC. 587C. EXEMPTIONS.**

4 “(a) IN GENERAL.—The following in vitro clinical
5 tests are exempt from premarket review under section
6 587B, and may be lawfully marketed subject to other ap-
7 plicable requirements of this Act:

8 “(1) TESTS EXEMPT FROM SECTION 510(k).—

9 “(A) EXEMPTION.—An in vitro clinical
10 test is exempt from premarket review under
11 section 587B and may be lawfully marketed
12 subject to the other applicable requirements of
13 this Act, if the developer of the in vitro clinical
14 test—

15 “(i) maintains documentation dem-
16 onstrating that the test meets and con-
17 tinues to meet the criteria set forth in sub-
18 paragraph (B); and

19 “(ii) makes such documentation avail-
20 able to the Secretary upon request.

21 “(B) CRITERIA FOR EXEMPTION.—An in
22 vitro clinical test is exempt as specified in sub-
23 paragraph (A) if such test—

1 “(i)(I) was offered for clinical use
2 prior to the date of enactment of the
3 VALID Act of 2022;

4 “(II) immediately prior to such date
5 of enactment was exempt pursuant to sub-
6 section (l) or (m)(2) of section 510 from
7 the requirements for submission of a re-
8 port under section 510(k); or

9 “(III)(aa) was not offered for clinical
10 use prior to such date of enactment;

11 “(bb) is not an instrument; and

12 “(cc) falls within a category of tests
13 that was exempt from the requirements for
14 submission of a report under section
15 510(k) as of such date of enactment (in-
16 cluding class II devices and excluding class
17 I devices described in section 510(l));

18 “(ii) meets the applicable standard as
19 described in section 587(2);

20 “(iii) is not offered with labeling and
21 advertising that is false or misleading; and

22 “(iv) is not likely to cause or con-
23 tribute to serious adverse health con-
24 sequences.

1 “(C) EFFECT ON SPECIAL CONTROLS.—
2 For any in vitro clinical test, or category of in
3 vitro clinical tests, that is exempt from pre-
4 market review based on the criteria in subpara-
5 graph (B), any special control that applied to a
6 device within a predecessor category imme-
7 diately prior to the date of enactment of the
8 VALID Act of 2022 shall be deemed a miti-
9 gating measure applicable under section 587E
10 to an in vitro clinical test within the successor
11 category, except to the extent such mitigating
12 measure is withdrawn or changed in accordance
13 with section 587E.

14 “(D) NEAR-PATIENT TESTING.—Not later
15 than 1 year after the date of enactment of the
16 VALID Act of 2022, the Secretary shall issue
17 draft guidance indicating categories of tests
18 that shall be exempt from premarket review
19 under section 587B when offered for near-pa-
20 tient testing (point of care), which were not ex-
21 empt from submission of a report under section
22 510(k) pursuant to subsection (l) or (m)(2) of
23 section 510 and regulations imposing limita-
24 tions on exemption for in vitro devices intended
25 for near-patient testing (point of care).

1 “(2) LOW-RISK TESTS.—

2 “(A) EXEMPTION.—An in vitro clinical
3 test is exempt from premarket review under
4 section 587B and may be lawfully marketed
5 subject to the other applicable requirements of
6 this Act, including section 587J(b)(6), if such
7 test meets the definition of low-risk under sec-
8 tion 587 and if the developer of the test—

9 “(i) maintains documentation dem-
10 onstrating that the in vitro clinical test
11 meets and continues to meet the criteria
12 set forth in paragraph (2); and

13 “(ii) makes such documentation avail-
14 able to the Secretary upon request.

15 “(B) CRITERIA FOR EXEMPTION.—An in
16 vitro clinical test is exempt as specified in sub-
17 paragraph (A) if—

18 “(i) the in vitro clinical test meets the
19 applicable standard as described in 587(2);

20 “(ii) the labeling and advertising are
21 not false or misleading;

22 “(iii) the in vitro clinical test is not
23 likely to cause or contribute to serious ad-
24 verse health consequences; and

1 “(iv) the in vitro clinical test is listed
2 pursuant to section 587J or falls within a
3 category of tests listed as described in sub-
4 paragraph (C).

5 “(C) LIST OF LOW-RISK TESTS.—

6 “(i) IN GENERAL.—The Secretary
7 shall maintain, and make publicly available
8 on the website of the Food and Drug Ad-
9 ministration, a list of in vitro clinical tests,
10 and categories of in vitro clinical tests,
11 that are low-risk in vitro clinical tests for
12 purposes of the exemption under this para-
13 graph.

14 “(ii) INCLUSION.—The list under
15 clause (i) shall consist of—

16 “(I) all in vitro clinical tests and
17 categories of in vitro clinical tests that
18 are exempt from premarket review
19 pursuant to subsection (d)(1) or
20 (d)(3); and

21 “(II) all in vitro clinical tests and
22 categories of in vitro clinical tests that
23 are designated by the Secretary pur-
24 suant to subparagraph (C) as low-risk
25 for purposes of this paragraph.

1 “(D) DESIGNATION OF TESTS AND CAT-
2 EGORIES.—Without regard to subchapter II of
3 chapter 5 of title 5, United States Code, the
4 Secretary may designate, in addition to the
5 tests and categories described in subparagraph
6 (C)(i), additional in vitro clinical tests, and cat-
7 egories of in vitro clinical tests, as low-risk in
8 vitro clinical tests for purposes of the exemption
9 under this paragraph. The Secretary may make
10 such a designation on the Secretary’s own ini-
11 tiative or in response to a request by a devel-
12 oper pursuant to subsection (a) or (b) of section
13 587F. In making such a designation for a test
14 or category of tests, the Secretary shall con-
15 sider—

16 “(i) whether the test, or category of
17 tests, is low-risk;

18 “(ii) the existence of and ability to de-
19 velop mitigating measures sufficient for
20 such test category to meet the low-risk
21 standard; and

22 “(iii) such other factors as the Sec-
23 retary determines to be appropriate for the
24 protection of the public health.

25 “(3) HUMANITARIAN TEST EXEMPTION.—

1 “(A) IN GENERAL.—An in vitro clinical
2 test that meets the criteria under subparagraph
3 (B) is exempt from premarket review under sec-
4 tion 587B and may be lawfully offered subject
5 to the other applicable requirements of this sub-
6 chapter, if the developer of the test—

7 “(i) maintains documentation (which
8 may include literature citations in special-
9 ized medical journals, textbooks, special-
10 ized medical society proceedings, and gov-
11 ernmental statistics publications, or, if no
12 such studies or literature citations exist,
13 credible conclusions from appropriate re-
14 search or surveys) demonstrating that such
15 test meets and continues to meet the cri-
16 teria described in this subsection; and

17 “(ii) makes such documentation avail-
18 able to the Secretary upon request.

19 “(B) CRITERIA FOR EXEMPTION.—An in
20 vitro clinical test is exempt as described in sub-
21 paragraph (A) if—

22 “(i) the in vitro clinical test is in-
23 tended by the developer for use for a diag-
24 nostic purpose for a disease or condition
25 that affects not more than 10,000 (or such

1 other higher number determined by the
2 Secretary) individuals in the United States
3 per year; and

4 “(ii) the in vitro clinical test meets
5 the applicable standard described in sec-
6 tion 587(2);

7 “(iii) the labeling and advertising for
8 the in vitro clinical test are not false or
9 misleading;

10 “(iv) the in vitro clinical test is not
11 likely to cause or contribute to serious
12 health consequences; and

13 “(v) the in vitro clinical test is not in-
14 tended for screening.

15 “(C) EXCEPTION FOR CERTAIN TESTS.—
16 An in vitro clinical test intended to inform the
17 use of a specific individual or specific type of bi-
18 ological product, drug, or device shall be eligible
19 for an exemption from premarket review under
20 this subsection only if, the developer submits a
21 request under subsection (m) for informal feed-
22 back and the Secretary determines that such in
23 vitro clinical test is eligible for an exemption
24 from premarket review under this subsection.

1 “(4) CUSTOM TESTS AND LOW-VOLUME
2 TESTS.—An in vitro clinical test is exempt from pre-
3 market review under section 587B, quality require-
4 ments under section 587K, and listing requirements
5 under section 587J, and may be lawfully marketed
6 subject to the other applicable requirements of this
7 Act, if—

8 “(A) such in vitro clinical test—

9 “(i) is a test protocol performed for
10 not more than 5 patients per year (or such
11 other higher number determined by the
12 Secretary), in a laboratory certified by the
13 Secretary under section 353 of the Public
14 Health Service Act that—

15 “(I) meets the requirements to
16 perform tests of high-complexity in
17 which the test protocol was developed;
18 or

19 “(II) meets the requirements to
20 perform tests of high-complexity with-
21 in the same corporate organization
22 and having common ownership by the
23 same parent corporation as the lab-
24 oratory in which such test protocol
25 was developed; or

1 “(ii) is an in vitro clinical test devel-
2 oped or modified to diagnose a unique pa-
3 thology or physical condition of a specific
4 patient or patients, upon order of a health
5 professional or other specially qualified
6 person designated under regulations, for
7 which no other in vitro clinical test is com-
8 mercially available in the United States,
9 and is—

10 “(I) not intended for use with re-
11 spect to more than 5 (or such other
12 higher number determined by the Sec-
13 retary) other patients; and

14 “(II) after the development of
15 such test, not included in any test
16 menu or template test report or other
17 promotional materials, and is not oth-
18 erwise advertised; and

19 “(B) the developer of the in vitro clinical
20 test—

21 “(i) maintains documentation dem-
22 onstrating that such test meets the appli-
23 cable criteria described in subparagraph
24 (A);

1 “(ii) makes such documentation, such
2 as a prescription order requesting the cus-
3 tom test for an individual patient, available
4 to the Secretary upon request; and

5 “(iii) informs the Secretary, on an an-
6 nual basis, in a manner prescribed by the
7 Secretary by guidance, that such test was
8 offered.

9 “(5) IN VITRO CLINICAL TESTS UNDER A TECH-
10 NOLOGY CERTIFICATION ORDER.—An in vitro clin-
11 ical test that is within the scope of a technology cer-
12 tification order, as described in section 587D(a), is
13 exempt from premarket review under section
14 587B.”.

15 “(6) MODIFIED TESTS.—

16 “(A) IN GENERAL.—An in vitro clinical
17 test that is modified is exempt from premarket
18 review under section 587B if—

19 “(i)(I) the modification is made by—

20 “(aa) the developer that obtained
21 premarket approval for the unmodi-
22 fied version of the test under section
23 587B; or

24 “(bb) a clinical laboratory cer-
25 tified by the Secretary under section

1 353 of the Public Health Service Act
2 that meets the requirements for per-
3 forming high complexity testing, to a
4 lawfully offered in vitro clinical test,
5 including another developer’s lawfully
6 offered in vitro clinical test, excluding
7 investigational in vitro clinical tests
8 offered under section 587S, and the
9 modified test is performed—

10 “(AA) in the same clinical
11 laboratory in which it was devel-
12 oped for which a certification is
13 still in effect under section 353
14 that meets the requirements to
15 perform tests of high complexity;

16 “(BB) by another clinical
17 laboratory for which a certificate
18 is in effect under section 353
19 that meets the requirements to
20 perform tests of high complexity,
21 is within the same corporate or-
22 ganization, and has common
23 ownership by the same parent
24 corporation as the laboratory in
25 which the test was developed; or

1 “(CC) by a clinical labora-
2 tory for which a certificate is in
3 effect under section 353 that
4 meets the requirements to per-
5 form tests of high complexity and
6 is within a public health labora-
7 tory network coordinated [or
8 managed] by the Centers for Dis-
9 ease Control and Prevention, if
10 the test was developed by the
11 Centers for Disease Control and
12 Prevention or another laboratory
13 within such public health labora-
14 tory network; or

15 “(II) the modification does not—

16 “(aa) constitute a significant
17 change to the indications for use;

18 “(bb) cause the test to no longer
19 comply with applicable mitigating
20 measures under section 587E or re-
21 strictions under section 587O;

22 “(cc) significantly change per-
23 formance claims or significantly and
24 adversely change performance, unless
25 provided for under an approved

1 change protocol under section
2 587(a)(2)(H); or

3 “(dd) constitute an adverse
4 change in the safety of the in vitro
5 clinical test for individuals who come
6 in contact with the in vitro clinical
7 test;

8 “(ii) the test meets the applicable
9 standard as described in section 587(2);

10 “(iii) the labeling and advertising are
11 not false or misleading; and

12 “(iv) the test is not likely to cause or
13 contribute to serious adverse health con-
14 sequences.

15 “(B) CERTAIN MODIFICATIONS.—A modi-
16 fication to extend specimen stability is exempt
17 from premarket review under section 587B if
18 the modified test meets the requirements in
19 clauses (iii) through (v) of subparagraph (A).

20 “(C) MODIFICATIONS UNDER A CHANGE
21 PROTOCOL.—Notwithstanding subparagraph
22 (A), a modification made under a change pro-
23 tocol pursuant to subsection (a)(2)(H) of sec-
24 tion 587B is exempt from review under such
25 section.

1 “(D) DOCUMENTATION.—A person who
2 modifies an in vitro clinical test in a manner
3 that is a modification described in subpara-
4 graph (A) shall—

5 “(i) document the modification that
6 was made and the basis for determining
7 that the modification, considering the
8 changes individually and collectively, is a
9 type of modification described in subpara-
10 graph (A), (B), or (C); and

11 “(ii) provide such documentation to
12 the Secretary upon request or inspection.

13 “(E) GUIDANCE.—Not later than 30
14 months after the date of enactment of the
15 VALID Act of 2022, the Secretary shall issue
16 guidance regarding the in vitro clinical tests
17 that are modified and exempt from premarket
18 review under section 587B pursuant to this
19 paragraph.

20 “(b) MANUAL TESTS.—

21 “(1) EXEMPTION.—An in vitro clinical test is
22 exempt from all requirements of this subchapter if
23 the output of such in vitro clinical test is the result
24 of direct, manual observation, without the use of
25 automated instrumentation or software for inter-

1 mediate or final interpretation, by a qualified labora-
2 tory professional, and such in vitro clinical test—

3 “(A) is designed, developed, and used with-
4 in a single clinical laboratory for which a cer-
5 tificate is in effect under section 353 of the
6 Public Health Service Act that meets the re-
7 quirements under section 353 for performing
8 high-complexity testing;

9 “(B) is not a specimen receptacle, instru-
10 ment, or an in vitro clinical test that includes
11 an instrument or specimen receptacle that is
12 not approved under or exempt from section
13 587B;

14 “(C) is not a high-risk test, or is a high-
15 risk test that the Secretary has determined
16 meets at least one condition in paragraph (2)
17 and is otherwise appropriate for this exemption;
18 and

19 “(D) is not intended for testing donors,
20 donations, or recipients of blood, blood compo-
21 nents, human cells, tissues, cellular-based prod-
22 ucts, or tissue-based products.

23 “(2) HIGH-RISK TEST LIMITATION OR CONDI-
24 TION.—A high-risk test may be exempt under para-

1 graph (1) from the requirements of this subchapter
2 only if—

3 “(A) no component or part of such test, in-
4 cluding any reagent, is introduced into inter-
5 state commerce under the exemption under
6 paragraph (5), and any article for taking or de-
7 riving specimens from the human body used in
8 conjunction with the test remains subject to the
9 requirements of this subchapter; or

10 “(B) the test has been developed in accord-
11 ance with the applicable test design and quality
12 requirements under section 587J.

13 “(c) PUBLIC HEALTH SURVEILLANCE ACTIVITIES.—

14 “(1) IN GENERAL.—The provisions of this sub-
15 chapter shall not apply to a test intended by the de-
16 veloper to be used solely for public health surveil-
17 lance activities.

18 “(2) EXCLUSION.—An in vitro clinical test used
19 for public health surveillance activities is not ex-
20 cluded from the provisions of this subchapter pursu-
21 ant to this subsection if such test is intended for use
22 in making clinical decisions for individual patients.

23 “(d) GENERAL LABORATORY EQUIPMENT.—Any in-
24 strument that does not produce an analytical result, and
25 that functions as a component of pre-analytical procedures

1 related to in vitro clinical tests, is not subject to the re-
2 quirements of this subchapter, provided that the instru-
3 ment is operating in a clinical laboratory that is certified
4 under section 353 of the Public Health Service Act.

5 “(e) COMPONENTS AND PARTS.—

6 “(1) IN GENERAL.—Subject to paragraph (2), a
7 component or part described in section
8 201(ss)(2)(E) is—

9 “(A) exempt from the requirements of this
10 subchapter if it is intended for further develop-
11 ment as described in paragraph (3); or

12 “(B) subject to the requirements of this
13 subchapter and regulated based on its risk
14 when used as intended by the developer, not-
15 withstanding its subsequent use by a developer
16 as a component, part, or raw material of an-
17 other in vitro clinical test.

18 “(2) INAPPLICABILITY TO OTHER TESTS.—Not-
19 withstanding paragraph (1), an in vitro clinical test
20 that is described in section 201(ss)(1)(B) and that
21 uses a component or part described in such subpara-
22 graph shall be subject to the requirements of this
23 subchapter, unless the test is otherwise exempt
24 under this section.

1 “(3) FURTHER DEVELOPMENT.—A component,
2 part, or raw material (as described in paragraph
3 (1)) is intended for further development (for pur-
4 poses of such paragraph) if—

5 “(A) it is intended solely for use in the de-
6 velopment of another in vitro clinical test; and

7 “(B) in the case of such a test that is in-
8 troduced or delivered for introduction into
9 interstate commerce after the date of enactment
10 of the VALID Act of 2022, the labeling of such
11 test bears the following statement: ‘This prod-
12 uct is intended solely for further development of
13 an in vitro clinical test and is exempt from
14 FDA regulation. This product must be evalu-
15 ated by the in vitro clinical test developer if it
16 is used with or in the development of an in vitro
17 clinical test.’.

18 “(f) GENERAL EXEMPTION AUTHORITY.—The Sec-
19 retary may, by order published in the Federal Register
20 following notice and an opportunity for comment, exempt
21 a class of persons from any section under this subchapter
22 upon a finding that such exemption is appropriate for the
23 protection of the public health and other relevant consider-
24 ations.

1 “(g) EXEMPTION.—An in vitro clinical test that is in-
2 tended solely for use in forensic analysis or law enforce-
3 ment activity is exempt from the requirements of this sub-
4 chapter. An in vitro clinical test that is intended for use
5 in making clinical decisions for individual patients, or
6 whose individually identifiable results may be reported
7 back to an individual patient or the patient’s health care
8 provider, even if also intended for forensic analysis or law
9 enforcement purposes, is not intended solely for forensic
10 analysis or law enforcement for purposes of this sub-
11 section.

12 “(h) REVOCATION.—

13 “(1) IN GENERAL.—The Secretary may revoke
14 any exemption with respect to in vitro clinical tests
15 with the same indications for use if new clinical in-
16 formation indicates that the exemption of an in vitro
17 clinical test or tests from premarket review under
18 section 587B has a reasonable probability of severe
19 adverse health consequences, including the absence,
20 delay, or discontinuation of appropriate medical
21 treatment.

22 “(2) PROCESS.—Any action under paragraph
23 (1) shall be made by publication of a notice of such
24 proposed action on the website of the Food and
25 Drug Administration, the consideration of comments

1 to a public docket on such proposal, and publication
2 of a final action on such website within 60 calendar
3 days of the close of the comment period posted to
4 such public docket, notwithstanding subchapter II of
5 chapter 5 of title 5, United States Code.

6 “(i) PRE-ANALYTICAL INSTRUMENT.—A pre-analyt-
7 ical instrument is exempt from premarket review under
8 section 587B and may be lawfully offered subject to the
9 other applicable requirements of this Act, if either of the
10 following applies:

11 “(1) Such instrument provides additional infor-
12 mation regarding the sample or performs an action
13 on the sample but is not preparing or processing the
14 sample and does not perform any function of an an-
15 alytical instrument. Such types of pre-analytical in-
16 struments include barcode readers, sample movers,
17 and sample identifiers.

18 “(2) Such instrument processes or prepares the
19 sample prior to use on an analytical instrument,
20 does not perform any function of an analytical in-
21 strument, and does not select, isolate, or prepare a
22 part of a sample based on specific properties. Such
23 types of pre-analytical instruments may include sam-
24 ple mixers, DNA extractors and those used to dilute
25 samples.

1 **“SEC. 587D. TECHNOLOGY CERTIFICATION.**

2 “(a) DEFINITIONS.—In this section:

3 “(1) ELIGIBLE IN VITRO CLINICAL TEST.—The
4 term ‘eligible in vitro clinical test’ means an in vitro
5 clinical test that is not—

6 “(A) a component or part of an in vitro
7 clinical test as described in section
8 201(ss)(2)(E);

9 “(B) an instrument under section
10 201(ss)(2)(B) or an in vitro clinical test that
11 includes an instrument that is not approved
12 under, or exempt from, section 587B;

13 “(C) a specimen receptacle under section
14 201(ss)(2)(C) or an in vitro clinical test that in-
15 cludes a specimen receptacle that is not ap-
16 proved under, or exempt from, section 587B;

17 “(D) an in vitro clinical test, including re-
18 agents used in such tests, intended for use for
19 testing donors, donations, and recipients of
20 blood, blood components, human cells, tissues,
21 cellular-based products, or tissue-based prod-
22 ucts;

23 “(E) high-risk;

24 “(F) a combination product unless such
25 test has been determined to be eligible to be in-
26 troduced into interstate commerce under a tech-

1 nology certification order pursuant to the regu-
2 latory pathway designation process described in
3 section 587F, or as described in subsection (k);
4 or

5 “(G) a first-of-a-kind in vitro clinical test,
6 unless such test has been determined to be eli-
7 gible to be introduced into interstate commerce
8 under a technology certification order pursuant
9 to the regulatory pathway designation process
10 described in section 587F, or as described in
11 subsection (k).

12 “(2) ELIGIBLE PERSON.—The term ‘eligible
13 person’ means an in vitro clinical test developer un-
14 less such developer—

15 “(A) is a laboratory subject to section 353
16 of the Public Health Service Act and does not
17 have in effect a certificate applicable to the cat-
18 egory of laboratory examination or other proce-
19 dure;

20 “(B) was a laboratory, or an owner or op-
21 erator or any employee of a laboratory, found
22 to have committed a significant violation of sec-
23 tion 353 of the Public Health Service Act that
24 resulted in a suspended, revoked, or limited cer-
25 tificate within the 2-year period preceding the

1 date of the submission of the application for a
2 technology certificate under subsection (c) and
3 such violation has not been resolved; or

4 “(C) has been found to have submitted in-
5 formation to the Secretary, or otherwise dis-
6 seminated information, that—

7 “(i) made false or misleading state-
8 ments relevant to the requirements of this
9 subchapter; or

10 “(ii) violated any requirement of this
11 Act, where such violation exposed individ-
12 uals to serious risk of illness, injury, or
13 death, unless—

14 “(I) such violation has been re-
15 solved; or

16 “(II) such violation is not perti-
17 nent to any in vitro clinical test within
18 the scope of the technology certifi-
19 cation that such developer seeks.

20 “(b) APPLICABILITY.—

21 “(1) IN GENERAL.—An in vitro clinical test is
22 not subject to section 587B and may be introduced
23 into interstate commerce if the in vitro clinical
24 test—

25 “(A) is an eligible in vitro clinical test;

1 “(B) is developed by an eligible person;

2 “(C) falls within the scope of a technology
3 certification order issued under this section and
4 that is in effect;

5 “(D) complies with the conditions of the
6 technology certification order, including with
7 applicable mitigating measures under section
8 587E, restrictions under section 587O, and per-
9 formance standards under section 587R; and

10 “(E) meets the applicable standard de-
11 scribed in section 587(2).

12 “(2) SCOPE.—

13 “(A) IN GENERAL.—Subject to subpara-
14 graph (B), the scope of a technology certifi-
15 cation order issued under this section shall
16 apply to multiple in vitro clinical tests utilizing
17 the technology do not significantly differ in con-
18 trol mechanisms, energy sources, or operating
19 principles and for which development, including
20 design, and analytical and clinical validation, of
21 the in vitro clinical tests would be addressed
22 through similar procedures, and be no broader
23 than—

24 “(i) a single technology type; or

1 “(ii) a fixed combination of tech-
2 nologies.

3 “(B) TECHNOLOGY TYPE.—A technology
4 type described in this paragraph may include
5 clot detection, colorimetric (non-immunoassay),
6 electrochemical (non-immunoassay), enzymatic
7 (non-immunoassay), flow cytometry,
8 fluorometry (non-immunoassay), immunoassay,
9 mass spectrometry or chromatography, micro-
10 bial culture, next generation sequencing,
11 nephelometric or turbidimetric (non-
12 immunoassay), singleplex or multiplex non-NGS
13 nucleic acid analysis, slide-based technology,
14 spectroscopy, and any other technology, as the
15 Secretary determines appropriate.

16 “(c) APPLICATION FOR TECHNOLOGY CERTIFI-
17 CATION.—

18 “(1) IN GENERAL.—A developer seeking a tech-
19 nology certification order shall submit an application
20 under this subsection, which shall contain the infor-
21 mation specified under paragraph (2).

22 “(2) CONTENT OF APPLICATION.—A developer
23 that submits an application for a technology certifi-
24 cation shall include all necessary information to
25 make a showing that all eligible in vitro clinical tests

1 developed within the scope of the technology certifi-
2 cation order will meet the applicable standard, in-
3 cluding—

4 “(A) the name and address of the devel-
5 oper;

6 “(B) a table of contents for the application
7 and the identification of the information the de-
8 veloper claims as trade secret or confidential
9 commercial or financial information;

10 “(C) the signature of the individual filing
11 the application or an authorized representative;

12 “(D) a statement identifying the scope of
13 the proposed technology certification intended
14 to be introduced into interstate commerce under
15 the application;

16 “(E) information establishing that the de-
17 veloper submitting the application is an eligible
18 person;

19 “(F) quality procedures showing that eligi-
20 ble in vitro clinical tests covered under the tech-
21 nology certification will conform to the applica-
22 ble quality requirements of section 587K with
23 respect to—

1 “(i) design controls, including related
2 purchasing controls and acceptance activi-
3 ties;

4 “(ii) complaint investigation, adverse
5 event reporting, and corrections and re-
6 movals; and

7 “(iii) process validation, as applicable;

8 “(G) procedures for analytical and clinical
9 validation, including all procedures for valida-
10 tion, verification, and acceptance criteria, and
11 an explanation as to how such procedures, when
12 used, provide a showing of analytical validity of
13 eligible in vitro clinical tests within the pro-
14 posed scope of the technology certification order
15 that is analytically and clinically valid;

16 “(H) procedures that provide a showing
17 that in vitro clinical tests covered by the pro-
18 posed scope of the technology certification order
19 will be safe for individuals who come into con-
20 tact with in vitro clinical tests covered by such
21 order;

22 “(I) a proposed listing submission under
23 section 587J(b) for in vitro clinical tests that
24 the developer intends to introduce into inter-
25 state commerce upon receiving a technology cer-

1 tification order, which shall not be construed to
2 limit the developer from introducing additional
3 tests not included in such submission under the
4 same technology certification order;

5 “(J) information concerning one or more
6 representative in vitro clinical tests, including—

7 “(i) a test within the scope of the
8 technology certification application with
9 the appropriate analytical complexity at
10 the time of the submission of the applica-
11 tion under this section to serve as the rep-
12 resentative test and validate and run with-
13 in the developer’s stated scope;

14 “(ii) the information specified in sub-
15 section (a) or (b) of section 587B, as ap-
16 plicable, for the representative in vitro clin-
17 ical test or tests, including information and
18 data required pursuant to subsection
19 (a)(2)(G) of section 587B, unless the Sec-
20 retary determines that such information is
21 not necessary;

22 “(iii) a summary of a risk assessment
23 of the in vitro clinical test;

24 “(iv) an explanation of the choice of
25 the representative in vitro clinical test or

1 tests for the technology certification appli-
2 cation and how such test adequately dem-
3 onstrates the range of procedures that the
4 developer includes in the application under
5 subparagraphs (F), (G), (H), and (I); and

6 “(v) a brief explanation of the ways in
7 which the procedures included in the appli-
8 cation under subparagraphs (F), (G), (H),
9 and (I) have been applied to the represent-
10 ative in vitro clinical test or tests; and

11 “(K) such other information necessary to
12 make a determination on a technology certifi-
13 cation application as the Secretary may deter-
14 mine necessary.

15 “(3) REFERENCE TO EXISTING APPLICA-
16 TIONS.—With respect to the content requirements in
17 the technology certification application described in
18 paragraph (2), a developer may incorporate by ref-
19 erence any content of an application previously sub-
20 mitted by the developer.

21 “(d) ACTION ON AN APPLICATION FOR TECHNOLOGY
22 CERTIFICATION.—

23 “(1) SECRETARY RESPONSE.—

24 “(A) IN GENERAL.—As promptly as prac-
25 ticable, and not later than 90 days after receipt

1 of an application under subsection (c), the Sec-
2 retary shall—

3 “(i) issue a technology certification
4 order granting the application, which shall
5 specify the scope of the technology certifi-
6 cation, if the Secretary finds that all of the
7 grounds in paragraph (3) are met; or

8 “(ii) deny the application if the Sec-
9 retary finds (and sets forth the basis of
10 such finding as part of or accompanying
11 such denial) that one or more grounds for
12 granting the application specified in para-
13 graph (3) are not met.

14 “(B) EXTENSION.—The timeline described
15 in subparagraph (A) may be extended by mu-
16 tual agreement between the Secretary and the
17 applicant.

18 “(2) DEFICIENT APPLICATIONS.—

19 “(A) IN GENERAL.—If, after receipt of an
20 application under this section, the Secretary de-
21 termines that any portion of such application is
22 deficient, the Secretary, not later than 60 days
23 after receipt of such application, shall provide
24 to the applicant a description of such defi-

1 deficiencies and identify the information required to
2 resolve such deficiencies.

3 “(B) CONVERTING TO PREMARKET APPLI-
4 CATIONS.—When responding to the deficiency
5 letter, the developer may convert the application
6 for technology certification under subsection (c)
7 into a premarket application under section
8 587B.

9 “(3) TECHNOLOGY CERTIFICATION ORDER.—
10 The Secretary shall issue an order granting a tech-
11 nology certification under this section if, on the
12 basis of the information submitted to the Secretary
13 as part of the application and any other information
14 with respect to such applicant, the Secretary finds
15 that—

16 “(A) there is a showing that in vitro clin-
17 ical tests within the scope of the technology cer-
18 tification order will meet the applicable stand-
19 ard;

20 “(B) the methods used in, and the facili-
21 ties or controls used for, the development of eli-
22 gible in vitro clinical tests covered by the pro-
23 posed scope of the technology certification con-
24 form to the applicable requirements of section
25 587K with respect to—

1 “(i) design controls, including related
2 purchasing controls and acceptance activi-
3 ties;

4 “(ii) complaint investigation, adverse
5 event reporting, and corrections and re-
6 movals; and

7 “(iii) process validation, as applicable;

8 “(C) based on a fair evaluation of all mate-
9 rial facts, the applicant’s proposed labeling and
10 advertising are not false or misleading in any
11 particular;

12 “(D) the application does not contain a
13 false statement of material fact;

14 “(E) there is a showing that the represent-
15 ative in vitro clinical test or tests—

16 “(i) meet the applicable standard; and

17 “(ii) reasonably represent the range of
18 procedures required to be submitted in the
19 application;

20 “(F) the applicant has agreed to permit,
21 upon request, authorized employees of the Food
22 and Drug Administration or persons accredited,
23 or recognized under this Act, an opportunity to
24 inspect at a reasonable time and in a reason-
25 able manner the facilities and all pertinent

1 equipment, finished and unfinished materials,
2 containers, and labeling therein, including all
3 things (including records, files, papers, and con-
4 trols) bearing on whether an in vitro clinical
5 test is adulterated, misbranded, or otherwise in
6 violation of this Act, and permits such author-
7 ized employees or persons accredited under this
8 Act to view and to copy and verify all records
9 pertinent to the application and the in vitro
10 clinical test; and

11 “(G) based on other data and information
12 the Secretary may require under subsection
13 (c)(2)(K), the Secretary finds that such data
14 and information support granting a technology
15 certification order.

16 “(4) REVIEW OF DENIALS.—An applicant
17 whose application has been denied under this sub-
18 section may obtain review of such denial under sec-
19 tion 587P.

20 “(e) SUPPLEMENTS.—

21 “(1) SUPPLEMENTAL APPLICATIONS.—

22 “(A) IN GENERAL.—With respect to any of
23 the following changes related to an in vitro clin-
24 ical test under a technology certification order,
25 a supplemental application to a technology cer-

1 tification order shall be submitted by the holder
2 of the technology certification order describing
3 such proposed changes, prior to introducing the
4 in vitro clinical test that is the subject of the
5 technology certification order into interstate
6 commerce—

7 “(i) any significant change to the pro-
8 cedures provided in support of the applica-
9 tion for technology certification submitted
10 under subparagraph (G) or (H) of sub-
11 section (c)(2); or

12 “(ii) any significant change to the
13 procedures provided in support of the ap-
14 plication for technology certification sub-
15 mitted under subparagraph (F) of sub-
16 section (c)(2).

17 “(B) SECRETARY ACTION ON SUPPLE-
18 MENTAL APPLICATIONS.—Any action by the
19 Secretary on a supplemental application shall
20 be in accordance with subsection (d), and any
21 order resulting from such supplement shall be
22 treated as an amendment to a technology cer-
23 tification order.

24 “(2) CONTENT OF APPLICATION.—

1 “(A) IN GENERAL.—A supplemental appli-
2 cation for a change to an in vitro clinical test
3 under a technology certification order shall—

4 “(i) contain all necessary information
5 to make a showing that any in vitro clin-
6 ical test affected by such change that is
7 within the scope of the technology certifi-
8 cation order will meet the applicable stand-
9 ard; and

10 “(ii) be limited to such information
11 that is needed to support the change.

12 “(B) CONTENT.—Unless otherwise speci-
13 fied by the Secretary, a supplemental applica-
14 tion under this subsection shall include—

15 “(i) a description of the change, in-
16 cluding a rationale for implementing such
17 change;

18 “(ii) a description of how the change
19 was evaluated;

20 “(iii) data from a representative in
21 vitro clinical test or tests that supports a
22 showing that, in using the modified proce-
23 dure or procedures, all eligible in vitro clin-
24 ical tests within the scope of the tech-

1 nology certification will meet the applicable
2 standard;

3 “(iv) as applicable, information to
4 demonstrate that the modified procedure
5 or procedures submitted under subsection
6 (c)(2)(F) continue to conform to applicable
7 requirements under section 587K; and

8 “(v) any other information requested
9 by the Secretary.

10 “(3) CHANGES IN RESPONSE TO A PUBLIC
11 HEALTH RISK.—

12 “(A) IN GENERAL.—If the holder of a
13 technology certification makes a change to an
14 in vitro clinical test or tests to address a poten-
15 tial risk to public health by adding a new speci-
16 fication or test method, such holder may imme-
17 diately implement such change and shall submit
18 a notification for such change to the Secretary
19 within 30 days.

20 “(B) CONTENT.—Any notification to the
21 Secretary under this paragraph shall include—

22 “(i) a summary of the relevant
23 change;

24 “(ii) the rationale for implementing
25 such change;

1 “(iii)(I) if such a change necessitates
2 a change to the procedures reviewed as
3 part of the granted technology certification
4 order, the modified procedures; or

5 “(II) if the procedures were not
6 changed, an explanation as to why they
7 were not changed; and

8 “(iv) if such a change necessitates a
9 change to the procedures reviewed as part
10 of the granted technology certification
11 order, data from a representative in vitro
12 clinical test or tests that support a showing
13 that, in using the modified procedures, all
14 eligible in vitro clinical tests within the
15 scope of the technology certification will
16 meet the applicable standard.

17 “(f) TEMPORARY HOLD.—

18 “(1) IN GENERAL.—Subject to the process
19 specified in paragraph (2), and based on one or
20 more findings under paragraph (4), the Secretary
21 may issue a temporary hold prohibiting any holder
22 of a technology certification order issued under this
23 section from introducing into interstate commerce
24 an in vitro clinical test that was not previously the
25 subject of a listing under section 587J. The tem-

1 porary hold shall identify the grounds for the tem-
2 porary hold under paragraph (4) and the rationale
3 for such finding.

4 “(2) PROCESS FOR ISSUING A TEMPORARY
5 HOLD.—If the Secretary makes a finding that a
6 temporary hold may be warranted based on one or
7 more grounds specified in paragraph (4), the Sec-
8 retary shall promptly notify the holder of the tech-
9 nology certification order of such finding and pro-
10 vide 30 calendar days for the developer to come into
11 compliance with or otherwise resolve the finding.

12 “(3) WRITTEN REQUESTS.—Any written re-
13 quest to the Secretary from the holder of a tech-
14 nology certification order that a temporary hold
15 under paragraph (1) be removed shall receive a deci-
16 sion, in writing and specifying the reasons therefore,
17 within 90 days after receipt of such request. Any
18 such request shall include information to support the
19 removal of the temporary hold.

20 “(4) GROUNDS FOR TEMPORARY HOLD.—The
21 Secretary may initiate a temporary hold under this
22 subsection upon a finding that the holder of a tech-
23 nology certification order—

1 “(A) is not in compliance with the condi-
2 tions of the technology certification order pur-
3 suant to subsection (b)(1)(D);

4 “(B) offers one or more in vitro clinical
5 tests with advertising or labeling that is false or
6 misleading;

7 “(C) has reported a correction or removal
8 of an in vitro clinical test that is offered under
9 a technology certification order under this sec-
10 tion and has failed to demonstrate that the
11 issue or issues causing the correction or re-
12 moval does not adversely impact the ability of
13 other in vitro clinical tests offered under the
14 same technology certification order to meet the
15 applicable standard; or

16 “(D) has introduced into interstate com-
17 merce an in vitro clinical test under a tech-
18 nology certification order and such test is adul-
19 terated or misbranded, based on a determina-
20 tion by the Secretary, and has failed to dem-
21 onstrate that the issue or issues causing the
22 adulteration or misbranding does not adversely
23 impact the ability of other in vitro clinical tests
24 offered under the same technology certification

1 granted under this section to meet the applica-
2 ble standard.

3 “(g) WITHDRAWAL.—The Secretary may, after due
4 notice and opportunity for an informal hearing, issue an
5 order withdrawing a technology certification order includ-
6 ing all tests introduced into interstate commerce under the
7 technology certification order if the Secretary finds that—

8 “(1) the application, supplement, or report
9 under subsection (h) contains false or misleading in-
10 formation or fails to reveal a material fact;

11 “(2) such holder fails to correct false or mis-
12 leading labeling or advertising upon the request of
13 the Secretary;

14 “(3) in connection with a technology certifi-
15 cation, the holder provides false or misleading infor-
16 mation to the Secretary; or

17 “(4) the holder of such technology certification
18 order fails to correct the grounds for a temporary
19 hold within a timeframe specified in the temporary
20 hold order.

21 “(h) REPORTS TO CONGRESS.—

22 “(1) IN GENERAL.—Not later than 1 year after
23 the effective date of the VALID Act of 2022, and
24 annually thereafter for the next 4 years, the Sec-
25 retary shall submit to the Committee on Health,

1 Education, Labor, and Pensions of the Senate and
2 the Committee on Energy and Commerce of the
3 House of Representatives, and make publicly avail-
4 able, including through posting on the website of the
5 Food and Drug Administration, a report containing
6 the information described in paragraph (2).

7 “(2) CONTENT.—

8 “(A) IN GENERAL.—Each report under
9 paragraph (1) shall address, at a minimum—

10 “(i) the total number of applications
11 for technology certifications filed, granted,
12 withdrawn and denied;

13 “(ii) the total number of technology
14 certification orders the Secretary put on
15 temporary hold under subsection (h) and
16 the number of technology certification or-
17 ders withdrawn under subsection (i);

18 “(iii) the types of technologies for
19 which the Secretary granted technology
20 certification orders;

21 “(iv) the total number of holders of
22 technology certification orders that are in
23 effect; and

24 “(v) the total number of in vitro clin-
25 ical test categories that required premarket

1 review under section 587B that were redesi-
2 gnated as eligible in vitro clinical tests
3 under this section.

4 “(B) FINAL REPORT.—The fifth report
5 submitted under paragraph (1) shall include a
6 summary of, and responses to, comments raised
7 in the docket.

8 “(C) PERFORMANCE REPORTS.—The re-
9 ports required under this section may be issued
10 with performance reports as required under sec-
11 tion 829 of the VALID Act of 2022.

12 “(i) PUBLIC MEETING AND INPUT.—

13 “(1) PUBLIC DOCKET.—Not later than 30 days
14 after the date of enactment of the VALID Act of
15 2022, the Secretary shall establish a public docket to
16 receive comments concerning recommendations for
17 implementation of this section, including criteria and
18 procedures for subsections (c) through (h). The pub-
19 lic docket shall remain open for at least 1 year after
20 the establishment of the public docket.

21 “(2) PUBLIC MEETING.—Not later than 180
22 days after the date of enactment of the VALID Act
23 of 2022, the Secretary shall convene a public meet-
24 ing to which stakeholders from organizations rep-
25 resenting patients and consumers, academia, and the

1 in vitro clinical test industry are invited to discuss
2 the technology certification process including appli-
3 cation requirements, inspections, alignment with
4 third-party accreditors, and the definition of the
5 term ‘technology’ under section 587.

6 “(j) REGULATIONS.—The Secretary shall issue regu-
7 lations regarding the technology certification process, in-
8 cluding describing criteria or procedures relating to tech-
9 nology certification under this section, which shall be sub-
10 ject to public comment for a minimum of 60 days from
11 issuance prior to finalizing such regulations after consid-
12 ering the comments received. The regulation shall include
13 an outline of the application process, opportunities to meet
14 with officials of the Food and Drug Administration, and
15 plans to streamline inspections.

16 “(k) NOTIFICATION.—

17 “(1) IN GENERAL.—Notwithstanding subsection
18 (a)(1), a first-of-a-kind in vitro clinical test or a
19 combination product that meets the definition of a
20 moderate-risk test under section 587A may be intro-
21 duced into interstate commerce under a technology
22 certification order that has been issued by the Sec-
23 retary, subject to other applicable requirements if—

24 “(A) the developer provides notification to
25 the Secretary 60 days prior to introducing such

1 tests into interstate commerce that includes in-
2 formation demonstrating that the test is mod-
3 erate-risk and within the scope of the applicable
4 technology certification order; and

5 “(B) the Secretary has not issued a notifi-
6 cation to the developer under paragraph (2) be-
7 fore such time has elapsed.

8 “(2) NOTIFICATION FROM SECRETARY.—The
9 Secretary shall issue a notification to the developer
10 that such test may not be introduced into interstate
11 commerce under such order if the Secretary deter-
12 mines that—

13 “(A) such test—

14 “(i) does not meet the definition of a
15 moderate-risk test under section 587A;

16 “(ii) is not eligible to be introduced
17 into interstate commerce under the ref-
18 erenced technology certification order
19 issued by the Secretary; or

20 “(iii) is not eligible for technology cer-
21 tification under subsection (b)(2); or

22 “(B) based on the information included in
23 the notification submitted by the developer pur-
24 suant to this subsection, there is insufficient in-
25 formation for the Secretary to make the deter-

1 minations described in clauses (i), (ii), and (iii)
2 of subparagraph (A).

3 **“SEC. 587E. MITIGATING MEASURES.**

4 “(a) ESTABLISHMENT OF MITIGATING MEASURES.—

5 “(1) ESTABLISHING, CHANGING, OR WITH-
6 DRAWING.—

7 “(A) ESTABLISHMENT.—The Secretary
8 may establish and require, on the basis of evi-
9 dence, mitigating measures for any in vitro clin-
10 ical test or category of in vitro clinical tests
11 with the same indications for use that is intro-
12 duced or delivered for introduction into inter-
13 state commerce after the establishment of such
14 mitigating measures.

15 “(B) METHODS OF ESTABLISHMENT.—The
16 Secretary may establish mitigating measures—

17 “(i) under the process set forth in
18 subparagraph (D);

19 “(ii) as provided under section 587F;
20 or

21 “(iii) through a premarket approval or
22 technology certification order, which may
23 establish mitigating measures for an indi-
24 vidual in vitro clinical test or a category of
25 in vitro clinical tests.

1 “(C) METHODS OF CHANGE OR WITH-
2 DRAWAL.—The Secretary may change or with-
3 draw mitigating measures—

4 “(i) under the process set forth in
5 subparagraph (D); or

6 “(ii) as provided under section 587F.

7 “(D) PROCESS FOR ESTABLISHMENT,
8 CHANGE, OR WITHDRAWAL.—Notwithstanding
9 subchapter II of chapter 5 of title 5, United
10 States Code, the Secretary may, upon the ini-
11 tiative of the Secretary or upon petition of an
12 interested person—

13 “(i) establish, change, or withdraw
14 mitigating measures for an in vitro clinical
15 test or category of in vitro clinical tests
16 by—

17 “(I) publishing a proposed order
18 in the Federal Register;

19 “(II) providing an opportunity
20 for public comment for a period of not
21 less than 30 60 calendar days; and

22 “(III) after consideration of any
23 comments submitted, publishing a
24 final order in the Federal Register
25 that responds to the comments sub-

1 mitted, and which shall include a rea-
2 sonable transition period.

3 “(E) EFFECT OF MITIGATING MEASURES
4 ON GRANDFATHERED TESTS.—A mitigating
5 measure shall not be required by the Secretary
6 for an in vitro clinical test subject to section
7 587G(a), unless otherwise provided under sec-
8 tion 587F.

9 “(2) IN VITRO CLINICAL TESTS PREVIOUSLY
10 CLEARED OR EXEMPT AS DEVICES WITH SPECIAL
11 CONTROLS.—

12 “(A) IN GENERAL.—Any special controls
13 applicable to an in vitro clinical test previously
14 cleared or exempt under section 510(k), or clas-
15 sified under section 513(f)(2) prior to date of
16 enactment of the VALID Act of 2022, including
17 any such special controls established during the
18 period beginning on the date of enactment of
19 the VALID Act of 2022 and ending on the ef-
20 fective date of such Act (as described in section
21 5(b) of such Act)—

22 “(i) shall continue to apply to such in
23 vitro clinical test after such effective date;
24 and

1 “(ii) are deemed to be mitigating
2 measures as of the effective date specified
3 in section 825(a)(1)(A) of the VALID Act
4 of 2022.

5 “(B) CHANGES.—Notwithstanding sub-
6 paragraph (A), the Secretary may establish,
7 change, or withdraw mitigating measures for
8 such tests or category of tests using the proce-
9 dures under paragraph (1).

10 “(b) DOCUMENTATION.—

11 “(1) IN VITRO CLINICAL TESTS SUBJECT TO
12 PREMARKET REVIEW.—The developer of an in vitro
13 clinical test subject to premarket review under sec-
14 tion 587B and to which mitigating measures apply
15 shall—

16 “(A) in accordance with section
17 587B(c)(2)(G)(i), submit documentation to the
18 Secretary as part of the application for the test
19 under subsection (c) or (d) of section 587B
20 demonstrating that such mitigating measures
21 have been met;

22 “(B) if such application is approved, main-
23 tain documentation demonstrating that such
24 mitigating measures continue to be met fol-
25 lowing a test modification by the developer; and

1 “(C) make such documentation available to
2 the Secretary upon request or inspection.

3 “(2) OTHER TESTS.—The developer of an in
4 vitro clinical test that is offered under a technology
5 certification order or other exemption from pre-
6 market review under section 587B and to which
7 mitigating measures apply shall—

8 “(A) maintain documentation in accord-
9 ance with the applicable quality requirements
10 under section 587J demonstrating that such
11 mitigating measures continue to be met fol-
12 lowing a test modification by the developer;

13 “(B) make such documentation available to
14 the Secretary upon request or inspection; and

15 “(C) include in the performance summary
16 for such test a brief description of how such
17 mitigating measures are met, if applicable.

18 **“SEC. 587F. REGULATORY PATHWAY DESIGNATION.**

19 “(a) PATHWAY DETERMINATIONS.—

20 “(1) IN GENERAL.—After considering available
21 evidence with respect to an in vitro clinical test or
22 category of in vitro clinical tests with the same in-
23 tended use, including the identification, establish-
24 ment, and implementation of mitigating measures
25 under section 587E, as appropriate, the Secretary

1 may, upon the initiative of the Secretary or upon re-
2 quest of a developer, determine that—

3 “(A) such in vitro clinical test is high-risk
4 and subject to premarket review under section
5 587B;

6 “(B) such in vitro clinical tests, including
7 a first of a kind test, is moderate-risk and sub-
8 ject to abbreviated premarket review under sec-
9 tion 587B(d) or technology certification under
10 section 587D(b)(2); or

11 “(C) such in vitro clinical test, including a
12 first of a kind test is low-risk or otherwise ex-
13 empt from premarket review under section
14 587B.

15 “(2) REQUESTS.—

16 “(A) SUBMISSIONS BY DEVELOPERS.—

17 “(i) SPECIAL PREMARKET REVIEW;
18 TECHNOLOGY CERTIFICATION.—A devel-
19 oper submitting a request that the Sec-
20 retary make a determination as described
21 in paragraph (1)(B) shall submit informa-
22 tion to support that the in vitro clinical
23 test is moderate-risk or propose mitigating
24 measures, if applicable, that would support
25 such a determination.

1 “(ii) LOW-RISK; EXEMPT FROM PRE-
2 MARKET REVIEW.—A developer submitting
3 a request that the Secretary make a deter-
4 mination as described in paragraph (1)(C)
5 shall submit information that the in vitro
6 clinical test is low-risk, or otherwise appro-
7 priate for exemption from premarket re-
8 view under section 587B and propose miti-
9 gating measures, if applicable, that would
10 support such a determination.

11 “(B) RESPONSE BY THE SECRETARY.—
12 After receiving a request under clause (i) or (ii)
13 of subparagraph (A), the Secretary shall pro-
14 vide a timely response describing whether or
15 not the Secretary will initiate the process for
16 making a determination under paragraph
17 (1)(B) or (1)(C) as described in paragraph (4).

18 “(3) SUFFICIENCY OF MITIGATING MEAS-
19 URES.—When determining whether mitigating meas-
20 ures for an in vitro clinical test, or category of in
21 vitro clinical tests, are sufficient to make such test
22 moderate-risk or low-risk, the Secretary shall take
23 into account the following:

24 “(A) The degree to which the technology
25 for the intended use of the in vitro clinical test

1 is well-characterized, taking into consideration
2 factors that include one or more of the fol-
3 lowing:

4 “(i) Peer-reviewed literature.

5 “(ii) Practice guidelines.

6 “(iii) Consensus standards.

7 “(iv) Recognized standards of care.

8 “(v) Use of such technology, including
9 historical use.

10 “(vi) Multiple scientific publications
11 by different authors.

12 “(vii) Adoption by the scientific or
13 clinical community.

14 “(viii) Real world evidence.

15 “(B) Whether the criteria for performance
16 of the test are well-established to be sufficient
17 for the intended use.

18 “(C) The clinical circumstances under
19 which the in vitro clinical test is used, including
20 whether the in vitro clinical test is the sole de-
21 terminate for the diagnosis or treatment of the
22 targeted disease, and the availability of other
23 tests (such as confirmatory or adjunctive tests)
24 or relevant material standards.

1 “(D) Whether such mitigating measures
2 sufficiently mitigate the risk of harm such that
3 the test or category of tests is moderate-risk or
4 low-risk.

5 “(4) PROCESS.—

6 “(A) IN GENERAL.—For a test that is not
7 first-of-a-kind, any action under paragraph (1)
8 shall be made by publication of a notice of such
9 proposed action on the website of the Food and
10 Drug Administration, the consideration of com-
11 ments to a public docket on such proposal, and
12 publication of a final action on such website
13 within 60 calendar days of the close of the com-
14 ment period posted to such public docket, not-
15 withstanding subchapter II of chapter 5 of title
16 5, United States Code.

17 “(B) PROCESS FOR FIRST-OF-A-KIND
18 TEST.—In the case of an in vitro clinical test
19 that is first-of-a-kind, the process is as follows:

20 “(i) Any determination that the test is
21 subject to premarket approval or abbrevi-
22 ated premarket review under subpara-
23 graph (A) or (B) of paragraph (1) shall be
24 published on the website of the Food and
25 Drug Administration, notwithstanding sub-

1 clause II of chapter 5 of title 5, United
2 States Code, only after the in vitro clinical
3 test is approved under section 587B. Until
4 that time, the determination shall not be
5 binding on other in vitro clinical tests.

6 “(ii) Any determination other than
7 those made under clause (i) shall be made
8 by publication of a notice of final action on
9 the website of the Food and Drug Admin-
10 istration, notwithstanding subchapter II of
11 chapter 5 of title 5, United States Code.

12 “(b) TRANSITION PERIOD.—Upon a decision by the
13 Secretary to change a regulatory pathway designation, or
14 reclassifies an in vitro clinical test, or category of in vitro
15 clinical tests, the Secretary shall provide an appropriate
16 transition period with respect to any new requirements.

17 “(c) APPEALS.—A decision by the Secretary under
18 this section shall be deemed a significant decision subject
19 to appeal under section 587P.

20 “(d) ADVISORY COMMITTEE.—The Secretary may re-
21 quest recommendations from an advisory committee under
22 section 587H pursuant to carrying out this section.

23 “(e) REQUEST FOR INFORMAL FEEDBACK.—Before
24 submitting a premarket application or technology certifi-
25 cation application for an in vitro clinical test—

1 “(1) the developer of the test may submit to the
2 Secretary a written request for a meeting, con-
3 ference, or written feedback to discuss and provide
4 information relating to the regulation of such in
5 vitro clinical test which may include—

6 “(A) the submission process and the type
7 and amount of evidence expected to dem-
8 onstrate the applicable standard;

9 “(B) which regulatory pathway is appro-
10 priate for an in vitro clinical test; and

11 “(C) an investigation plan for an in vitro
12 clinical test, including a clinical protocol; and

13 “(2) upon receipt of such a request, the Sec-
14 retary shall—

15 “(A) if a meeting is requested—

16 “(i) within 60 calendar days after
17 such receipt, or within such time period as
18 may be agreed to by the developer, meet or
19 confer with the developer submitting the
20 request; and

21 “(ii) within 15 calendar days after
22 such meeting or conference, provide to the
23 developer a written record or response de-
24 scribing the issues discussed and conclu-

1 sions reached in the meeting or conference;
2 and

3 “(B) if written feedback is requested, pro-
4 vide feedback to the requestor within 75 days
5 after such receipt.

6 **“SEC. 587G. GRANDFATHERED IN VITRO CLINICAL TESTS.**

7 “(a) IN GENERAL.—Subject to subsection (d), an in
8 vitro clinical test is exempt from the requirements of this
9 subchapter specified in subsection (b) if—

10 “(1) the test was first offered for clinical use
11 before the date of enactment of the VALID Act of
12 2022;

13 “(2) the was developed by a clinical laboratory
14 for which a certificate was in effect under section
15 353 of the Public Health Service Act that meets the
16 requirements for performing tests of high com-
17 plexity;

18 “(3) the test is performed—

19 “(A) in the same clinical laboratory in
20 which the test was developed for which a certifi-
21 cation is still in effect under section 353 of the
22 Public Health Service Act that meets the re-
23 quirements to perform tests of high complexity;

24 “(B) by another clinical laboratory for
25 which a certificate is in effect under section 353

1 of such Act that meets the requirements to per-
2 form tests of high complexity, and that is with-
3 in the same corporate organization and having
4 common ownership by the same parent corpora-
5 tion as the laboratory in which the test was de-
6 veloped; or

7 “(C) in the case of a test that was devel-
8 oped by the Centers for Disease Control and
9 Prevention or another laboratory a public
10 health laboratory network coordinated or man-
11 aged by the Centers for Disease Control and
12 Prevention, by a clinical laboratory for which a
13 certificate is in effect under section 353 of such
14 Act that meets the requirements to perform
15 tests of high complexity, and that is within a
16 public health laboratory network coordinated or
17 managed by the Centers for Disease Control
18 and Prevention;

19 “(4) the test does not have in effect an ap-
20 proval under section 515, a clearance under section
21 510(k), an authorization under section 513(f)(2), or
22 an exemption under section 520(m), or licensure
23 under section 351 of the Public Health Service Act;

24 “(5) any modification to the test on or after the
25 date of enactment of the VALID Act of 2022 made

1 by the initial developer and conform with section
2 587C(a)(6)(A)(ii) and does not meet the criterial in
3 subsection (d)(1);

4 “(6) the test is not for investigational use;

5 “(7) the test is offered with an order from an
6 authorized person as required under section 353 of
7 the Public Health Service Act, and was offered with
8 a prescription required under section 809.30(f) of
9 title 21, Code of Federal Regulations prior to the ef-
10 fective date of this subchapter;

11 “(8) the test is not for use with home specimen
12 collection, unless the specimen is collected with a
13 collection container, receptacle, or kit that—

14 “(A) has been approved, cleared, or au-
15 thorized by the Secretary for home specimen
16 collection and the collection is performed pursu-
17 ant to the approved, cleared, or authorized la-
18 beling, including any indication for use as pre-
19 scription use or over-the-counter use, or

20 “(B) is exempt from premarket review and
21 its use is consistent with applicable limitations
22 on the exemption;

23 “(9) is not a specimen receptacle or instrument

24 “(10) each test report template for the test
25 bears a statement that reads as follows: ‘This in

1 vitro clinical test has not been reviewed by the Food
2 and Drug Administration.’; and

3 “(11) the developer of the test—

4 “(A) maintains documentation dem-
5 onstrating that the test meets and continues to
6 meet the criteria set forth in this subsection;
7 and

8 “(B) makes such documentation available
9 to the Secretary upon request.

10 “(b) EXEMPTIONS APPLICABLE TO GRAND-
11 FATHERED TESTS.—An in vitro clinical test that meets
12 the criteria specified in subsection (a) is exempt from pre-
13 market review under 587B, labeling requirements under
14 587L, and test design requirements and quality require-
15 ments under 587K, and may be lawfully offered subject
16 to the other applicable requirements of this Act.

17 “(c) MODIFICATIONS.—In the case of an in vitro clin-
18 ical test that meets the criteria specified in subsection (a),
19 such test continues to qualify for the exemptions described
20 in subsection (b) if the test is modified and the modifica-
21 tion is not of a type described in subsection (a)(5), and
22 the person modifying such in vitro clinical test—

23 “(1) documents each such modification and
24 maintains documentation of the basis for such deter-
25 mination;

1 “(2) provides such documentation relating to
2 the change to the Secretary upon request or inspec-
3 tion; and

4 “(3) does not modify the in vitro clinical test
5 such that it no longer meets the criteria under sub-
6 section (a).

7 “(d) REQUEST FOR INFORMATION.—

8 “(1) CRITERIA.—The criteria described in this
9 paragraph are any of the following:

10 “(A) There is insufficient valid scientific
11 evidence to support that the test is analytically
12 valid or clinically valid.

13 “(B) Such in vitro clinical test is being of-
14 fered by its developer with any false or mis-
15 leading analytical or clinical claims.

16 “(C) It is probable that such in vitro clin-
17 ical test will cause serious adverse health con-
18 sequences.

19 “(2) PROCESS.—

20 “(A) WRITTEN REQUEST FOR INFORMA-
21 TION.—The Secretary may issue a written re-
22 quest to a developer identifying specific sci-
23 entific concerns, based on credible information,
24 with an in vitro clinical test, which indicate that
25 one or more of the criteria described in para-

1 graph (1) apply to such in vitro clinical tests.
2 Such written request shall include specific infor-
3 mation requests pertaining to such criteria.

4 “(B) DEADLINE FOR SUBMITTING INFOR-
5 MATION.—Not later than 45 days after receiv-
6 ing a request for information under subpara-
7 graph (A)—

8 “(i) the developer of an in vitro clin-
9 ical test—

10 “(I) may seek a teleconference
11 prior to the submission of information
12 under clause (ii) to discuss the Sec-
13 retary’s request; and

14 “(II) shall submit the informa-
15 tion requested pursuant to subpara-
16 graph (A) within 30 days of receipt of
17 such request; and

18 “(ii) the Secretary shall—

19 “(I) schedule a teleconference re-
20 quested under clause (i)(I); and

21 “(II) hold a teleconference so re-
22 quested within 10 days of the Sec-
23 retary’s receipt of the information re-
24 quested under clause (i)(II).

1 “(C) REVIEW DEADLINE.—Upon receiving
2 a submission under subparagraph (B), the Sec-
3 retary shall—

4 “(i) review the submitted information
5 within 45 calendar days of such receipt,
6 which may include communication with the
7 developer; and

8 “(ii) determine whether the criteria
9 listed in paragraph (1) apply to the in
10 vitro clinical test and communicate such
11 determination to the developer as described
12 in subparagraph (D).

13 “(D) COMMUNICATION AND RESULTS OF
14 DETERMINATION.—The Secretary shall notify
15 the developer, in writing, of the Secretary’s de-
16 termination under subparagraph (C), as follows:

17 “(i) If the Secretary determines that
18 none of the criteria listed in paragraph (1)
19 apply to the in vitro clinical test, such test
20 shall be exempt from relevant requirements
21 of this subchapter, as set forth in sub-
22 section (b), subject to applicable limitation.

23 “(ii) If the Secretary determines that
24 one or more of the criteria listed in sub-
25 paragraph (1) apply to the test but such a

1 determination may be resolved within a
2 reasonable time, and the test has not been
3 previously subject to this subsection on the
4 basis of the same or substantially similar
5 scientific concerns identified in the written
6 request issued under paragraph
7 (d)(2)(A)—

8 “(I) the Secretary shall notify the
9 developer of such a determination and
10 allow the developer to seek a tele-
11 conference to discuss the finding;

12 “(II) the developer shall submit
13 information demonstrating resolution
14 of the determination within 15 days of
15 receiving the notification; and

16 “(III) the Secretary shall make a
17 determination within 30 days of the
18 submission of information as to
19 whether the criteria under paragraph
20 (1) apply to the test.

21 “(iii) If the Secretary determines that
22 none of the criteria listed in paragraph (1)
23 apply to the test, such test shall be exempt
24 from relevant requirements of the sub-

1 chapter as set forth in subsection (b), sub-
2 ject to applicable limitations.

3 “(iv) If the Secretary determines that
4 one or more of the criteria listed in para-
5 graph (1) apply to the in vitro clinical test,
6 such test is not exempt as set forth in this
7 section and shall not be offered unless ap-
8 proved under section 587B, offered under
9 a technology certification order under sec-
10 tion 587D, or offered as a low-risk test.
11 upon a determination by the Secretary
12 pursuant to section 587F.

13 “(v) If the Secretary determines that
14 one or more of the criteria listed in para-
15 graph (1) apply to the in vitro clinical test
16 and clause (ii) does not apply, the in vitro
17 clinical test is not exempt as set forth in
18 section and shall not be offered unless ap-
19 proved under section 587B, offered under
20 a technology certification order under sec-
21 tion 587D, or offered as a low-risk test
22 upon a determination by the Secretary
23 pursuant to section 587F.

1 **“SEC. 587H. ADVISORY COMMITTEES.**

2 “(a) IN GENERAL.—The Secretary may establish ad-
3 visory committees or use advisory committee panels of ex-
4 perts established before the date of enactment of the
5 VALID Act of 2022 (including a device classification
6 panel under section 513) for the purposes of providing ex-
7 pert scientific advice and making recommendations related
8 to—

9 “(1) the approval of an application for an in
10 vitro clinical test submitted under this subchapter,
11 including for evaluating, as applicable, the analytical
12 validity, clinical validity, and safety of in vitro clin-
13 ical tests;

14 “(2) the potential effectiveness of mitigating
15 measures for a determination of the applicable regu-
16 latory pathway under section 587F(b) or risk eval-
17 uation for an in vitro clinical test or tests;

18 “(3) quality requirements under section 587K
19 or applying such requirements to in vitro clinical
20 tests developed or imported by developers;

21 “(4) appeals under section 587P; or

22 “(5) such other purposes as the Secretary de-
23 termines appropriate.

24 “(b) APPOINTMENTS.—

25 “(1) VOTING MEMBERS.—The Secretary shall
26 appoint to each committee established under sub-

1 section (a), as voting members, individuals who are
2 qualified by training and experience to evaluate in
3 vitro clinical tests referred to the committee for the
4 purposes specified in subsection (a), including indi-
5 viduals with, to the extent feasible, scientific exper-
6 tise in the development of such in vitro clinical tests,
7 laboratory operations, and the use of in vitro clinical
8 tests. The Secretary shall designate one member of
9 each committee to serve as chair.

10 “(2) NONVOTING MEMBERS.—In addition to the
11 individuals appointed pursuant to paragraph (1), the
12 Secretary shall appoint to each committee estab-
13 lished under subsection (a), as nonvoting members—

14 “(A) a representative of consumer inter-
15 ests; and

16 “(B) a representative of interests of in
17 vitro clinical test developers not directly af-
18 fected by the matter to be brought before the
19 committee.

20 “(3) LIMITATION.—No individual who is a reg-
21 ular full-time employee of the United States and en-
22 gaged in the administration of this Act may be a
23 member of any advisory committee established under
24 subsection (a).

1 “(4) EDUCATION AND TRAINING.—The Sec-
2 retary shall, as appropriate, provide education and
3 training to each new committee member before such
4 member participates in a committee’s activities, in-
5 cluding education regarding requirements under this
6 Act and related regulations of the Secretary, and the
7 administrative processes and procedures related to
8 committee meetings.

9 “(5) MEETINGS.—The Secretary shall ensure
10 that scientific advisory committees meet regularly
11 and at appropriate intervals so that any matter to
12 be reviewed by such a committee can be presented
13 to the committee not more than 60 calendar days
14 after the matter is ready for such review. Meetings
15 of the committee may be held using electronic or tel-
16 ephonic communication to convene the meetings.

17 “(6) COMPENSATION.—Members of an advisory
18 committee established under subsection (a), while at-
19 tending meetings or conferences or otherwise en-
20 gaged in the business of the advisory committee—

21 “(A) shall be entitled to receive compensa-
22 tion at rates to be fixed by the Secretary, but
23 not to exceed the daily equivalent of the rate in
24 effect for positions classified above level GS–15
25 of the General Schedule; and

1 “(B) may be allowed travel expenses as au-
2 thorized by section 5703 of title 5, United
3 States Code, for employees serving intermit-
4 tently in the Government service.

5 “(c) GUIDANCE.—The Secretary may issue guidance
6 on the policies and procedures governing advisory commit-
7 tees established under subsection (a).

8 **“SEC. 587I. BREAKTHROUGH IN VITRO CLINICAL TESTS.**

9 “(a) IN GENERAL.—The purpose of this section is
10 to encourage the Secretary, and provide the Secretary with
11 sufficient authority, to apply efficient and flexible ap-
12 proaches to expedite the development of, and prioritize the
13 review of, in vitro clinical tests that represent break-
14 through technologies.

15 “(b) ESTABLISHMENT OF PROGRAM.—The Secretary
16 shall establish a program to expedite the development of,
17 and provide for the priority review of, in vitro clinical
18 tests.

19 “(c) ELIGIBILITY.—The program developed under
20 subsection (b) shall be available for any in vitro clinical
21 test that—

22 “(1) provides or enables more effective treat-
23 ment or diagnosis of life-threatening or irreversibly
24 debilitating human disease or conditions compared
25 to existing approved or cleared alternatives, includ-

1 ing an in vitro clinical test offered under a tech-
2 nology certification order; and

3 “(2) is a test—

4 “(A) that represents a breakthrough tech-
5 nology;

6 “(B) for which no approved or cleared al-
7 ternative in vitro clinical test exists, including
8 no in vitro clinical test offered under a tech-
9 nology certification order;

10 “(C) that offers a clinically meaningful ad-
11 vantage over any existing alternative in vitro
12 clinical test that is approved or cleared (includ-
13 ing any in vitro clinical test offered under a
14 technology certification order), including the po-
15 tential to reduce or eliminate the need for hos-
16 pitalization, improve patient quality of life, fa-
17 cilitate patients’ ability to manage their own
18 care (such as through self-directed personal as-
19 sistance), or establish long-term clinical effi-
20 ciencies; or

21 “(D) the availability of which is in the best
22 interest of patients or public health.

23 “(d) DESIGNATION.—

24 “(1) REQUEST.—To receive breakthrough des-
25 ignation under this section, an applicant may re-

1 quest that the Secretary designate the in vitro clin-
2 ical test for expedited development and priority re-
3 view. Any such request for designation may be made
4 at any time prior to, or at the time of, the submis-
5 sion of an application under section 587B or 587D,
6 and shall include information demonstrating that the
7 test meets the criteria described in subsection (c).

8 “(2) DETERMINATION.—Not later than 60 cal-
9 endar days after the receipt of a request under para-
10 graph (1), the Secretary shall determine whether the
11 in vitro clinical test that is the subject of the request
12 meets the criteria described in subsection (c). If the
13 Secretary determines that the test meets the criteria,
14 the Secretary shall designate the test for expedited
15 development and priority review.

16 “(3) REVIEW.—Review of a request under para-
17 graph (1) shall be undertaken by a team that is
18 composed of experienced staff and senior managers
19 of the Food and Drug Administration.

20 “(4) WITHDRAWAL.—

21 “(A) IN GENERAL.—The designation of an
22 in vitro clinical test under this subsection is
23 deemed to be withdrawn, and such in vitro clin-
24 ical test shall no longer be eligible for designa-
25 tion under this section, if an application for ap-

1 proval for such test under section 587B or
2 587D is denied. Such test shall be eligible for
3 breakthrough designation upon a new request
4 for such designation.

5 “(B) EXCEPTION.—The Secretary may not
6 withdraw a designation granted under this sub-
7 section based on the subsequent approval or
8 technology certification of another in vitro clin-
9 ical test that—

10 “(i) is designated under this section;

11 or

12 “(ii) was given priority review under
13 section 515B.

14 “(e) ACTIONS.—For purposes of expediting the devel-
15 opment and review of in vitro clinical tests under this sec-
16 tion, the Secretary may take the actions and additional
17 actions set forth in paragraphs (1) and (2), respectively,
18 of section 515B(e) when reviewing such tests. Any ref-
19 erence or authorization in section 515B(e) with respect
20 to a device shall be deemed a reference or authorization
21 with respect to an in vitro clinical test for purposes of this
22 section.

23 “(f) GUIDANCE.—Not later than the date specified
24 for final guidance under section 825 of the VALID Act

1 of 2022, the Secretary shall issue final guidance on the
2 implementation of this section. Such guidance shall—

3 “(1) set forth the process by which a person
4 may seek a designation under subsection (d);

5 “(2) provide a template for request under sub-
6 section (d);

7 “(3) identify the criteria the Secretary will use
8 in evaluating a request for designation; and

9 “(4) identify the criteria and processes the Sec-
10 retary will use to assign a team of staff, including
11 team leaders, to review in vitro clinical tests des-
12 ignated for expedited development and priority re-
13 view, including any training required for such per-
14 sonnel to ensure effective and efficient review.

15 “(g) RULES OF CONSTRUCTION.—Nothing in this
16 section shall be construed to affect—

17 “(1) the criteria and standards for evaluating
18 an application pursuant to section 587B or 587D,
19 including the recognition of valid scientific evidence
20 as described in section 587(17) and consideration
21 and application of the least burdensome means de-
22 scribed under section 587AA(e);

23 “(2) the authority of the Secretary with respect
24 to clinical holds under section 587R;

1 “(3) the authority of the Secretary to act on an
2 application pursuant to section 587B before comple-
3 tion of an establishment inspection, as the Secretary
4 determines appropriate; or

5 “(4) the authority of the Secretary with respect
6 to postmarket surveillance under sections 587L(d)
7 and 587Y.

8 **“SEC. 587J. REGISTRATION AND LISTING.**

9 “(a) REGISTRATION REQUIREMENT.—

10 “(1) IN GENERAL.—Each person described in
11 subsection (b)(1) shall—

12 “(A) during the period beginning on Octo-
13 ber 1 and ending on December 31 of each year,
14 register with the Secretary the name of such
15 person, places of business of such person, all es-
16 tablishments engaged in the activities specified
17 under this paragraph, the establishment reg-
18 istration number of each such establishment,
19 and a point of contact for each such establish-
20 ment, including an electronic point of contact;
21 and

22 “(B) submit an initial registration con-
23 taining the information required under subpara-
24 graph (A) not later than—

1 “(i) the effective date of this section if
2 such establishment is engaged in any activ-
3 ity described in subsection (b)(1) on such
4 effective date, unless the Secretary estab-
5 lishes by guidance a date later than such
6 implementation date for all or a category
7 of such establishments; or

8 “(ii) 30 days prior to engaging in any
9 activity described in subsection (b)(1), if
10 such establishment is not engaged in any
11 activity described in this paragraph on
12 such effective date.

13 “(2) REGISTRATION NUMBERS.—The Secretary
14 may assign a registration number to any person or
15 an establishment registration number to any estab-
16 lishment registered in accordance with this section.
17 Registration information shall be made publicly
18 available by publication on the website maintained
19 by the Food and Drug Administration, in accord-
20 ance with subsection (d).

21 “(3) INSPECTION.—Each person or establish-
22 ment that is required to be registered with the Sec-
23 retary under this section shall be subject to inspec-
24 tion pursuant to section 704.

1 “(b) LISTING INFORMATION FOR IN VITRO CLINICAL
2 TESTS.—

3 “(1) IN GENERAL.—Each person who—

4 “(A) is a developer; and

5 “(B) introduces or proposes to begin the
6 introduction or delivery for introduction into
7 interstate commerce through an exemption
8 under subsection (a)(1), (a)(2), (a)(3), or (g) of
9 section 587C or section 587G or through the
10 filing of an application under section 587B or
11 section 587D,

12 shall submit a listing to the Secretary containing the
13 information described in paragraph (2), (4), or (5),
14 as applicable, in accordance with the applicable
15 schedule described under subsection (c). Such listing
16 shall be prepared in such form and manner as the
17 Secretary may specify in guidance. Listing informa-
18 tion shall be submitted through the comprehensive
19 test information system in accordance with section
20 587T, as appropriate.

21 “(2) SUBMISSIONS.—Each developer submitting
22 a listing under paragraph (1) shall electronically
23 submit to the comprehensive test information system
24 described in section 587T the following information,
25 as applicable, for each in vitro clinical test for which

1 such person is a developer in the form and manner
2 prescribed by the Secretary, taking into account
3 least burdensome principles:

4 “(A) Name of the establishment and its es-
5 tablishment registration number.

6 “(B) Contact information for the official
7 correspondent for the listing.

8 “(C) Name (common name and trade
9 name, if applicable) of the in vitro clinical test
10 and its test listing number (when available).

11 “(D) The certificate number for any lab-
12 oratory certified by the Secretary under section
13 353 of the Public Health Service Act that
14 meets the requirements to perform high-com-
15 plexity testing and that is the developer of the
16 in vitro clinical test, and the certificate number
17 under such section for any laboratory that is
18 performing the test, is within the same cor-
19 porate organization, and has common ownership
20 by the same parent corporation.

21 “(E) Whether the in vitro clinical test is,
22 as applicable, offered as a test approved under
23 section 587B, cleared to be offered under a
24 granted technology certification order, or of-

1 ferred as an exempt in vitro clinical test under
2 section 587A.

3 “(F) Indications for use information under
4 section 587(10).

5 “(G) A brief summary of the analytical
6 and clinical performance of the in vitro clinical
7 test, and as applicable, the lot release criteria.

8 “(H) A brief description of conformance
9 with any applicable mitigating measures, re-
10 strictions, and standards.

11 “(I) Representative labeling for the in vitro
12 clinical test, as appropriate.

13 “(3) TEST LISTING NUMBER.—The Secretary
14 may assign a test listing number to each in vitro
15 clinical test that is the subject of a listing under this
16 section. The process for assigning test listing num-
17 bers may be established through guidance, and may
18 include the recognition of standards, formats, or
19 conventions developed by a third-party organization.

20 “(4) ABBREVIATED LISTING.—A person who is
21 not a developer but is otherwise required to register
22 pursuant to subsection (a) shall submit an abbrevi-
23 ated listing to the Secretary containing the infor-
24 mation described in subparagraphs (A) through (C)
25 of paragraph (2), and the name of the developer.

1 The information shall be submitted in accordance
2 with the applicable schedule described under sub-
3 section (c). Such abbreviated listing shall be pre-
4 pared in such form and manner as the Secretary
5 may specify through guidance. Listing information
6 shall be submitted to the comprehensive test infor-
7 mation system in accordance with section 587T, as
8 appropriate.

9 “(5) GRANDFATHERED TESTS.—A developer of-
10 fering a test that is a grandfathered in vitro clinical
11 test under section 587G(a) shall submit listing infor-
12 mation required under subparagraphs (A) through
13 (F) of paragraph (2), and may submit a statement
14 of the performance specifications for such in vitro
15 clinical tests.

16 “(6) EXEMPT TESTS.—A developer of an in
17 vitro clinical test who introduces or proposes to
18 begin the introduction or delivery for introduction
19 into interstate commerce that is otherwise exempt
20 from the requirement to submit listing information
21 pursuant to an exemption under section 587C may
22 submit listing information under this subsection.

23 “(c) TIMELINES FOR SUBMISSION OF LISTING IN-
24 FORMATION.—

1 “(1) IN GENERAL.—The timelines for submis-
2 sion of registration and listing under subsections (a)
3 and (b) are as follows:

4 “(A) For an in vitro clinical test that was
5 listed as a device under section 510(j) prior to
6 the effective date of this section, a person shall
7 maintain a device listing under section 510
8 until such time as the system for submitting
9 the listing information required under sub-
10 section (b) becomes available and thereafter
11 shall submit the listing information not later
12 than the later of 1 year after the system for
13 submitting the listing under this section be-
14 comes available or the effective date of this sec-
15 tion.

16 “(B) For an in vitro clinical test that is
17 subject to grandfathering under section
18 587G(a) a person shall submit the listing infor-
19 mation required under subsection (b)(5) not
20 later than the later of 1 year after the system
21 for submitting the listing under this section be-
22 comes available or the effective date of this sec-
23 tion.

24 “(C) For an in vitro clinical test that is
25 not described in subparagraph (A) or (B), a

1 person shall submit the required listing infor-
2 mation as follows:

3 “(i) For an in vitro clinical test that
4 is not exempt from premarket approval
5 under section 587B, a person shall submit
6 the required listing information, prior to
7 offering the in vitro clinical test and not
8 later than 30 business days after the date
9 of approval of the premarket approval ap-
10 plication.

11 “(ii) For an in vitro clinical test that
12 is exempt from premarket review under
13 section 587C, the required listing informa-
14 tion shall be submitted prior to offering
15 the in vitro clinical test.

16 “(2) UPDATES.—

17 “(A) UPDATES AFTER CHANGES.—Each
18 developer required to submit listing information
19 under this section shall update such informa-
20 tion within 10 business days of any change that
21 causes any previously listed information to be
22 inaccurate or incomplete.

23 “(B) ANNUAL UPDATES.—Each developer
24 required to submit listing information under
25 this section shall update its information annu-

1 ally during the period beginning on October 1
2 and ending on December 31 of each year.

3 “(d) PUBLIC AVAILABILITY OF LISTING INFORMA-
4 TION.—

5 “(1) IN GENERAL.—Listing information sub-
6 mitted pursuant to this section shall be made pub-
7 licly available on the website of the Food and Drug
8 Administration in accordance with paragraph (3).

9 “(2) CONFIDENTIALITY.—Listing information
10 for an in vitro clinical test that is subject to pre-
11 market approval or technology certification shall re-
12 main confidential until such date as the in vitro clin-
13 ical test receives the applicable premarket approval
14 or the developer receives a technology certification
15 order and for subsequent tests introduced under a
16 technology certification order until their introduc-
17 tion.

18 “(3) EXCEPTIONS FROM PUBLIC AVAILABILITY
19 REQUIREMENTS.—The public listing requirements of
20 this subsection shall not apply to any registration
21 and listing information submitted under subsection
22 (a) or (b), if the Secretary determines that such in-
23 formation—

24 “(A) is a trade secret or confidential com-
25 mercial information; or

1 “(B) if posted, would present a risk to na-
2 tional security.

3 “(e) SUBMISSION OF INFORMATION BY ACCREDITED
4 PERSONS.—If agreed upon by the developer, the informa-
5 tion required under this section may be submitted by a
6 person accredited under section 587Q.

7 **“SEC. 587K. TEST DESIGN AND QUALITY REQUIREMENTS.**

8 “(a) APPLICABILITY.—

9 “(1) IN GENERAL.—Each developer and each
10 other person required to register under section
11 587I(b)(1) shall establish and maintain quality re-
12 quirements in accordance with the applicable re-
13 quirements set forth in subsection (b).

14 “(2) CERTIFIED LABORATORY REQUIRE-
15 MENTS.—A developer shall establish and maintain
16 quality requirement under subsection (b)(2) or
17 (b)(3), as applicable, if such developer is a clinical
18 laboratory certified by the Secretary under section
19 353 of the Public Health Service Act that—

20 “(A) is certified to perform high-com-
21 plexity testing;

22 “(B) develops an in vitro clinical test that
23 is for use only—

1 “(i) within the laboratory certified by
2 the Secretary under such section 353 in
3 which such test was developed; or

4 “(ii) within another laboratory cer-
5 tified by the Secretary under such section
6 353 if such laboratory is—

7 “(I) within the same corporate
8 organization and has common owner-
9 ship by the same parent corporation
10 as the laboratory in which the test
11 was developed; or

12 “(II) within a public health lab-
13 oratory network coordinated or man-
14 aged by the Centers for Disease Con-
15 trol and Prevention, if the test is de-
16 veloped by a public health laboratory
17 or the Centers for Disease Control
18 and Prevention; and

19 “(C) does not manufacture, produce, or
20 distribute in vitro clinical tests other than lab-
21 oratory test protocols.

22 “(3) REGULATIONS.—The Secretary shall pro-
23 mulgate quality system regulations implementing
24 this section. In promulgating such regulations under
25 this section, the Secretary shall consider whether,

1 and to what extent, international harmonization is
2 appropriate.

3 “(4) QUALITY SYSTEMS FOR HYBRID DEVEL-
4 OPERS OF BOTH LABORATORY TEST PROTOCOLS AND
5 OTHER IN VITRO CLINICAL TESTS.—An entity that
6 develops both finished products and laboratory test
7 protocols and other in vitro clinical tests shall com-
8 ply with subsection (b)(1) for activities related to the
9 development of any in vitro clinical test that is not
10 a laboratory test protocol product and with sub-
11 section (b)(2) or (b)(3), as applicable, for activities
12 related to the development of any laboratory test
13 protocol.

14 “(b) QUALITY REQUIREMENTS.—

15 “(1) IN GENERAL.—The quality requirements
16 applicable under this section shall—

17 “(A) avoid duplication of regulations under
18 section 353 of the Public Health Service Act;
19 and

20 “(B) shall include the following, as applica-
21 ble, subject to subparagraph (A) and para-
22 graphs (2) and (3)—

23 “(i) management responsibilities;

24 “(ii) quality audits;

25 “(iii) personnel;

- 1 “(iv) design controls;
2 “(v) document controls;
3 “(vi) purchasing controls;
4 “(vii) identification and traceability;
5 “(viii) production and process con-
6 trols;
7 “(ix) acceptance activities;
8 “(x) nonconforming in vitro clinical
9 tests;
10 “(xi) corrective and preventive action;
11 “(xii) labeling and packaging controls;
12 “(xiii) handling, storage, distribution,
13 and installation;
14 “(xiv) complaints and records;
15 “(xv) servicing; and
16 “(xvi) statistical techniques.

17 “(2) EXCEPTION FOR LABORATORY TEST PRO-
18 TOCOLS.—Developers that are developing test proto-
19 cols for use as described in subsection (a)(2)(B)(i)
20 are exempt from the requirements under paragraph
21 (1)(B) except for the requirements described in
22 clauses (iv), (vi), (ix), (xi), and (xiv) of such para-
23 graph.

24 “(3) QUALITY REQUIREMENTS FOR CERTAIN
25 LABORATORIES DISTRIBUTING LABORATORY TEST

1 PROTOCOLS WITHIN ORGANIZATIONS OR PUBLIC
2 HEALTH NETWORKS.—Quality requirements applica-
3 ble to the developer who is distributing a laboratory
4 test protocol as described in subsection (a)(2)(B)(ii)
5 shall consist of the following:

6 “(A) Clauses (iv), (vi), (ix), (xi), (xiv), (xii)
7 of paragraph (1)(B).

8 “(B) The requirement to maintain records
9 of the laboratories to which the laboratory test
10 protocol is distributed.

11 “(c) REGULATIONS.—In implementing quality re-
12 quirements for test developers that participate in inter-
13 national audit programs under this section, the Secretary
14 shall—

15 “(1) for purposes of facilitating international
16 harmonization, consider whether the developer par-
17 ticipates in an international audit program in which
18 the United States participates and recognizes com-
19 pliance with, or conformance to, such standards rec-
20 ognized by the Secretary; and

21 “(2) ensure a least burdensome approach de-
22 scribed in section 587AA(c) by leveraging, to the ex-
23 tent applicable, the quality assurance requirements
24 applicable to developers certified by the Secretary
25 under section 353 of the Public Health Service Act.

1 **“SEC. 587L. LABELING REQUIREMENTS.**

2 “(a) IN GENERAL.—An in vitro clinical test shall
3 bear or be accompanied by labeling, as applicable, that
4 meets the requirements set forth in subsections (b) and
5 (c), unless such test is exempt under subsection (d) or (e).

6 “(b) LABELS.—

7 “(1) IN GENERAL.—The label of an in vitro
8 clinical test, shall meet the requirements set forth in
9 paragraph (2) if there is an immediate container to
10 which the label is applied.

11 “(2) REGULATIONS.—The label of an in vitro
12 clinical test shall state the name and place of busi-
13 ness of its developer and meet the requirements set
14 forth in regulations promulgated in accordance with
15 this section.

16 “(c) LABELING.—

17 “(1) IN GENERAL.—Labeling of an in vitro clin-
18 ical test, including labeling in the form of a package
19 insert, website, standalone laboratory reference docu-
20 ment, or other similar document shall include—

21 “(A) adequate directions for use and shall
22 meet the requirements set forth in regulations
23 promulgated under this section, except as pro-
24 vided in subsection (d) or (e); and

25 “(B) the information described in para-
26 graph (2), as applicable.

1 “(2) CONTENT.—Labeling of an in vitro clinical
2 test shall include—

3 “(A) the test listing number that was pro-
4 vided to the developer at the time of listing;

5 “(B) information to facilitate reporting an
6 adverse event;

7 “(C) information regarding accessing the
8 performance summary data displayed in the
9 listing database for the test;

10 “(D) the indications of use of the in vitro
11 clinical test; and

12 “(E) any warnings, contraindications, or
13 limitations.

14 “(3) PUBLIC AVAILABILITY OF INFORMATION.—
15 The Secretary shall make all of the information de-
16 scribed in paragraph (2) with respect to each in
17 vitro clinical test available to the public, as applica-
18 ble, in accordance with section 587T, except to the
19 extent that the Secretary determines that such infor-
20 mation—

21 “(A) is trade secret or confidential com-
22 mercial information; or

23 “(B) if posted, would present a risk to na-
24 tional security.

1 “(4) ADDITIONAL REQUIREMENTS.—Labeling
2 for an in vitro clinical test used for
3 immunohematology testing shall meet the applicable
4 requirements set forth in part 660 of title 21, Code
5 of Federal Regulations (or any successor regula-
6 tions), related to the labeling of blood grouping re-
7 agents, reagent red blood cells, and anti-human
8 globulin.

9 “(d) EXEMPTIONS AND ALTERNATIVE REQUIRE-
10 MENTS.—

11 “(1) IN GENERAL.—

12 “(A) IN GENERAL.—With respect to an in
13 vitro clinical test that meets the criteria of sub-
14 paragraph (B), the ‘state in one place’ regula-
15 tions under section 809.10(b) of title 21, Code
16 of Federal Regulations (or any successor regu-
17 lations) may be satisfied by the laboratory post-
18 ing such information on its website or in mul-
19 tiple documents, if such documents are main-
20 tained and accessible in one place.

21 “(B) APPLICABLE TESTS.—An in vitro
22 clinical test meets the criteria of this subpara-
23 graph if such test is—

24 “(i) developed by a laboratory cer-
25 tified by the Secretary under section 353

1 of the Public Health Service Act that
2 meets the requirements to perform tests of
3 high-complexity; and

4 “(ii) performed in—

5 “(I) the same laboratory in which
6 such test was developed; or

7 “(II) by another laboratory cer-
8 tified by the Secretary under section
9 353 of the Public Health Service Act
10 that—

11 “(aa) meets the require-
12 ments to perform tests of high
13 complexity; and

14 “(bb) is under common own-
15 ership and control as the labora-
16 tory that developed the test.

17 “(2) TEST INSTRUMENT LABELING.—Unless
18 the instrument is the entire test system, the labeling
19 for an instrument is not required to bear the infor-
20 mation indicated in paragraphs (3), (4), (5), (7),
21 (8), (9), (10), (11), (12), and (13) of section
22 809.10(b) of title 21, Code of Federal Regulations
23 (or any successor regulations).

24 “(3) REAGENT LABELING.—For purposes of
25 compliance with subsection (c)(1), the labeling for a

1 reagent intended for use as a replacement in an in
2 vitro clinical test may be limited to that information
3 necessary to identify the reagent adequately and to
4 describe its proper use in the test.

5 “(4) INVESTIGATIONAL USE.—A shipment or
6 other delivery of an in vitro clinical test for inves-
7 tigational use pursuant to section 587S shall be ex-
8 empt from the labeling requirements of subsections
9 (b) and (c)(1) and from any standard promulgated
10 through regulations, except as required under sec-
11 tion 353 of the Public Health Service Act or section
12 587R of this Act.

13 “(5) GENERAL PURPOSE LABORATORY RE-
14 AGENTS.—The labeling of general purpose labora-
15 tory reagents (such as hydrochloric acid) whose uses
16 are generally known by persons trained in their use
17 need not bear the directions for use required by sub-
18 section (c)(1)(A).

19 “(6) OVER-THE-COUNTER TEST SPECIMEN RE-
20 CEPTACLE LABELING.—The labeling for over-the-
21 counter test specimen receptacles for drugs of abuse
22 testing shall bear the name and place of business of
23 the developer included in the registration under sec-
24 tion 587J and any information specified in applica-

1 ble regulations promulgated under this section, in
2 language appropriate for the intended users.

3 “(e) TESTS IN THE STRATEGIC NATIONAL STOCK-
4 PILE.—

5 “(1) IN GENERAL.—The Secretary may grant
6 an exception or alternative to any provision listed in
7 this section, unless explicitly required by a statutory
8 provision outside this subchapter, for specified lots,
9 batches, or other units of an in vitro clinical test, if
10 the Secretary determines that compliance with such
11 labeling requirement could adversely affect the avail-
12 ability of such products that are, or will be, included
13 in the Strategic National Stockpile under section
14 319F–2 of the Public Health Service Act.

15 “(2) REGULATIONS.—The Secretary may issue
16 regulations amending section 809.11 of title 21,
17 Code of Federal Regulations (or any successor regu-
18 lation) to apply in full or in part to in vitro clinical
19 tests and in vitro clinical test developers.

20 “(f) REGULATIONS.—The Secretary shall issue or re-
21 vise regulations related to standardized, general content
22 and format for in vitro clinical test labeling pursuant to
23 this subsection.

1 **“SEC. 587M. ADVERSE EVENT REPORTING.**

2 “(a) IN GENERAL.—Each in vitro clinical test devel-
3 oper shall establish and maintain a system for establishing
4 and maintaining records of adverse events and reporting
5 adverse events in accordance with this section.

6 “(b) SUBMISSION OF INDIVIDUAL REPORTS.—A de-
7 veloper shall submit an individual adverse event not later
8 than 5 calendar days after the developer receives or be-
9 comes aware of an adverse event that reasonably suggests
10 that an in vitro clinical test may—

11 “(1) have caused or contributed to a patient or
12 user death; or

13 “(2) present an imminent threat to public
14 health.

15 “(c) SUBMISSION OF QUARTERLY REPORTS.—As ap-
16 plicable, a developer shall submit quarterly reports that
17 include any in vitro clinical test errors and serious injuries
18 that occurred during the applicable quarter. Such quar-
19 terly reports shall be submitted not later than the end of
20 the quarter following the quarter in which the developer
21 receives or becomes aware of such adverse events.

22 “(d) DEFINITIONS.—For the purposes of this sec-
23 tion—

24 “(1) the term ‘in vitro clinical test error’ means
25 a failure of an in vitro clinical test to meet its per-
26 formance specifications, or to otherwise perform as

1 intended by the developer, including an inaccurate
2 result resulting from such failure; and

3 “(2) the term ‘serious injury’ means—

4 “(A) a significant delay in a diagnosis that
5 results in the absence, delay, or discontinuation
6 of critical medical treatment or that irreversibly
7 or seriously and negatively alters the course of
8 a disease or condition; or

9 “(B) an injury that—

10 “(i) is life threatening;

11 “(ii) results in permanent impairment
12 of a body function or permanent damage
13 to a body structure; or

14 “(iii) necessitates medical or surgical
15 intervention to preclude permanent impair-
16 ment of a body function or permanent
17 damage to a body structure.

18 “(e) REGULATIONS.—The Secretary shall promulgate
19 regulations to implement this section.

20 **“SEC. 587N. CORRECTIONS AND REMOVALS.**

21 “(a) REGULATIONS.—The Secretary shall promulgate
22 regulations, or amend existing regulations, as appropriate,
23 to implement this section.

24 “(b) REPORTS OF CORRECTIONS AND REMOVALS.—

1 “(1) IN GENERAL.—Each in vitro clinical test
2 developer shall report to the Secretary any correc-
3 tion or removal of an in vitro clinical test under-
4 taken by such developer if the correction or removal
5 was undertaken—

6 “(A) to reduce the risk to health posed by
7 the in vitro clinical test; or

8 “(B) to remedy a violation of this Act
9 caused by the in vitro clinical test which may
10 present a risk to health.

11 “(2) EXCEPTION FOR IN VITRO CLINICAL TESTS
12 OFFERED UNDER A TECHNOLOGY CERTIFICATION
13 ORDER.—For any eligible test offered under a tech-
14 nology certification order under section 587D, a cor-
15 rection and removal report for any correction or re-
16 moval of an in vitro clinical test should demonstrate
17 that the issue or issues causing the correction or re-
18 moval do not adversely impact the ability of other in
19 vitro clinical tests offered under the same technology
20 certification order to meet the applicable standard.

21 “(c) TIMING.—A developer shall submit any report
22 required under this subsection to the Secretary within 15
23 business days of initiating such correction or removal.

24 “(d) RECORDKEEPING.—A developer of an in vitro
25 clinical test that undertakes a correction or removal of an

1 in vitro clinical test which is not required to be reported
2 under this subsection shall keep a record of such correc-
3 tion or removal.

4 “(e) RECALL COMMUNICATIONS.—Upon the vol-
5 untary reporting of a correction or removal by the devel-
6 oper—

7 “(1) the Secretary shall classify such correction
8 or removal under this section within 15 calendar
9 days; and

10 “(2) not later than 45 calendar days after the
11 developer or other responsible party notifies the Sec-
12 retary that it has completed a recall action, the Sec-
13 retary shall provide the developer or other respon-
14 sible party with a written statement closing the re-
15 call action or stating the reasons the Secretary can-
16 not close the recall at that time.

17 **“SEC. 5870. RESTRICTED IN VITRO CLINICAL TESTS.**

18 “(a) APPLICABILITY.—

19 “(1) IN GENERAL.—For the types of in vitro
20 clinical tests described in paragraph (3) the Sec-
21 retary may require, in issuing an approval of an in
22 vitro clinical test under section 587B, granting a
23 technology certification order under section 587D, or
24 in issuing a determination under section 587F(a), or
25 by issuing a regulation, that such test, or category

1 of tests, be restricted to sale, distribution, or use
2 upon such conditions as the Secretary may prescribe
3 under paragraph (2).

4 “(2) CONDITIONS.— The Secretary may pre-
5 scribe conditions under this section, based on avail-
6 able evidence, with respect to an in vitro clinical test
7 described in paragraph (3), that are determined to
8 be needed due to the potential for harmful effect of
9 such test (including any resulting absence, signifi-
10 cant delay, or discontinuation of appropriate medical
11 treatment), and are necessary to ensure that the test
12 meets the applicable standard.

13 “(3) IN VITRO CLINICAL TESTS SUBJECT TO
14 RESTRICTIONS.—The restrictions or conditions au-
15 thorized under this section may be applied by the
16 Secretary to any high-risk or moderate-risk in vitro
17 clinical test, prescription home-use in vitro clinical
18 test, direct-to-consumer in vitro clinical test, or over-
19 the-counter in vitro clinical test.

20 “(b) LABELING AND ADVERTISING OF A RESTRICTED
21 IN VITRO CLINICAL TEST.—The labeling and advertising
22 of an in vitro clinical test to which restrictions apply under
23 subsection (a) shall bear such appropriate statements of
24 the restrictions as the Secretary may prescribe in an ap-
25 proval under section 587B, an order under section 587D,

1 a determination under section 587F(a), or in regulation,
2 as applicable.

3 “(c) DEVICE RESTRICTIONS.—An in vitro clinical
4 test that was offered as a restricted device prior to the
5 date of enactment of this subchapter—

6 “(1) shall continue to comply with the applica-
7 ble restrictions under section 515 or section 520(e)
8 until the this subchapter takes effect; and

9 “(2) except for in vitro clinical tests required to
10 meet section 809.30 of title 21, Code of Federal
11 Regulations prior to the effective date of this sub-
12 chapter specified in section 825(a)(1)(A) of the
13 VALID Act of 2022, such restrictions shall be
14 deemed to be restrictions under this Act as of such
15 effective date.

16 **“SEC. 587P. APPEALS.**

17 “(a) SIGNIFICANT DECISION.—

18 “(1) IN GENERAL.—The Secretary shall main-
19 tain a substantive summary of the scientific and reg-
20 ulatory rationale for any significant decision of the
21 Food and Drug Administration pursuant to section
22 587F, regarding—

23 “(A) the submission of an application for,
24 or a review of, an in vitro clinical test under
25 section 587B or section 587D;

1 “(B) an exemption under section 587C; or

2 “(C) any requirements for mitigation
3 measures to an in vitro clinical test or category
4 of in vitro clinical tests.

5 Such summaries shall include documentation of sig-
6 nificant controversies or differences of opinion and
7 the resolution of such controversies or differences of
8 opinion.

9 “(2) PROVISION OF DOCUMENTATION.—Upon
10 request, the Secretary shall furnish a substantive
11 summary described in paragraph (1) to the person
12 who has made, or is seeking to make, a submission
13 described in such paragraph.

14 “(3) APPLICATION OF LEAST BURDENSOME RE-
15 QUIREMENTS.—The substantive summary required
16 under this subsection shall include a brief statement
17 regarding how the least burdensome requirements
18 were considered and applied consistent with section
19 587AA(c), as applicable.

20 “(b) REVIEW OF SIGNIFICANT DECISIONS.—

21 “(1) REQUEST FOR SUPERVISORY REVIEW OF
22 SIGNIFICANT DECISION.—A developer may request a
23 supervisory review of the significant decision de-
24 scribed in subsection (a)(1). Such review may be
25 conducted at the next supervisory level or higher

1 above the agency official who made the significant
2 decision.

3 “(2) SUBMISSION OF REQUEST.—A developer
4 requesting a supervisory review under paragraph (1)
5 shall submit such request to the Secretary not later
6 than 30 days after the decision for which the review
7 is requested and shall indicate in the request wheth-
8 er such developer seeks an in-person meeting or a
9 teleconference review.

10 “(3) TIMEFRAME.—The Secretary shall sched-
11 ule an in-person or teleconference review, if so re-
12 quested, not later than 30 days after such request
13 is made. The Secretary shall issue a decision to the
14 developer requesting a review under this subsection
15 not later than 45 days after the request is made
16 under paragraph (1), or, in the case of a developer
17 who requests an in-person meeting or teleconference,
18 30 days after such meeting or teleconference.

19 “(c) ADVISORY PANELS.—The process established
20 under subsection (a) shall permit the appellant to request
21 review by an advisory committee established under section
22 587G when there is a dispute involving substantial sci-
23 entific fact. If an advisory panel meeting is held, the Sec-
24 retary shall make a determination under this subsection

1 not later than 45 days after the requested advisory com-
2 mittee meeting has concluded.

3 “(d) **LEAST BURDENSOME REVIEW.**—Any developer
4 who has submitted an application under section 587B or
5 587D may request a supervisory review of a request for
6 additional information during an evaluation of such sub-
7 mission within 60 calendar days of receipt of the addi-
8 tional information request from the Secretary.

9 “(e) **AVAILABILITY OF ALL REMEDIES.**—The proce-
10 dures set forth in this section shall be in addition to, and
11 not in lieu of, other remedies available to the developer.

12 **“SEC. 587Q. ACCREDITED PERSONS.**

13 “(a) **IN GENERAL.**—

14 “(1) **AUTHORIZATION.**—Beginning on the date
15 of enactment of the VALID Act of 2022, the Sec-
16 retary shall accredit persons for any of the following
17 purposes:

18 “(A) Reviewing applications for premarket
19 approval under section 587B and making find-
20 ings with respect to such applications.

21 “(B) Reviewing applications for technology
22 certification under section 587D and making
23 recommendations to the Secretary with respect
24 to such applications.

1 “(C) Conducting inspections as specified in
2 subsection (c) of in vitro clinical test developers
3 and other persons required to register pursuant
4 to section 587I.

5 “(2) PERSONS SUBMITTING APPLICATIONS.—A
6 person submitting an application for premarket ap-
7 proval under section 587B or an application for
8 technology certification under section 587D may
9 submit such application to the Secretary or to a per-
10 son accredited pursuant to subparagraph (A) or (B)
11 of paragraph (1).

12 “(b) ACCREDITED PERSONS APPLICATION REVIEWS,
13 FINDINGS AND RECOMMENDATIONS.—

14 “(1) REQUIREMENTS FOR PREMARKET APPLI-
15 CATION.—

16 “(A) REVIEW AND FINDING REQUIRE-
17 MENTS.—An accredited person receiving an ap-
18 plication for premarket approval under section
19 587B shall either—

20 “(i) provide to the Secretary, together
21 with the application for premarket ap-
22 proval submitted by the applicant, a find-
23 ing that the criteria for approval of the ap-
24 plication under section 587B(g)(2)(A) are
25 met and issue a copy of such finding to the

1 applicant, which finding shall plainly
2 state—

3 “(I) the basis for the accredited
4 person’s finding that the criteria
5 under section 587B(g)(2)(A) are met;
6 and

7 “(II) any proposed restrictions,
8 mitigating measures, or conditions of
9 approval under section
10 587B(g)(2)(B), as applicable; or

11 “(ii) provide a notification to the ap-
12 plicant that the accredited person cannot
13 find that the criteria for approval of the
14 application under section 587B(g)(2)(A)
15 are met and the reasons for such decision.

16 “(B) REQUESTING MISSING OR CLARI-
17 FYING INFORMATION.—After receipt of an ap-
18 plication under this section, the Secretary may
19 request missing or clarifying information from
20 the applicant concerning the application, which
21 the applicant shall promptly provide.

22 “(C) SECRETARY ACTION ON FINDING
23 THAT APPROVAL CRITERIA ARE MET.—If the
24 accredited person transmits a finding to the
25 Secretary under clause (i) of subparagraph (A),

1 then prior to the date that is 45 calendar days
2 after the transmittal date the Secretary shall—

3 “(i) approve the application for pre-
4 market approval under section 587B(g)(2)
5 with appropriate restrictions, mitigating
6 measures, or conditions of approval, as ap-
7 plicable; or

8 “(ii) deny approval of the application
9 by issuing a written notice that reflects ap-
10 propriate management input and concur-
11 rence to the accredited person and the ap-
12 plicant detailing the scientific basis for the
13 Secretary’s determination that the criteria
14 for issuance of an approval under section
15 587B(g)(2)(A) have not been met.

16 “(D) EFFECT OF INACTION ON FINDING.—

17 If the Secretary fails to take an action under
18 subparagraph (C) the Secretary shall—

19 “(i) within 45 calendar days after the
20 transmittal date, provide written feedback
21 to the applicant that—

22 “(I) includes all outstanding
23 issues with the application preventing
24 the Secretary from taking an action
25 under subparagraph (B);

1 “(II) reflects appropriate man-
2 agement input and concurrence; and

3 “(III) includes action items for
4 the Secretary, the applicant, or both,
5 as appropriate, with an estimated date
6 of completion for the Secretary and
7 the applicant to complete their respec-
8 tive tasks, as applicable; and

9 “(ii) promptly schedule a meeting or
10 teleconference to discuss the feedback pro-
11 vided under clause (i), unless the Secretary
12 and applicant agree that the outstanding
13 issues are adequately presented through
14 written correspondence and a meeting or
15 teleconference is not necessary.

16 “(2) REQUIREMENTS FOR TECHNOLOGY CER-
17 TIFICATION.—

18 “(A) REVIEW AND RECOMMENDATION RE-
19 QUIREMENTS.—An accredited person receiving
20 an application for technology certification under
21 section 587D shall either—

22 “(i) provide to the Secretary, together
23 with the application for technology certifi-
24 cation submitted by the applicant, a rec-
25 ommendation that the criteria for issuance

1 of a technology certification order under
2 section 587D(f)(3) are met and issue a
3 copy of such recommendation to the appli-
4 cant, which recommendation shall plainly
5 state the basis for the accredited person's
6 recommendation that the criteria under
7 section 587D(f)(3) are met; or

8 “(ii) provide a notification to the ap-
9 plicant that the accredited person cannot
10 recommend that the criteria for issuance of
11 a technology certification order under sec-
12 tion 587D(f)(3) are met and the reasons
13 for such decision.

14 “(B) REQUESTING MISSING OR CLARI-
15 FYING INFORMATION.—After receipt of an ap-
16 plication under this section, the Secretary may
17 request missing or clarifying information from
18 the applicant concerning the application, which
19 the applicant shall promptly provide.

20 “(C) SECRETARY ACTION ON REC-
21 OMMENDATION FOR ISSUANCE OF A TECH-
22 NOLOGY CERTIFICATION ORDER.—If the accred-
23 ited person transmits a recommendation to the
24 Secretary under clause (i) of subparagraph (A),

1 then prior to the date that is 60 calendar days
2 after the transmittal date the Secretary shall—

3 “(i) issue the technology certification
4 order under section 587D(f)(3), consistent
5 with such recommendation from the ac-
6 credited person; or

7 “(ii) deny approval of the application
8 by issuing a written notice to the accred-
9 ited person and the applicant detailing the
10 scientific basis for a determination by the
11 Secretary that the criteria for issuance of
12 a technology certification order under sec-
13 tion 587D(f)(3) have not been met.

14 “(c) REQUIREMENTS FOR INSPECTIONS.—

15 “(1) IN GENERAL.—When conducting inspec-
16 tion, persons accredited under subparagraph
17 (a)(1)(B) shall record in writing their specific obser-
18 vations and shall present their observations to the
19 designated representative of the inspected establish-
20 ment.

21 “(2) INSPECTION REPORT REQUIREMENTS.—

22 Each person accredited under this subparagraph
23 (a)(1)(C) shall prepare and submit to the Secretary
24 an inspection report in a form and manner des-
25 ignated by the Secretary for conducting inspections.

1 Any statement or representation made by an em-
2 ployee or agent of an establishment to a person ac-
3 credited to conduct inspections under subparagraph
4 (a)(1)(C) shall be subject to section 1001 of title 18,
5 United States Code.

6 “(3) SAVINGS CLAUSE.—Nothing in this section
7 affects the authority of the Secretary to inspect any
8 in vitro clinical test developer or other person reg-
9 istered under section 587I or recognize inspections
10 conducted by auditing organizations as described
11 under section 704(g)(15).

12 “(4) INSPECTION LIMITATIONS.—The Secretary
13 shall ensure that inspections carried out under this
14 section are not duplicative of inspections carried out
15 under section 353 of the Public Health Service Act.
16 Inspections under this section shall be limited to the
17 data and information necessary—

18 “(A) for routine surveillance activities of
19 facilities associated with an approved applica-
20 tion under section 587B or issuance of a tech-
21 nology certification order under section 587D;
22 or

23 “(B) to meet the requirements for pre-
24 market approval under section 587B or

1 issuance of a technology certification order
2 under section 587D, as applicable.

3 “(d) ACCREDITATION.—

4 “(1) ACCREDITATION PROGRAM.—The Sec-
5 retary may provide for accreditation under this sec-
6 tion through programs administered by the Food
7 and Drug Administration, by other non-Federal gov-
8 ernment agencies, or by qualified nongovernmental
9 organizations. A person may be accredited for the
10 review of applications submitted under sections
11 587B as described in subsection (a)(1)(A), for the
12 review of applications submitted under section 587D
13 as described in subsection (a)(1)(B) and to conduct
14 inspection activities under subsection (a)(1)(C), or
15 for a subset of such reviews or activities.

16 “(2) ELIGIBLE PERSONS.—

17 “(A) MINIMUM QUALIFICATIONS.—An ac-
18 credited person, at a minimum, shall—

19 “(i) not be an employee of the Federal
20 Government;

21 “(ii) not engage in the activities of a
22 developer, as defined in section 587(7);

23 “(iii) not be a person required to reg-
24 ister under section 587I, unless such per-
25 son has established sufficient processes

1 and protocols to separate activities to de-
2 velop in vitro clinical tests and the activi-
3 ties for which such person would be ac-
4 credited under subsection (a) and discloses
5 applicable information under this section;

6 “(iv) not be owned or controlled by,
7 and shall have no organizational, material,
8 or financial affiliation with, an in vitro
9 clinical test developer or other person re-
10 quired to register under section 587I;

11 “(v) be a legally constituted entity
12 permitted to conduct the activities for
13 which it seeks accreditation;

14 “(vi) ensure that the operations of
15 such person are in accordance with gen-
16 erally accepted professional and ethical
17 business practices; and

18 “(vii) include in its request for accred-
19 itation a commitment to, at the time of ac-
20 creditation and at any time it is per-
21 forming activities pursuant to this sec-
22 tion—

23 “(I) certify that the information
24 reported to the Secretary accurately
25 reflects the data or protocol reviewed,

1 and the documented inspection find-
2 ings, as applicable;

3 “(II) limit work to that for which
4 competence and capacity are available;

5 “(III) treat information received
6 or learned, records, reports, and rec-
7 ommendations as proprietary informa-
8 tion of the person submitting such in-
9 formation; and

10 “(IV) in conducting the activities
11 for which the person is accredited in
12 respect to a particular in vitro clinical
13 test, protect against the use of any
14 employee or consultant who has a fi-
15 nancial conflict of interest regarding
16 that in vitro clinical test.

17 “(B) WAIVER.—The Secretary may waive
18 any requirements in clauses (i), (ii), (iii), or (iv)
19 of subparagraph (A) upon making a determina-
20 tion that such person has implemented other
21 appropriate controls sufficient to ensure a com-
22 petent and impartial review.

23 “(3) ACCREDITATION PROCESS.—

24 “(A) ACCREDITATION PROCESS GUIDANCE
25 AND REGULATIONS.—Not later than 180 days

1 after the date of enactment of the VALID Act
2 of 2022, the Secretary shall issue draft guid-
3 ance specifying the process for submitting a re-
4 quest for accreditation and reaccreditation
5 under this section, including the form and con-
6 tent of information to be submitted, including
7 the criteria that the Secretary will consider to
8 accredit or deny accreditation and, not later
9 than 1 year after the close of the comment pe-
10 riod for the draft guidance, issue final guid-
11 ance.

12 “(B) RESPONSE TO REQUEST.—The Sec-
13 retary shall respond to a request for accredita-
14 tion or reaccreditation within 60 calendar days
15 of the receipt of the request. The Secretary’s
16 response may be to accredit or reaccredit the
17 person, to deny accreditation, or to request ad-
18 ditional information in support of the request.
19 If the Secretary requests additional informa-
20 tion, the Secretary shall respond within 60 cal-
21 endar days of receipt of such additional infor-
22 mation to accredit or deny the accreditation.

23 “(C) TYPE OF ACCREDITATION.—The ac-
24 creditation or reaccreditation of a person shall
25 specify the particular activity or activities under

1 subsection (a) for which such person is accred-
2 ited, and shall include any limitation to certain
3 eligible in vitro clinical tests.

4 “(D) PUBLIC LIST.—The Secretary shall
5 publish on the website of the Food and Drug
6 Administration a list of persons who are accred-
7 ited under this section. Such list shall be up-
8 dated on at least a monthly basis. The list shall
9 specify the particular activity or activities under
10 this section for which the person is accredited.

11 “(E) AUDIT.—The Secretary may audit
12 the performance of persons accredited under
13 this section for purposes of ensuring that such
14 persons continue to meet the published criteria
15 for accreditation, and may modify the scope or
16 particular activities for which a person is ac-
17 credited if the Secretary determines that such
18 person fails to meet one or more criteria for ac-
19 creditation.

20 “(F) SUSPENSION OR WITHDRAWAL.—The
21 Secretary may suspend or withdraw accredita-
22 tion of any person accredited under this section,
23 after providing notice and an opportunity for an
24 informal hearing, when such person is substan-
25 tially not in compliance with the requirements

1 of this section or the published criteria for ac-
2 creditation, or poses a threat to public health,
3 or fails to act in a manner that is consistent
4 with the purposes of this section.

5 “(G) REACCREDITATION.—Accredited per-
6 sons may be initially accredited for up to 3
7 years. After expiration of such initial period,
8 persons may be reaccredited for unlimited addi-
9 tional 35-year periods, as determined by the
10 Secretary.

11 “(e) COMPENSATION OF ACCREDITED PERSONS.—
12 Compensation of an accredited person shall be determined
13 by agreement between the accredited person and the per-
14 son who engages the services of the accredited person, and
15 shall be paid by the person who engages such services.

16 “(f) INTERNATIONAL HARMONIZATION.—Notwith-
17 standing any other provision of this section, to facilitate
18 international harmonization the Secretary may recognize
19 persons accredited or recognized by governments, who
20 have also entered into information sharing agreements, in-
21 cluding confidentiality commitments, with the Commis-
22 sioner of Food and Drugs.

23 “(g) INFORMATION SHARING AGREEMENTS.—An ac-
24 credited person may enter into an agreement with a test
25 developer to provide information to the comprehensive test

1 information system under section 587T, including any re-
2 quirements under section 587I.

3 “(h) REPORTS.—Not later than 2 years after the ef-
4 fective date of the VALID Act of 2022, and annually
5 thereafter for the next 4 years, the Secretary shall post
6 on the website of the Food and Drug Administration, a
7 report describing the Secretary’s performance in imple-
8 menting this section, including the Secretary’s progress in
9 minimizing duplicative reviews of applications for which
10 an accredited person finds the criteria for approval are
11 met. Such reports shall include, for each period—

12 “(1) with regard to premarket approval applica-
13 tions—

14 “(A) the total number of findings trans-
15 mitted to the Secretary under subsection
16 (b)(1)(A)(i);

17 “(B) the total number of determinations
18 made by the Secretary under subsection
19 (b)(1)(B)(i) within 30 calendar days of the
20 transmittal date to approve an application;

21 “(C) the total number of determinations
22 made by the Secretary under subsection
23 (b)(1)(B)(ii) within 30 calendar days of the
24 transmittal date to deny approval of an applica-
25 tion; and

1 “(D) the total number of applications that
2 were approved and the total number of applica-
3 tions that were denied approval, after the Sec-
4 retary failed to make a determination within 30
5 calendar days of the transmittal date under
6 subsection (b)(1)(B); and

7 “(2) with regard to applications for technology
8 certification—

9 “(A) the total number of recommendations
10 transmitted to the Secretary under subsection
11 (b)(2)(A)(i);

12 “(B) the total number of determinations
13 made by the Secretary under subsection
14 (b)(2)(B)(i) to issue a technology certification
15 order, including determinations made within 30
16 days of the transmittal date;

17 “(C) the total number of determinations
18 made by the Secretary under subsection
19 (b)(2)(B)(ii) to deny the application for tech-
20 nology certification, including determinations
21 made within 30 calendar days of the trans-
22 mittal date; and

23 “(D) the total number of technology cer-
24 tification orders issued, and the total number of
25 applications for technology certification that

1 were denied, including applications denied after
2 the Secretary failed to make a determination
3 within 30 calendar days of the transmittal date
4 under subsection (b)(2)(B).

5 **“SEC. 587R. RECOGNIZED STANDARDS.**

6 “(a) IN GENERAL.—The Secretary may recognize all
7 or part of appropriate standards established by nationally
8 or internationally recognized standards development orga-
9 nizations for which a person may submit a declaration of
10 conformity in order to meet a requirement under this sub-
11 chapter to which that standard is applicable. Standards
12 for in vitro diagnostic devices previously recognized under
13 section 514(c) shall be considered recognized standards
14 under this section. Recognized and proposed standards
15 shall be accessible to the public at no charge. The applica-
16 tion of any such consensus standard shall only apply pro-
17 spectively. The Secretary shall issue regulations estab-
18 lishing the criteria and process, for such recognition and
19 adoption.

20 “(b) AMENDMENT PROCESS.—The procedures estab-
21 lished in this section or in regulation or guidance issued
22 under this section shall apply to amendment of an existing
23 standard.

1 **“SEC. 587S. INVESTIGATIONAL USE.**

2 “(a) IN GENERAL.—Subject to the conditions pre-
3 scribed in subsections (c), (d), (e), (f), and (g) of this sec-
4 tion, an in vitro clinical test for investigational use shall
5 be exempt from the requirements of this subchapter other
6 than sections 587A, 587P, 587T, and 587V. The Sec-
7 retary may amend parts 50, 54, and 56 of title 21 of the
8 Code of Federal Regulations, or any successor regulations,
9 to apply to in vitro clinical tests to permit the investiga-
10 tional use of such tests by experts qualified by scientific
11 training and experience.

12 “(b) REGULATIONS.—

13 “(1) IN GENERAL.—Not later than 2 years
14 after the date of enactment of the VALID Act of
15 2022, the Secretary shall promulgate regulations, or
16 amend existing regulations, to implement this sec-
17 tion.

18 “(2) VARIATION.—The requirements in the reg-
19 ulations promulgated under this section shall take
20 into account variations based on—

21 “(A) the scope and duration of clinical
22 testing to be conducted under investigation that
23 is the subject of such application;

24 “(B) the number of human subjects that
25 are to be involved in such testing;

1 “(C) the need to permit changes to be
2 made to the in vitro clinical test involved during
3 testing conducted in accordance with a plan re-
4 quired under subsection (c)(5); or

5 “(D) whether the clinical testing of such in
6 vitro clinical test is for the purpose of devel-
7 oping data to obtain approval to offer such test.

8 “(c) APPLICATION FOR INVESTIGATIONAL USE.—
9 The following shall apply with respect to in vitro clinical
10 tests for investigational use:

11 “(1) SIGNIFICANT RISK AND OTHER STUD-
12 IES.—In the case of an in vitro clinical test the in-
13 vestigational use of which poses a significant risk to
14 the human subject, a sponsor of an investigation of
15 such a test seeking an investigational use exemption
16 shall submit to the Secretary an investigational use
17 application with respect to the in vitro clinical test
18 in accordance with paragraphs (3) and (4). For pur-
19 poses of this subparagraph, the term ‘significant
20 risk’ means, with respect to an in vitro clinical test
21 and that the use of such in vitro clinical test—

22 “(A) is of substantial importance in per-
23 forming an activity or activities described in
24 section 201(ss)(1) for, a serious or life-threat-
25 ening disease or condition without confirmation

1 of the diagnosis by a medically established diag-
2 nostic product or procedure;

3 “(B) requires an invasive sampling proce-
4 dure that presents a significant risk to the
5 human subject, provided that routine
6 venipuncture shall not be considered an invasive
7 sampling procedure; or

8 “(C) otherwise presents a potential for se-
9 rious risk to the health of a human subject.

10 “(2) NON-SIGNIFICANT RISK STUDIES.—In the
11 case of an in vitro clinical test, the investigational
12 use of which is not described in paragraph (1)—

13 “(A) the sponsor of such investigation
14 shall—

15 “(i) ensure such investigation is con-
16 ducted in compliance with an investiga-
17 tional plan approved by an institutional re-
18 view committee and the labeling of the in
19 vitro clinical test involved clearly and con-
20 spicuously states, ‘For investigational use
21 only’, as specified in paragraph (4)(A)(ii);

22 “(ii) ensure each investigator obtains
23 informed consent as required under part
24 50, 54, and 56 of title 21, Code of Federal
25 Regulations (or any successor regulations),

1 subject to the exceptions set forth in para-
2 graph (6)(C);

3 “(iii) establish and maintain records
4 with respect to all requirements in this
5 subparagraph;

6 “(iv) maintain records and make re-
7 ports as established by the Secretary in
8 regulations issued under subsection (b);
9 and

10 “(v) ensure that investigators monitor
11 investigations, maintain records and make
12 reports as established by the Secretary in
13 regulations issued under subsection (b);
14 and

15 “(B) the sponsor may rely on any excep-
16 tion or exemption described in paragraph
17 (5)(B) or as established by the Secretary in
18 regulations issued under subsection (b).

19 “(3) APPLICATION.—An investigational use ap-
20 plication shall be submitted in such time and man-
21 ner and contain such information as the Secretary
22 may require in regulation, and shall include an in-
23 vestigational plan for proposed clinical testing and
24 assurances that the sponsor submitting the applica-
25 tion will—

1 “(A) establish and maintain records rel-
2 evant to the investigation of such in vitro clin-
3 ical test; and

4 “(B) submit to the Secretary annual re-
5 ports of data obtained as a result of the inves-
6 tigational use of the in vitro clinical test during
7 the period covered by the exemption that the
8 Secretary reasonably determines will enable the
9 Secretary—

10 “(i) to ensure compliance with the
11 conditions for the exemption specified in
12 paragraph (4);

13 “(ii) to review the progress of the in-
14 vestigation involved; and

15 “(iii) to evaluate the ability to meet
16 the applicable standard.

17 “(4) CONDITIONS FOR EXEMPTION.—

18 “(A) IN GENERAL.—An application for an
19 investigational use exemption with respect to a
20 significant risk study shall be granted if each of
21 the following conditions is met:

22 “(i) The risks to the subjects of the in
23 vitro clinical test are outweighed by the an-
24 ticipated benefits of the test to the subjects
25 and the importance of the knowledge to be

1 gained, and adequate assurance of in-
2 formed consent is provided in accordance
3 with paragraphs (6)(A)(iii) and (6)(B).

4 “(ii) The proposed labeling for the in
5 vitro clinical test involved clearly and con-
6 spicuously states ‘For investigational use
7 only’.

8 “(iii) Such other requirements the
9 Secretary determines—

10 “(I) are necessary for the protec-
11 tion of the public health and safety;
12 and

13 “(II) do not unduly delay inves-
14 tigation.

15 “(B) CERTAIN SIGNIFICANT RISK STUDIES
16 OF IN VITRO CLINICAL TESTS FOR AN UNMET
17 NEED.—The Secretary shall not impose a limit
18 on the sample size for a significant risk study
19 of an in vitro clinical test that has received
20 breakthrough designation under section 587I.

21 “(5) COORDINATION WITH INVESTIGATIONAL
22 NEW DRUG APPLICATIONS.—Any requirement for
23 the submission of a report to the Secretary pursuant
24 to an application for an investigational new drug ex-
25 emption involving an in vitro clinical test shall su-

1 persede the reporting requirement in paragraph
2 (3)(B), but only to the extent the requirement with
3 respect to the application for exemption with respect
4 to the drug is duplicative of the reporting require-
5 ment under such paragraph.

6 “(6) INVESTIGATIONAL PLAN, PROCEDURES,
7 AND CONDITIONS.—With respect to an investiga-
8 tional plan submitted under paragraph (3), the
9 sponsor submitting such plan shall—

10 “(A) promptly notify the Secretary of the
11 approval or the suspension or termination of
12 the approval of such plan by an institutional re-
13 view committee;

14 “(B) in the case of an in vitro clinical test
15 made available to investigators for clinical test-
16 ing, obtain agreements from each investigator
17 that any testing of the in vitro clinical test in-
18 volving human subjects will be under such in-
19 vestigator’s supervision and in accordance with
20 paragraph (C) and submit such agreements to
21 the Secretary that ensure—

22 “(i) all investigators will comply with
23 this section, regulations promulgated or re-
24 vised under this section, and applicable
25 human subjects regulations; and

1 “(ii) the investigator will ensure
2 that—

3 “(I) informed consent is obtained
4 as required under part 50 of title 21,
5 Code of Federal Regulations (or any
6 successor regulations), amended to
7 apply to in vitro clinical tests; and

8 “(II) the requirements for insti-
9 tutional review board under part 56 of
10 title 21 of the Code of Federal Regu-
11 lations (or successor regulations),
12 amended to apply to in vitro clinical
13 tests, are met; and

14 “(C) assure that informed consent will be
15 obtained from each human subject (or the rep-
16 resentative of such subject) of proposed clinical
17 testing involving such in vitro clinical test, ex-
18 cept where, subject to such other conditions as
19 the Secretary may prescribe—

20 “(i) the proposed clinical testing poses
21 no more than minimal risk to the human
22 subject and includes appropriate safe-
23 guards to protect the rights, safety, and
24 welfare of the human subject; or

1 “(ii) the investigator conducting or
2 supervising the clinical testing determines
3 in writing that there exists a life-threat-
4 ening situation involving the human sub-
5 ject of such testing which necessitates the
6 use of such in vitro clinical test and it is
7 not feasible to obtain informed consent
8 from the subject and there is not sufficient
9 time to obtain such consent from a rep-
10 resentative of such subject.

11 “(7) CONCURRED BY LICENSED PHYSICIAN.—
12 The determination required by paragraph (6)(C)(ii)
13 shall be concurred in writing by a licensed physician
14 who is not involved in the testing of the human sub-
15 ject with respect to which such determination is
16 made unless immediate use of the device is required
17 to save the life of the human subject of such testing
18 and there is not sufficient time to obtain such con-
19 currence.

20 “(d) REVIEW OF APPLICATIONS.—

21 “(1) IN GENERAL.—The Secretary may issue
22 an order approving an investigation as proposed, ap-
23 proving it with conditions or modifications, or dis-
24 approving it.

1 “(2) FAILURE TO ACT.—Unless the Secretary,
2 not later than the date that is 30 calendar days
3 after the date of the submission of an application for
4 an investigational use exemption that meets the re-
5 quirements of subsection (c), issues an order under
6 paragraph (1) and notifies the sponsor submitting
7 the application, the application shall be treated as
8 approved as of such date without further action by
9 the Secretary.

10 “(3) DENIAL.—The Secretary may deny an in-
11 vestigational use application submitted under this
12 subsection if the Secretary determines that the in-
13 vestigation with respect to which the application is
14 submitted does not conform to the requirements of
15 subsection (c). A notification of such denial sub-
16 mitted to the sponsor with respect to such a request
17 shall contain the order of disapproval and a complete
18 statement of the reasons for the Secretary’s denial
19 of the application.

20 “(e) WITHDRAWAL OF EXEMPTION.—

21 “(1) IN GENERAL.—The Secretary may, by ad-
22 ministrative order, withdraw an exemption approved
23 under this section with respect to an in vitro clinical
24 test, including an exemption treated as approved
25 based on the Secretary’s failure to act pursuant to

1 subsection (d)(2), if the Secretary determines that
2 an investigation conducted under such an exemption
3 does not meet the applicable conditions under sub-
4 section (c)(3) for such exemption.

5 “(2) OPPORTUNITY TO BE HEARD.—

6 “(A) IN GENERAL.—Subject to subpara-
7 graph (B), an order withdrawing an investiga-
8 tional use exemption granted under this section
9 may be issued only after the Secretary provides
10 the sponsor of the in vitro clinical test with an
11 opportunity for an informal hearing.

12 “(B) EXCEPTION.—An order referred to in
13 subparagraph (A) with respect to an investiga-
14 tional use exemption granted under this section
15 may be issued on a preliminary basis before the
16 provision of an opportunity for an informal
17 hearing if the Secretary determines that the
18 continuation of testing under the exemption will
19 result in an unreasonable risk to the public
20 health. The Secretary will provide an oppor-
21 tunity for an informal hearing promptly fol-
22 lowing any preliminary action under this sub-
23 paragraph.

24 “(f) CHANGES.—

1 “(1) IN GENERAL.—The regulations promul-
2 gated under subsection (b) shall provide, with re-
3 spect to an in vitro clinical test for which an exemp-
4 tion under this subsection is in effect, procedures
5 and conditions under which changes are allowed
6 without the additional approval of an application for
7 an exemption or submission of a supplement to such
8 an application. Such regulations shall provide that
9 such a change may be made if—

10 “(A) the sponsor determines, on the basis
11 of credible information (as defined in regula-
12 tions) that the change meets the conditions
13 specified in paragraph (2); and

14 “(B) the sponsor submits to the Secretary,
15 not later than 5 calendar days after making the
16 change, a notice of the change.

17 “(2) CONDITIONS.—The conditions specified in
18 this paragraph are that—

19 “(A) in the case of developmental changes
20 to an in vitro clinical test, including manufac-
21 turing changes, the changes—

22 “(i) do not constitute a significant
23 change in design or in basic principles of
24 operation;

1 “(ii) do not affect the rights, safety,
2 or welfare of the human subjects involved
3 in the investigation; and

4 “(iii) are made in response to infor-
5 mation gathered during the course of an
6 investigation; and

7 “(B) in the case of changes to clinical pro-
8 tocols applicable to the test, the changes do not
9 affect—

10 “(i) the validity of data or information
11 resulting from the completion of an ap-
12 proved clinical protocol, or the relationship
13 of likely patient risk to benefit relied upon
14 to approve a product;

15 “(ii) the scientific soundness of a plan
16 submitted under subsection (c)(3); or

17 “(iii) the rights, safety, or welfare of
18 the human subjects involved in the inves-
19 tigation.

20 “(g) CLINICAL HOLD.—

21 “(1) IN GENERAL.—At any time, the Secretary
22 may impose a clinical hold with respect to an inves-
23 tigation of an in vitro clinical test if the Secretary
24 makes a written determination described in para-
25 graph (2). The Secretary shall, in imposing such

1 clinical hold, specify the basis for the clinical hold,
2 including the specific information available to the
3 Secretary which served as the basis for such clinical
4 hold, and confirm such determination in writing.
5 The applicant may immediately appeal any such de-
6 termination pursuant to section 587P.

7 “(2) DETERMINATION.—

8 “(A) IN GENERAL.—For purposes of para-
9 graph (1), a determination described in this
10 subparagraph with respect to a clinical hold is
11 a determination that, based on credible evi-
12 dence, the in vitro clinical test involved rep-
13 resents an unreasonable risk to the safety of
14 the persons who are the subjects of the clinical
15 investigation, taking into account the qualifica-
16 tions of the clinical investigators, information
17 about the in vitro clinical test, the design of the
18 clinical investigation, the condition for which
19 the in vitro clinical test is to be investigated,
20 and the health status of the subjects involved.

21 “(B) REMOVAL OF CLINICAL HOLD.—Any
22 written request to the Secretary from the spon-
23 sor of an investigation that a clinical hold be re-
24 moved shall receive a decision, in writing and
25 specifying the reasons therefor, within 30 days

1 after receipt of such request. Any such request
2 shall include sufficient information to support
3 the removal of such clinical hold.

4 **“SEC. 587T. COMPREHENSIVE TEST INFORMATION SYSTEM.**

5 “(a) ESTABLISHMENT.—Not later than 2 years after
6 the date of enactment of the VALID Act of 2022, the Sec-
7 retary shall make available a comprehensive test informa-
8 tion system for in vitro clinical tests that is designed to—

9 “(1) provide a transparent interface on the
10 website of the Food and Drug Administration for
11 stakeholders, to the extent permitted by applicable
12 law, which may include access to the—

13 “(A) regulatory pathway designation infor-
14 mation for each in vitro clinical test or tests
15 with the same indications for use;

16 “(B) registration and listing information
17 provided by developers under section 587J, in-
18 cluding the use of a link for labels;

19 “(C) adverse event reports submitted
20 under section 587M, as appropriate;

21 “(D) reports of corrections and removals
22 submitted under section 587N; and

23 “(E) other information pertaining to an in
24 vitro clinical test or tests with the same indica-

1 tions for use, as the Secretary determines ap-
2 propriate; and

3 “(2) provide a secure portal for electronic sub-
4 mission, including applications and other in vitro
5 clinical test submissions, registration and listing in-
6 formation, and adverse event reports, which provides
7 protections from unauthorized disclosure of informa-
8 tion, including of—

9 “(A) trade secret or commercial confiden-
10 tial information; and

11 “(B) national security, countermeasure, or
12 other information restricted from disclosure
13 pursuant to any provision of law.

14 “(b) **SUBMISSION FUNCTION.**—The comprehensive
15 test information system shall serve as the electronic sub-
16 mission service for test developers submitting information
17 for applications under sections 587B and 587D.

18 **“SEC. 587U. PREEMPTION.**

19 “(a) **IN GENERAL.**—Except as provided in subsection
20 (b), no State, Tribal, or local government (or political sub-
21 division thereof) may establish or continue in effect any
22 requirement that—

23 “(1) is different from, or in addition to, any re-
24 quirement applicable to an in vitro clinical test
25 under this Act; or

1 “(2) with respect to the analytical validity, clin-
2 ical validity, or safety for individuals who come into
3 contact with such an in vitro clinical test under this
4 Act.

5 “(b) EXCEPTIONS.—Subsection (a) shall not be con-
6 strued to affect the authority of a State, Tribal, or local
7 government to do any of the following:

8 “(1) To license laboratory personnel, health
9 care practitioners, or health care facilities or to reg-
10 ulate any aspect of a health care practitioner-patient
11 relationship.

12 “(2) To enforce laws of general applicability,
13 such as zoning laws, environmental laws, labor laws,
14 and general business laws.

15 “(3) To authorize laboratories to develop and
16 perform an in vitro clinical test, pursuant to a law
17 enacted by a State prior to January 1, 2022, as long
18 as such law does not impose requirements that are
19 different from any requirement applicable to an in
20 vitro clinical test under this Act. If a State has en-
21 acted such a law, the Secretary may exempt such
22 laboratories in that State from compliance with this
23 subchapter.

24 “(c) CLARIFICATION.—Nothing in this section shall
25 be construed to—

1 “(1) modify any action for damages or the li-
2 ability of any person under the law of any State; or

3 “(2) shift liability to health care practitioners
4 or other users.

5 **“SEC. 587V. ADULTERATION.**

6 “An in vitro clinical test shall be deemed to be adul-
7 terated:

8 “(1) If it consists in whole or in part of any
9 filthy, putrid, or decomposed substance.

10 “(2) If it has been developed, prepared, packed,
11 or held under insanitary conditions whereby it may
12 have been contaminated with filth, or whereby it
13 may have been rendered injurious to health.

14 “(3) If its container or package is composed, in
15 whole or in part, of any poisonous or deleterious
16 substance which may render the contents injurious
17 to health.

18 “(4) If it bears or contains, for purposes of
19 coloring only, a color additive which is unsafe within
20 the meaning of section 721(a).

21 “(5) If its analytical or clinical validity, as ap-
22 plicable, or with respect to a specimen receptacle, its
23 safety, falls below that which it purports or is rep-
24 resented to possess.

1 “(6) If it is required to be, declared to be, pur-
2 ports to be, or is represented as being, in conformity
3 with any performance standard established or recog-
4 nized under section 587R and is not in conformity
5 with such standard.

6 “(7) If it is required to be in compliance with
7 mitigating measures established under section 587E
8 and is not in conformity with such mitigating meas-
9 ures.

10 “(8) If it fails to have in effect an approved
11 premarket application under section 587B unless
12 such in vitro clinical test is in compliance with the
13 requirements for—

14 “(A) offering without an approved pre-
15 market application under section 587D;

16 “(B) an exemption from premarket ap-
17 proval under section 587C or 587G; or

18 “(C) investigational use pursuant to sec-
19 tion 587S.

20 “(9) If it is not in conformity with any condi-
21 tion established under section 587B or 587D.

22 “(10) If it purports to be an in vitro clinical
23 test subject to an exemption under section 587C and
24 it fails to meet or maintain any criteria, condition,
25 or requirement of such exemption.

1 “(11) If it has been granted an exemption
2 under section 587S for investigational use, and the
3 person granted such exemption or any investigator
4 who uses such in vitro clinical test under such ex-
5 emption fails to comply with a requirement pre-
6 scribed by or under such section.

7 “(12) If it fails to meet the quality require-
8 ments prescribed in or established under section
9 587K (as applicable), or the methods used in, or fa-
10 cilities or controls used for, its development, pack-
11 aging, storage, or installation are not in conformity
12 with applicable requirements established under such
13 section.

14 “(13) If it has been developed, processed, pack-
15 aged, or held in any establishment, factory, or ware-
16 house and the owner, operator or agent of such es-
17 tablishment, factory, or warehouse delays, denies, or
18 limits an inspection, or refuses to permit entry or in-
19 spection.

20 “(14) If it is not in compliance with any restric-
21 tion required under section 587O.

22 **“SEC. 587W. MISBRANDING.**

23 “An in vitro clinical test shall be deemed to be mis-
24 branded:

1 “(1) If its labeling is false or misleading in any
2 particular.

3 “(2) If in a package form unless it bears a label
4 containing—

5 “(A) the name and place of business of the
6 test developer, packager, or distributor; and

7 “(B) an accurate statement of the quantity
8 of contents in terms of weight, measure, or nu-
9 merical count with respect to small packages,
10 unless an exemption is granted by the Secretary
11 by the issuance of guidance.

12 “(3) If any word, statement, or other informa-
13 tion required by or under authority of this Act to
14 appear on the label or labeling, including a test re-
15 port, is not prominently placed thereon with such
16 conspicuousness (as compared with other words,
17 statements, designs, or devices, in the labeling) and
18 in such terms as to render it likely to be read and
19 understood by the ordinary individual under cus-
20 tomary conditions of purchase and use.

21 “(4) Unless its labeling bears adequate direc-
22 tions for use and such adequate warnings as are
23 necessary for the protection of users of the in vitro
24 clinical test and recipients of the results of such in
25 vitro clinical test, including patients, consumers, do-

1 nors, and related health care professionals. Required
2 labeling for in vitro clinical tests intended for use in
3 health care facilities, blood establishments, or by a
4 health care professional may be made available solely
5 by electronic means, provided that the labeling com-
6 plies with all applicable requirements of law, and
7 that the test developer, or distributor affords such
8 users the opportunity to request the labeling in
9 paper form, and after such request, promptly pro-
10 vides the requested information without additional
11 cost.

12 “(5) If there is a reasonable probability that it
13 could cause serious or adverse health consequences
14 or death, including through absence, delay, or dis-
15 continuation in diagnosis or treatment, when used in
16 the manner prescribed, recommended, or suggested
17 in the labeling thereof.

18 “(6) If it was developed, sterilized, packaged,
19 repackaged, relabeled, installed, or imported in an
20 establishment not duly registered under section
21 587J or it was not included in a listing under sec-
22 tion 587J, in accordance with timely reporting re-
23 quirements under this subchapter.

24 “(7) In the case of any in vitro clinical test sub-
25 ject to restrictions under section 587O, (1) if its ad-

1 advertising is false or misleading in any particular, (2)
2 if it is offered for clinical use, sold, distributed, or
3 used in violation of such restrictions, or (3) unless
4 the test developer or distributor includes in all ad-
5 vertisements and other descriptive printed matter
6 that such person issues or causes to be issued, a
7 brief statement of the indications for use of the in
8 vitro clinical test and relevant warnings, precautions,
9 side effects, and contraindications. This subsection
10 shall not be applicable to any printed matter that
11 the Secretary determines to be labeling as defined in
12 section 201(m).

13 “(8) If it is subject to a mitigating measure es-
14 tablished under section 587E and does not bear such
15 labeling as may be prescribed in such mitigating
16 measure.

17 “(9) If it is subject to a standard established
18 under section 587R and it does not bear such label-
19 ing as may be prescribed in such standard.

20 “(10) Unless it bears such labeling as may be
21 required by or established under an applicable label-
22 ing requirement under this Act.

23 “(11) If there was a failure to comply with any
24 requirement prescribed in or under section 587D,
25 587J, 587K, 587L, 587M, 587N, 587X, 587Y,

1 587Z, or to provide any report, material, or other in-
2 formation required with respect to in vitro clinical
3 tests under this subchapter.

4 **“SEC. 587X. POSTMARKET SURVEILLANCE.**

5 “(a) IN GENERAL.—

6 “(1) IN GENERAL.—In addition to other appli-
7 cable requirements under this Act, the Secretary
8 may issue an order requiring a developer of a high-
9 risk or moderate-risk in vitro clinical test to conduct
10 postmarket surveillance of such in vitro clinical test,
11 if the failure of the in vitro clinical test is reasonably
12 likely to result in serious adverse health con-
13 sequences or death from use of such in vitro clinical
14 test.

15 “(2) CONSIDERATION.—In determining whether
16 to require a developer to conduct postmarket surveil-
17 lance of an in vitro clinical test, the Secretary shall
18 take into consideration the benefits and risks for the
19 patient and the least burdensome principles under
20 section 587B(j).

21 “(b) SURVEILLANCE APPROVAL.—

22 “(1) IN GENERAL.—Each developer required to
23 conduct surveillance of an in vitro clinical test shall
24 submit, within 30 days of receiving an order from
25 the Secretary, a plan for the required surveillance.

1 The Secretary, within 60 days of the receipt of such
2 plan, shall determine if the person designated to
3 conduct the surveillance has the appropriate quali-
4 fications and experience to undertake such surveil-
5 lance and if the plan will result in useful data that
6 can reveal unforeseen adverse events or other infor-
7 mation necessary to protect the health of patients or
8 the public.

9 “(2) TIMELINE.—The developer shall com-
10 mence surveillance under this section not later than
11 15 months after the day on which the Secretary or-
12 ders such postmarket surveillance, unless the Sec-
13 retary determines more time is needed to commence
14 surveillance.

15 “(3) PROSPECTIVE SURVEILLANCE.—The Sec-
16 retary may order a prospective surveillance period of
17 up to 3 years. Any determination by the Secretary
18 that a longer period is necessary shall be made by
19 mutual agreement between the Secretary and the de-
20 veloper or, if no agreement can be reached, upon the
21 completion of a dispute resolution process pursuant
22 to section 562.

1 **“SEC. 587Y. ELECTRONIC FORMAT FOR SUBMISSIONS.**

2 “(a) IN GENERAL.—All submissions to the Food and
3 Drug Administration with respect to an in vitro clinical
4 test, unless otherwise agreed to by the Secretary, shall—

5 “(1) be made electronically; and

6 “(2) with respect to the information required
7 under sections 587B and 587D, utilize the system
8 described in section 587U.

9 “(b) ELECTRONIC FORMAT.—Beginning on such date
10 as the Secretary specifies in final guidance issued under
11 subsection (c), submissions for in vitro clinical tests, in-
12 cluding recommendations submitted by accredited and rec-
13 ognized persons under section 587Q, and any appeals of
14 action taken by the Secretary with respect to such submis-
15 sions, shall be submitted in such electronic format as spec-
16 ified by the Secretary in such guidance.

17 “(c) GUIDANCE.—The Secretary shall issue guidance
18 implementing this section. Such guidance may—

19 “(1) provide standards for the electronic sub-
20 mission required under subsection (a) or the submis-
21 sion in electronic format required under subsection
22 (b);

23 “(2) set forth criteria for waivers of, or exemp-
24 tions from, the requirements of subsection (a) or (b);
25 and

1 “(3) provide any other information for the effi-
2 cient implementation and enforcement of this sec-
3 tion.

4 **“SEC. 587Z. POSTMARKET REMEDIES.**

5 “(a) SAFETY NOTICE.—

6 “(1) IN GENERAL.—If the Secretary determines
7 that an in vitro clinical test presents an unreason-
8 able risk of substantial harm to the public health,
9 and notification under this subsection is necessary to
10 eliminate the unreasonable risk of such harm and no
11 more practicable means is available under the provi-
12 sions of this Act (other than this section) to elimi-
13 nate the risk, the Secretary may issue such order as
14 may be necessary to ensure that adequate safety no-
15 tice is provided in an appropriate form, by the per-
16 sons and means best suited under the circumstances,
17 to all health care professionals who prescribe, order,
18 or use the in vitro clinical test and to any other per-
19 son (including developers, importers, distributors, re-
20 tailers, and users) who should properly receive such
21 notice.

22 “(2) NOTICE TO INDIVIDUALS.—An order
23 under this subsection shall require that the individ-
24 uals subject to the risk with respect to which the
25 order is to be issued be included in the persons to

1 be notified of the risk unless the Secretary deter-
2 mines that notice to such individuals would present
3 a greater danger to the health of such individuals
4 than no such notice. If the Secretary makes such a
5 determination with respect to such individuals, the
6 order shall require the health care professionals who
7 prescribed, ordered, or used the in vitro clinical test
8 provide notification to the individuals for whom the
9 health professionals prescribed, ordered, or used
10 such test, of the risk presented by such in vitro clin-
11 ical test and of any action which may be taken by
12 or on behalf of such individuals to eliminate or re-
13 duce such risk. Before issuing an order under this
14 subsection, the Secretary shall consult with the per-
15 sons required to give notice under the order.

16 “(b) REPAIR, REPLACEMENT, OR REFUND.—

17 “(1) DETERMINATION AFTER AN INFORMAL
18 HEARING.—

19 “(A) IN GENERAL.—If, after affording op-
20 portunity for an informal hearing, the Secretary
21 determines that—

22 “(i) an in vitro clinical test presents
23 an unreasonable risk of substantial harm
24 to the public health;

1 “(ii) there are reasonable grounds to
2 believe that the in vitro clinical test was
3 not properly developed or manufactured
4 considering the state of the art as it ex-
5 isted at the time of its development;

6 “(iii) there are reasonable grounds to
7 believe that the unreasonable risk was not
8 caused by failure of a person other than a
9 developer, importer, distributor, or retailer
10 of the in vitro clinical test to exercise due
11 care in the installation, maintenance, re-
12 pair, or use of the in vitro clinical test; and

13 “(iv) the notice authorized by sub-
14 section (a) would not by itself be sufficient
15 to eliminate the unreasonable risk and ac-
16 tion described in paragraph (2) of this sub-
17 section is necessary to eliminate such risk,
18 the Secretary may order the developer, im-
19 porter, or any distributor of such in vitro clin-
20 ical test, or any combination of such persons, to
21 submit to him within a reasonable time a plan
22 for taking one or more of the actions described
23 in paragraph (2). An order issued under the
24 preceding sentence which is directed to more
25 than one person shall specify which person may

1 decide which action shall be taken under such
2 plan and the person specified shall be the per-
3 son who the Secretary determines bears the
4 principal, ultimate financial responsibility for
5 action taken under the plan unless the Sec-
6 retary cannot determine who bears such respon-
7 sibility or the Secretary determines that the
8 protection of the public health requires that
9 such decision be made by a person (including a
10 health professional or user of the in vitro clin-
11 ical test) other than the person the Secretary
12 determines bears such responsibility.

13 “(B) SECRETARY APPROVAL OF PLAN.—
14 The Secretary shall approve a plan submitted
15 pursuant to an order issued under subpara-
16 graph (A) unless the Secretary determines
17 (after affording opportunity for an informal
18 hearing) that the action or actions to be taken
19 under the plan or the manner in which such ac-
20 tion or actions are to be taken under the plan
21 will not assure that the unreasonable risk with
22 respect to which such order was issued will be
23 eliminated. If the Secretary disapproves a plan,
24 the Secretary shall order a revised plan to be
25 submitted within a reasonable time. If the Sec-

1 retary determines (after affording opportunity
2 for an informal hearing) that the revised plan
3 is unsatisfactory or if no revised plan or no ini-
4 tial plan has been submitted to the Secretary
5 within the prescribed time, the Secretary shall
6 (i) prescribe a plan to be carried out by the per-
7 son or persons to whom the order issued under
8 subparagraph (A) was directed, or (ii) after af-
9 fording an opportunity for an informal hearing,
10 by order prescribe a plan to be carried out by
11 a person who is a developer, importer, dis-
12 tributor, or retailer of the in vitro clinical test
13 with respect to which the order was issued but
14 to whom the order under subparagraph (A) was
15 not directed.

16 “(2) ACTIONS ON A PLAN.—The actions which
17 may be taken under a plan submitted under an
18 order issued under paragraph (1)(A) are as follows:

19 “(A) To repair the in vitro clinical test so
20 that it does not present the unreasonable risk
21 of substantial harm with respect to which the
22 order under paragraph (1)(A) was issued.

23 “(B) To replace the in vitro clinical test
24 with a like or equivalent test which is in con-

1 formity with all applicable requirements of this
2 Act.

3 “(C) To refund the purchase price of the
4 in vitro clinical test (less a reasonable allowance
5 for use if such in vitro clinical test has been in
6 the possession of the user for one year or more
7 at the time of notice ordered under subsection
8 (a), or at the time the user receives actual no-
9 tice of the unreasonable risk with respect to
10 which the order was issued under paragraph
11 (1)(A), whichever occurs first).

12 “(3) NO CHARGE.—No charge shall be made to
13 any person (other than a developer, importer, dis-
14 tributor or retailer) for using a remedy described in
15 paragraph (2) and provided under an order issued
16 under paragraph (1), and the person subject to the
17 order shall reimburse each person (other than a de-
18 veloper, manufacturer, importer, distributor, or re-
19 tailer) who is entitled to such a remedy for any rea-
20 sonable and foreseeable expenses actually incurred
21 by such person in using such remedy.

22 “(c) REIMBURSEMENT.—An order issued under sub-
23 section (b)(1)(A) with respect to an in vitro clinical test
24 may require any person who is a developer, importer, dis-
25 tributor, or retailer of the in vitro clinical test to reimburse

1 any other person who is a developer, importer, distributor,
2 or retailer of such in vitro clinical test for such other per-
3 son's expenses actually incurred in connection with car-
4 rying out the order if the Secretary determines such reim-
5 bursement is required for the protection of the public
6 health. Any such requirement shall not affect any rights
7 or obligations under any contract to which the person re-
8 ceiving reimbursement or the person making such reim-
9 bursement is a party.

10 “(d) RECALL AUTHORITY.—

11 “(1) IN GENERAL.—If the Secretary finds that
12 there is a reasonable probability that an in vitro
13 clinical test approved under section 587B or offered
14 under a technology certification order under section
15 587D would cause serious, adverse health con-
16 sequences or death, including by the absence, signifi-
17 cant delay, or discontinuation of appropriate medical
18 treatment, the Secretary shall issue an order requir-
19 ing the appropriate person (including the developers,
20 importers, distributors, or retailers of the in vitro
21 clinical test)—

22 “(A) to immediately cease distribution of
23 such in vitro clinical test; and

24 “(B) to immediately notify health profes-
25 sionals and applicable in vitro clinical test user

1 facilities of the order and to instruct such pro-
2 fessionals and facilities to cease use of such in
3 vitro clinical test.

4 “(2) INFORMAL HEARING.—The order issued
5 under paragraph (1)(A), shall provide the person
6 subject to the order with an opportunity for an in-
7 formal hearing, to be held not later than 10 calendar
8 days after the date of the issuance of the order, on
9 the actions required by the order and on whether the
10 order should be amended to require a recall of such
11 in vitro clinical test. If, after providing an oppor-
12 tunity for such a hearing, the Secretary determines
13 that inadequate grounds exist to support the actions
14 required by the order, the Secretary shall vacate the
15 order.

16 “(3) AMENDED ORDER.—

17 “(A) IN GENERAL.—If, after providing an
18 opportunity for an informal hearing under
19 paragraph (2), the Secretary determines that
20 the order should be amended to include a recall
21 of the in vitro clinical test with respect to which
22 the order was issued, the Secretary shall, except
23 as provided in subparagraph (B), amend the
24 order to require a recall. The Secretary shall
25 specify a timetable in which the recall will occur

1 and shall require periodic reports describing the
2 progress of the recall.

3 “(B) REQUIREMENTS.—An amended order
4 under subparagraph (A)—

5 “(i) shall not include recall of the in
6 vitro clinical test from individuals;

7 “(ii) shall not include recall of an in
8 vitro clinical test from test user facilities if
9 the Secretary determines that the risk of
10 recalling such in vitro clinical test from the
11 facilities presents a greater health risk
12 than the health risk of not recalling the in
13 vitro clinical test from use; and

14 “(iii) shall provide for notice to indi-
15 viduals subject to the risks associated with
16 the use of such in vitro clinical test. In
17 providing the notice required by this
18 clause, the Secretary may use the assist-
19 ance of health professionals who pre-
20 scribed, ordered, or used such an in vitro
21 clinical test for individuals.

22 “(4) CLARIFICATION.—The remedy provided by
23 this subsection shall be in addition to remedies pro-
24 vided by subsections (a), (b), and (c).

1 **“SEC. 587AA. APPLICABILITY.**

2 “(a) IN GENERAL.—An in vitro clinical test shall be
3 subject to the requirements of this subchapter, except as
4 otherwise provided in this subchapter.

5 “(b) INTERSTATE COMMERCE.—Any in vitro clinical
6 test that is offered, including by making available for clin-
7 ical use in the United States is deemed to be an act that
8 constitutes introduction into interstate commerce for pur-
9 poses of enforcing the requirements of this Act.

10 “(c) LEAST BURDENSOME REQUIREMENTS.—

11 “(1) IN GENERAL.—In carrying out this sub-
12 chapter, the Secretary shall consider the least bur-
13 densome means necessary to meet the applicable
14 standard, and other regulatory requirements, as de-
15 termined by the Secretary.

16 “(2) NECESSARY DEFINED.—For purposes of
17 paragraph (1) and paragraph (3), the term ‘nec-
18 essary’ means the minimum required information
19 that would support a determination by the Secretary
20 that the application meet the applicable standard or
21 regulatory requirement, as determined by the Sec-
22 retary.

23 “(d) SERVICE OF ORDERS.—Orders of the Secretary
24 under this section with respect to applications under sub-
25 section (a) or (b) of section 587B or supplements under
26 subsection (f) of such section shall be served—

1 “(1) in person by any officer or employee of the
2 Department of Health and Human Services des-
3 ignated by the Secretary; or

4 “(2) by mailing the order by registered mail or
5 certified mail or electronic equivalent addressed to
6 the applicant at the last known address in the
7 records of the Secretary.

8 “(e) LABORATORIES AND BLOOD AND TISSUE ES-
9 TABLISHMENTS.—

10 “(1) RELATION TO LABORATORY CERTIFI-
11 CATION PURSUANT TO SECTION 353 OF THE PUBLIC
12 HEALTH SERVICE ACT.—Nothing in this subchapter
13 shall be construed to modify the authority of the
14 Secretary with respect to laboratories or clinical lab-
15 oratories under section 353 of the Public Health
16 Service Act.

17 “(2) AVOIDING DUPLICATION.—In imple-
18 menting this subchapter, the Secretary shall avoid
19 issuing or enforcing regulations or guidance that are
20 duplicative of regulations or guidance under section
21 353 of the Public Health Service Act.

22 “(3) BLOOD AND TISSUE.—Nothing in this sub-
23 chapter shall be construed to modify the authority of
24 the Secretary with respect to laboratories, establish-
25 ments, or other facilities to the extent they are en-

1 gaged in the propagation, manufacture, or prepara-
2 tion, including filling, labeling, packaging, and stor-
3 age, of blood, blood components, human cells, tis-
4 sues, or tissue products pursuant to any require-
5 ments under this Act or section 351 or 361 of the
6 Public Health Service Act.

7 “(f) NOT COMBINATION PRODUCT.—A product con-
8 stituted of a device and an in vitro clinical test is not a
9 combination product and shall be regulated as a device.

10 “(g) PRACTICE OF MEDICINE.—Nothing in this sub-
11 chapter shall be construed to limit or interfere with the
12 authority of a health care practitioner to prescribe or ad-
13 minister any lawfully offered in vitro clinical test for any
14 condition or disease within a legitimate health care practi-
15 tioner-patient relationship pursuant to applicable Federal
16 or State law.

17 “(h) RULES OF CONSTRUCTION.—

18 “(1) SALE, DISTRIBUTION, LABELING.—Noth-
19 ing in this paragraph shall be construed to limit the
20 authority of the Secretary to establish or enforce re-
21 strictions on the sale, distribution, or labeling of an
22 in vitro clinical test under this Act.

23 “(2) PROMOTION OF UNAPPROVED USES.—
24 Nothing in this paragraph shall be construed to alter

1 any prohibition on the promotion of unapproved uses
2 of legally marketed in vitro clinical tests.

3 **“SEC. 587BB. JUDICIAL REVIEW.**

4 “(a) IN GENERAL.—Not later than 30 days after an
5 order issued pursuant to sections 587B or 587D, any per-
6 son adversely affected by such order may file a petition
7 with the United States Court of Appeals for the District
8 of Columbia or for the circuit wherein such person resides
9 or has a principal place of business for judicial review of
10 such order, in accordance with the procedure set forth in
11 section 517(a).

12 “(b) APPLICATION OF PROVISIONS.—Subsections (a)
13 through (e) of section 517 shall apply with respect to a
14 petition under subsection (a) of this section in the same
15 manner such subsections apply to a petition under section
16 517. Subsection (f) of section 517 shall apply to an order
17 issued under section 587B or 587D.”

18 **SEC. 824. ENFORCEMENT AND OTHER PROVISIONS.**

19 (a) PROHIBITED ACTS.—Section 301 of the Federal
20 Food, Drug, and Cosmetic Act (21 U.S.C. 331), as
21 amended by section 811, is further amended—

22 (1) in paragraphs (a), (b), (c), (g), (h), (k), (q),
23 (r), and (y), by inserting “in vitro clinical test,”
24 after “device,” each place it appears;

1 (2) in paragraph (g), by inserting after “mis-
2 branded”, “, and the development within any Terri-
3 tory of any in vitro clinical test that is adulterated
4 or misbranded”;

5 (3) in paragraph (y), by inserting “or 587Q”
6 after “section 523” each place it appears;

7 (4) in paragraph (ff), by striking “or device”
8 and inserting “, device, or in vitro clinical test”; and

9 (5) by adding at the end, the following:

10 “(jjj)(1) Forging, counterfeiting, simulating, or false-
11 ly representing, or without proper authority using any
12 mark, stamp, tag, label, or other identification upon any
13 in vitro clinical test or container, packaging, or labeling
14 thereof so as to render such in vitro clinical test a counter-
15 feit in vitro clinical test.

16 “(2) Making, selling, disposing of, or keeping in pos-
17 session, control, or custody, or concealing any punch, die,
18 plate, stone, or other thing designed to print, imprint, or
19 reproduce the trademark, trade name, or other identifying
20 mark or imprint of another or any likeness of any of the
21 foregoing upon any in vitro clinical test or container, pack-
22 aging, or labeling thereof so as to render such in vitro
23 clinical test a counterfeit in vitro clinical test.

24 “(3) The doing of any act which causes an in vitro
25 clinical test to be a counterfeit in vitro clinical test, or

1 the sale or dispensing, or the holding for sale or dis-
2 pensing, of a counterfeit in vitro clinical test.

3 “(kkk)(1) The introduction or delivery for introduc-
4 tion into interstate commerce of an in vitro clinical test
5 in violation of section 587B(a).

6 “(2) The making of a false, fraudulent, or deceptive
7 statement about an in vitro clinical test that is exempt
8 from premarket review under section 587C.

9 “(3) The failure to maintain complete and accurate
10 documentation for an exemption as required under section
11 587C or the failure to provide labeling required under sec-
12 tion 587L.

13 “(4) With respect to an in vitro clinical test, the sub-
14 mission of any report or listing under this Act that is false
15 or misleading in any material respect.

16 “(5) The failure to comply with a condition of ap-
17 proval, or restriction required under an approved applica-
18 tion under section 587B; the failure to perform a risk
19 analysis required by section 587B; the failure to submit
20 an annual update required under section 587J(e)(2)(B);
21 or the failure to complete postmarket surveillance as re-
22 quired under section 587X.

23 “(6) The failure to comply with applicable require-
24 ments to submit an application or report under section
25 587D(e).

1 “(7) The failure to comply with applicable mitigating
2 measures established under section 587E or to submit,
3 maintain, or make available the documentation required
4 under section 587E(b); or the failure to comply with appli-
5 cable performance standards established under section
6 587R.

7 “(8) The failure to register in accordance with section
8 587J, the failure to provide information required under
9 section 587J(b), or the failure to maintain or submit infor-
10 mation required under section 587J(c).

11 “(9) The failure to comply with requirements under
12 section 587M or 587N, the failure to comply with a re-
13 striction required under section 587O, or the failure to
14 comply with labeling and advertising requirements under
15 section 587O(b).

16 “(10) The failure to comply with the requirements
17 of section 587Q.

18 “(11) The failure to comply with any requirement of
19 section 587S; the failure to furnish any notification, infor-
20 mation, material, or report required under section 587S;
21 or the failure to comply with an order issued under section
22 587S.

23 “(12) The failure to furnish information requested by
24 the Secretary under 587G(d)(2).”.

1 (b) PENALTIES.—Section 303 of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 333) is amended—

3 (1) in subsection (b)(8), by inserting “or coun-
4 terfeit in vitro clinical test” after “counterfeit drug”;

5 (2) in subsection (c)—

6 (A) by striking “; or (5)” and inserting “;
7 (5)”; and

8 (B) by inserting before the period at the
9 end the following: “; or (6) for having violated
10 section 301(fff)(2) if such person acted in good
11 faith and had no reason to believe that use of
12 the punch, die, plate, stone, or other thing in-
13 volved would result in an in vitro clinical test
14 being a counterfeit in vitro clinical test, or for
15 having violated section 301(fff)(3) if the person
16 doing the act or causing it to be done acted in
17 good faith and had no reason to believe that the
18 in vitro clinical test was a counterfeit in vitro
19 clinical test”; and

20 (3) in subsection (f)(1)—

21 (A) in subparagraph (A)—

22 (i) by inserting “or in vitro clinical
23 tests” after “which relates to devices”;

24 (ii) by inserting “or section
25 587Q(a)(2)” after “section 704(g)”; and

1 (iii) by inserting “or in vitro clinical
2 tests, as applicable” before the period at
3 the end of the second sentence; and

4 (B) in subparagraph (B)(i), by striking “or
5 520(f)” and inserting “, 520(f), 587K, or
6 587M,”.

7 (c) SEIZURE.—Section 304 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

9 (1) in subsection (a)(2)—

10 (A) by striking “, and (E)” and inserting
11 “, (E)”; and

12 (B) by inserting before the period at the
13 end the following: “, and (F) Any in vitro clin-
14 ical test that is a counterfeit in vitro clinical
15 test, (G) Any container, packaging, or labeling
16 of a counterfeit in vitro clinical test, and (H)
17 Any punch, die, plate, stone, labeling, container,
18 or other thing used or designed for use in mak-
19 ing a counterfeit in vitro clinical test”;

20 (2) in subsection (d)(1), by inserting “in vitro
21 clinical test,” after “device,”; and

22 (3) in subsection (g)—

23 (A) in paragraph (1), by inserting “, in
24 vitro clinical test,” after “device” each place it
25 appears; and

1 (B) in paragraph (2)—

2 (i) in subparagraph (A), by inserting

3 “, in vitro clinical test,” after “device”;

4 and

5 (ii) in subparagraph (B), by inserting

6 “or in vitro clinical test” after “device”

7 each place it appears.

8 (d) DEBARMENT, TEMPORARY DENIAL OF AP-
9 PROVAL, AND SUSPENSION.—Section 306 of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is
11 amended by adding at the end the following:

12 “(n) IN VITRO CLINICAL TESTS; MANDATORY DE-
13 BARMENT REGARDING THIRD-PARTY INSPECTIONS AND
14 REVIEWS.—

15 “(1) IN GENERAL.—If the Secretary finds that
16 a person has been convicted of a felony for a viola-
17 tion of section 301(gg) or 301(jjj)(1), the Secretary
18 shall debar such person from being accredited under
19 section 587Q and from carrying out activities under
20 an agreement described in section 803(b).

21 “(2) DEBARMENT PERIOD.—The Secretary
22 shall debar a person under paragraph (1) for the fol-
23 lowing periods:

24 “(A) The period of debarment of a person
25 (other than an individual) shall not be less than

1 1 year or more than 10 years, but if an act
2 leading to a subsequent debarment under such
3 paragraph occurs within 10 years after such
4 person has been debarred under such para-
5 graph, the period of debarment shall be perma-
6 nent.

7 “(B) The debarment of an individual shall
8 be permanent.

9 “(3) TERMINATION OF DEBARMENT; JUDICIAL
10 REVIEW; OTHER MATTERS.—Subsections (c)(3), (d),
11 (e), (i), (j), and (l)(1) apply with respect to a person
12 (other than an individual) or an individual who is
13 debarred under paragraph (1) to the same extent
14 and in the same manner as such subsections apply
15 with respect to a person who is debarred under sub-
16 section (a)(1), or an individual who is debarred
17 under subsection (a)(2), respectively.”.

18 (e) EXPANDED ACCESS TO UNAPPROVED THERAPIES
19 AND DIAGNOSTICS.—Section 561 of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amend-
21 ed—

22 (1) in subsections (a) through (d)—

23 (A) by striking “or investigational devices”
24 each place it appears and inserting “, investiga-

1 tional devices, or investigational in vitro clinical
2 tests”; and

3 (B) by striking “or investigational device”
4 each place it appears (other than the second
5 such place in paragraph (3)(A)) of subsection
6 (c) and inserting “, investigational device, or
7 investigational in vitro clinical test”;

8 (2) in subsection (b)(4) by striking “or 520(g)”
9 and inserting “, 520(g), or 587S” each place it ap-
10 pears;

11 (3) in subsection (c)—

12 (A) by amending the subsection heading to
13 read: “TREATMENT INVESTIGATIONAL NEW
14 DRUG APPLICATIONS, TREATMENT INVESTIGA-
15 TIONAL DEVICE EXEMPTIONS, AND TREAT-
16 MENT INVESTIGATIONAL IN VITRO CLINICAL
17 TEST EXEMPTIONS.—”;

18 (B) in paragraph (3)(A), by striking “or
19 investigational device exemption in effect under
20 section 520(g)” and inserting “, investigational
21 device exemption in effect under section 520(g),
22 or investigational in vitro clinical test exemption
23 under section 587S”;

24 (C) by striking “or treatment investiga-
25 tional device exemption” each place it appears

1 and inserting “, treatment investigational device
2 exemption, or treatment investigational in vitro
3 clinical test exemption”;

4 (D) in paragraph (5), by striking “or
5 520(g)” and inserting “, 520(g), or 587S”;

6 (E) in the matter following paragraph (7)
7 by striking “or 520(g)” each place it appears
8 and inserting “, 520(g) or 587S”;

9 (4) by amending subsection (e) to read as fol-
10 lows:

11 “(e) DEFINITIONS.—In this section, the terms ‘inves-
12 tigational drug’, ‘investigational device’, ‘investigational in
13 vitro clinical test’, ‘treatment investigational new drug ap-
14 plication’, ‘treatment investigational device exemption’,
15 and ‘treatment investigational in vitro clinical test exemp-
16 tion’ shall have the meanings given the terms in regula-
17 tions prescribed by the Secretary.”.

18 (f) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section
19 569A(b) of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 360bbb–8a(b)) is amended by inserting “an in
21 vitro clinical test, as defined in subsection (ss) of such sec-
22 tion,” before “or a biological product”.

23 (g) PATIENT PARTICIPATION IN MEDICAL PRODUCT
24 DISCUSSION.—The heading of subsection (a) of section
25 569C of the Federal Food, Drug, and Cosmetic Act (21

1 U.S.C. 360bbb–8c) is amended by striking “Drugs and
2 Devices” and inserting “Drugs, Devices, and In Vitro
3 Clinical Tests”.

4 (h) REGULATIONS AND HEARINGS.—Section
5 701(h)(1)(C)(ii) of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 371(h)(1)(C)(ii)) is amended by inserting
7 “and in vitro clinical tests” after “devices”.

8 (i) RECORDS.—Section 703 of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 373) is amended—
10 (1) by inserting “in vitro clinical tests” after
11 “devices” each place such term appears; and
12 (2) by inserting “in vitro clinical test” after
13 “device” each place such term appears.

14 (j) FACTORY INSPECTION.—Section 704 of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C. 374) (other
16 than subsection (g)) is amended—

17 (1) by striking “drugs or devices” each place it
18 appears and inserting “drugs, devices, or in vitro
19 clinical tests”;

20 (2) in subsection (a)(1), in the fourth sentence,
21 by striking “or chapter IX” and inserting “section
22 587S, section 587M, section 587N, or chapter IX”;

23 (3) after making the amendments in para-
24 graphs (1) and (2), by inserting “in vitro clinical
25 tests,” after “devices,” each place it appears;

1 (4) in subsection (a)(2)(B)—

2 (A) by inserting “or in vitro clinical tests”
3 after “prescribe or use devices”; and

4 (B) by inserting “or in vitro clinical tests”
5 after “process devices”;

6 (5) by inserting “in vitro clinical test,” after
7 “device,” each place it appears;

8 (6) in subsection (e), by inserting “, or section
9 587M, 587N, or 587S,” after “section 519 or
10 520(g)”;

11 (7) in subsection (f)(3)—

12 (A) in subparagraph (A), by striking “or”
13 at the end;

14 (B) in subparagraph (B), by striking the
15 period at the end and inserting “; or”; and

16 (C) after subparagraph (B), by inserting
17 the following:

18 “(C) is accredited under section 587Q.”;

19 and

20 (8) by adding at the end the following:

21 “(i) For purposes of this section, the term ‘establish-
22 ment’ includes a laboratory performing an in vitro clinical
23 test.”.

1 (k) PUBLICITY.—Section 705(b) of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended
3 by inserting “in vitro clinical tests,” after “devices,”.

4 (l) PRESUMPTION.—Section 709 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 379a) is amended by
6 inserting “in vitro clinical test,” after “device,”.

7 (m) LISTING AND CERTIFICATION OF COLOR ADDI-
8 TIVES FOR FOODS, DRUGS, AND COSMETICS.—Section
9 721(a) of the Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. 379e(a)) is amended—

11 (1) in the matter preceding paragraph (1), by
12 inserting “or in vitro clinical tests” after “or de-
13 vices”; and

14 (2) in the flush text following paragraph (2)—

15 (A) by inserting “or an in vitro clinical
16 test” after “a device”; and

17 (B) by inserting “or in vitro clinical tests”
18 after “devices”.

19 (n) IMPORTS AND EXPORTS.—Section 801 of the
20 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381)
21 is amended—

22 (1) in subsection (a)—

23 (A) by inserting “in vitro clinical tests,”
24 after “devices,” each place it appears; and

1 (B) by inserting “in the case of an in vitro
2 clinical test, the test does not conform to the
3 applicable requirements of section 587K, or”
4 after “requirements of section 520(f), or”;

5 (2) in subsection (d)(3)—

6 (A) in subparagraph (A)—

7 (i) in the matter preceding clause (i),
8 by inserting “and no component of an in
9 vitro clinical test or other article of in vitro
10 clinical test that requires further proc-
11 essing,” after “health-related purposes”;

12 (ii) in clause (i), by striking “drug or
13 device” and inserting “drug, device, or in
14 vitro clinical test”; and

15 (iii) in clause (i)(I), by inserting “in
16 vitro clinical test,” after “device,”; and

17 (B) in subparagraph (B), by inserting “in
18 vitro clinical test,” after “device,”;

19 (3) in subsection (e)(1), by inserting “in vitro
20 clinical test,” after “device,”; and

21 (4) in subsection (o)—

22 (A) by inserting “or in vitro clinical test”
23 after “device”; and

1 (B) by inserting “section 587J of each for-
2 eign establishment” after “section 510(i) of
3 each establishment”.

4 (o) OFFICE OF INTERNATIONAL RELATIONS.—Sec-
5 tion 803 of the Federal Food, Drug, and Cosmetic Act
6 (21 U.S.C. 383) is amended—

7 (1) in subsection (b)—

8 (A) in the matter preceding paragraph (1),
9 by inserting “and in vitro clinical tests” after
10 “devices”; and

11 (B) in paragraph (1), by inserting “quality
12 requirements established under section 587K;
13 and” at the end; and

14 (2) in subsection (c)—

15 (A) in paragraph (2), by inserting “in vitro
16 clinical tests,” after “devices,”; and

17 (B) in paragraph (4), by inserting “or in
18 vitro clinical tests” after “devices”.

19 (p) RECOGNITION OF FOREIGN GOVERNMENT IN-
20 SPECTIONS.—Section 809(a)(1) of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 384e(a)(1)) is amend-
22 ed by inserting “, or of foreign establishments registered
23 under section 587J” after “510(h)”.

1 (q) FOOD AND DRUG ADMINISTRATION.—Section
2 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 393(b)(2)) is amended—

4 (1) in subparagraph (D), by striking “and” at
5 the end;

6 (2) in subparagraph (E), by striking the semi-
7 colon at the end and inserting “; and”; and

8 (3) by adding at the end the following:

9 “(F) in vitro clinical tests are analytically
10 and clinically valid;”.

11 (r) OFFICE OF WOMEN’S HEALTH.—Section 1011(b)
12 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 399b(b)) is amended—

14 (1) in paragraph (1), by inserting “in vitro clin-
15 ical tests,” after “devices,”; and

16 (2) in paragraph (4), by striking “and device
17 manufacturers” and inserting “device manufactur-
18 ers, and in vitro clinical test developers,”.

19 (s) COUNTERMEASURE PROVISIONS OF THE PUBLIC
20 HEALTH SERVICE ACT.—Title III of the Public Health
21 Service Act is amended—

22 (1) in section 319F–1(a)(2)(A) (42 U.S.C.
23 247d–6a(a)(2)(A))—

24 (A) in the matter preceding clause (i)—

1 (i) by striking “or device” and insert-
2 ing “device”; and

3 (ii) by inserting “or an in vitro clin-
4 ical tests (as that term is defined in sec-
5 tion 201(ss) of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 321(ss)),”
7 after “Act (21 U.S.C. 321(h)),”; and

8 (B) in each of clauses (ii) and (iii), by
9 striking “or device” and inserting “device, or in
10 vitro clinical test”;

11 (2) in section 319F-2(c)(1)(B) (42 U.S.C.
12 247d-6b(c)(1)(B))—

13 (A) by striking “or device” and inserting
14 “device”; and

15 (B) by inserting “, or an in vitro clinical
16 test (as that term is defined in section 201(ss)
17 of the Federal Food, Drug, and Cosmetic Act
18 (21 U.S.C. 321(ss)))” after “Act (21 U.S.C.
19 321(h)),”; and

20 (3) in section 319F-3(i)(7) (42 U.S.C. 247d-
21 6d(i)(7))—

22 (A) in the matter preceding subparagraph
23 (A)—

24 (i) by striking “or device” and insert-
25 ing “device”; and

1 (ii) by inserting “or an in vitro clin-
 2 ical tests (as that term is defined in sec-
 3 tion 201(ss) of the Federal Food, Drug,
 4 and Cosmetic Act (21 U.S.C. 321(ss)),”
 5 after “Act (21 U.S.C. 321(h))”;

6 (B) in subparagraph (A)—

7 (i) by moving the margin of clause
 8 (iii) 2 ems to the left; and

9 (ii) in clause (iii), by striking “or de-
 10 vice” and inserting “device, or in vitro clin-
 11 ical test”; and

12 (C) in subparagraph (B)—

13 (i) in clause (i), by inserting “or the
 14 subject of a technology certification order”
 15 after “approved or cleared”; and

16 (ii) in clause (ii), by striking “or
 17 520(g)” and inserting “, 520(g), or 587S”.

18 **SEC. 825. TRANSITION.**

19 (a) IMPLEMENTATION.—

20 (1) EFFECTIVE DATE.—

21 (A) IN GENERAL.—Except as otherwise
 22 provided in this section, the amendments made
 23 by this Act shall take effect on October 1, 2027
 24 (in this section and in subchapter J of chapter
 25 V of the Federal Food, Drug, and Cosmetic

1 Act, as added by this Act, referred to in this
2 section as the “effective date of this Act”).

3 (B) EXCEPTIONS.—

4 (i) IN GENERAL.—The Secretary of
5 Health and Human Services (in this sec-
6 tion referred to as the “Secretary”) may
7 take the actions described in paragraph
8 (3), and may expend such funds as the
9 Secretary determines necessary to ensure
10 an orderly transition, including prior to the
11 effect date of this Act.

12 (ii) IMPLEMENTATION OF CERTAIN
13 PROVISIONS.—The Secretary may imple-
14 ment sections 587J and 587U of the Fed-
15 eral Food, Drug, and Cosmetic Act (as
16 added by section 3) beginning on October
17 1, 2024, and such sections may take effect
18 not earlier than October 1, 2027, to the
19 extent and for the purposes indicated in
20 such sections. In the case of a developer
21 who, between October 1, 2024, and the ef-
22 fective date of this Act specified in sub-
23 paragraph (A), registers under such sec-
24 tion 587K with respect to an article that
25 is an in vitro clinical test, such developer

1 shall not be required to register with re-
2 spect to such article under section 510 of
3 such Act (21 U.S.C. 360).

4 (2) ACTIONS.—The Secretary—

5 (A) shall—

6 (i) within 1 year of the date of enact-
7 ment of this Act, hold the public meetings
8 described in section 587D(c) of the Fed-
9 eral Food, Drug, and Cosmetic Act (as
10 added by section 3);

11 (ii) within 3 years of the date of en-
12 actment of this Act, promulgate final regu-
13 lations required under the amendments
14 made by this Act; and

15 (iii) within 30 months of the date of
16 enactment of this Act, issue final guidance
17 on applicability requirements under
18 amendments made by this Act; and

19 (B) may take additional actions after the
20 date of enactment that the Secretary deter-
21 mines necessary to ensure an orderly transition,
22 which may not take effect until after the effec-
23 tive date, including—

1 (i) establishment of mitigating meas-
2 ures for an in vitro clinical test or category
3 of in vitro clinical tests; and

4 (ii) establishment of the comprehen-
5 sive test information system under section
6 587T.

7 (3) APPLICABILITY OF GUIDANCE AND REGULA-
8 TIONS.—Notwithstanding the date on which guid-
9 ance or regulations are issued under paragraph (3)
10 and section 587K, no guidance or regulations issued
11 pursuant to the amendments made by this Act shall
12 be implemented or take effect until the effective date
13 of this Act, as described in paragraph (1), except as
14 otherwise specified in this Act (including the amend-
15 ments made by this Act).

16 (b) APPLICATION OF AUTHORITIES TO IN VITRO
17 CLINICAL TESTS UNDER REVIEW ON THE EFFECTIVE
18 DATE OF THIS ACT.—For any in vitro clinical test, as
19 defined in section 201(ss) of the Federal Food, Drug, and
20 Cosmetic Act, as added by section 822, for which a sub-
21 mission for approval under section 515 of the Federal
22 Food, Drug, and Cosmetic Act (21 U.S.C. 360e), clear-
23 ance under section 510(k) of such Act (21 U.S.C. 360(k)),
24 authorization under section 513(f)(2) of such Act (21
25 U.S.C. 360c(f)(2)), or licensure under section 351 of the

1 Public Health Service Act (42 U.S.C. 262) is pending on
2 the effective date of this Act, including transitional in vitro
3 clinical tests as described in subsection (c), the Secretary
4 may review and take action on such submission after the
5 effective date of this Act according to the statutory provi-
6 sion under which such submission was submitted.

7 (c) APPLICATION OF AUTHORITIES TO TRANSI-
8 TIONAL IN VITRO CLINICAL TESTS.—

9 (1) DEFINITION.—For purposes of this section,
10 the term “transitional in vitro clinical test” means
11 an in vitro clinical test, as defined in section 201(ss)
12 of the Federal Food, Drug, and Cosmetic Act, as
13 added by this Act, that—

14 (A) is first offered for clinical use during
15 the period beginning on the date of enactment
16 of this Act and ending on the effective date of
17 this Act;

18 (B) is developed by a clinical laboratory
19 certified by the Secretary under section 353 of
20 the Public Health Service Act (42 U.S.C. 263a)
21 that meets the requirements for performing
22 high-complexity testing and performed—

23 (i) in the same clinical laboratory in
24 which the test was developed and for which
25 a certification is still in effect under such

1 section 353 that meets the requirements to
2 perform tests of high complexity;

3 (ii) by another laboratory for which a
4 certificate is in effect under such section
5 353 that meets the requirements to per-
6 form tests of high complexity, is within the
7 same corporate organization, and has com-
8 mon ownership by the same parent cor-
9 poration as the laboratory in which the
10 test was developed; or

11 (iii) in the case of a test that was de-
12 veloped by the Centers for Disease Control
13 and Prevention or another laboratory a
14 public health laboratory network coordi-
15 nated or managed by the Centers for Dis-
16 ease Control and Prevention, by a clinical
17 laboratory for which a certificate is in ef-
18 fect under section 353 of such Act that
19 meets the requirements to perform tests of
20 high complexity, and that is within a pub-
21 lic health laboratory network coordinated
22 or managed by the Centers for Disease
23 Control and Prevention; and

24 (C) when first offered, is not approved
25 under section 515 of the Federal Food, Drug,

1 and Cosmetic Act, cleared under section 510(k)
2 of such Act, authorized under section 513(f)(2)
3 of such Act, subject to a humanitarian device
4 exemption under section 520(m) of such Act
5 (21 U.S.C. 360j(m)), subject to an exemption
6 for investigation use under section 520(g) of
7 such Act (21 U.S.C. 360j(g)), authorized under
8 section 564 of such Act (21 U.S.C. 360bbb–3),
9 or licensed under section 351 of the Public
10 Health Service Act (42 U.S.C. 262).

11 (2) PREMARKET REVIEW OR TECHNOLOGY CER-
12 TIFICATION.—A transitional in vitro clinical test
13 that is the subject of an application for premarket
14 review under section 587B of the Federal Food,
15 Drug, and Cosmetic Act or technology certification
16 application under section 587D of such Act, as
17 added by this Act, may continue to be offered, sold,
18 or distributed until completion of the Secretary’s re-
19 view of the premarket application or technology cer-
20 tification application, if such application is sub-
21 mitted no later than 90 days after the effective date
22 of this Act.

23 (3) TESTS APPROVED BY NEW YORK STATE.—
24 Notwithstanding paragraph (2), a transitional in
25 vitro clinical test that has been approved by the New

1 York State Department of Health may continue to
2 be offered, sold, or distributed after the effective
3 date if—

4 (A) starting on the effective date of this
5 Act, the in vitro clinical test complies with the
6 requirements of subchapter J of the Federal
7 Food, Drug, and Cosmetic Act, as added by
8 this Act, except for sections 587B and design
9 control provisions of section 587K;

10 (B) each test report template for the test
11 bears a statement of adequate prominence that
12 reads as follows: “This in vitro clinical test was
13 developed and first introduced prior to the ef-
14 fective date of the VALID Act of 2022. This
15 test was approved by the New York State De-
16 partment of Health, but the test has not been
17 reviewed by the Food and Drug Administra-
18 tion.”;

19 (C) a premarket application under section
20 587B or technology certification application
21 under section 587D is submitted no later
22 than—

23 (i) 5 years after the effective date of
24 this Act, if the in vitro clinical test is ap-
25 proved by the New York State Department

1 of Health as a genetic testing molecular
2 test, a microbiology molecular test, an on-
3 cology molecular test, or any other type of
4 molecular test; or

5 (ii) 2 years after the effective date of
6 this Act, if the in vitro clinical test is ap-
7 proved by the New York State Department
8 of Health as a type of test not described
9 in clause (i); and

10 (D) a test in compliance with this para-
11 graph (3) may continue to be offered, sold, or
12 distributed until the completion of the Sec-
13 retary's review of the premarket application or
14 technology certification application referenced
15 in subparagraph (C).

16 (d) CONVERSION.—

17 (1) DEEMED PREMARKET APPROVAL.—Begin-
18 ning on the effective date of this Act—

19 (A) any in vitro clinical test (as defined in
20 section 201(ss) of the Federal Food, Drug, and
21 Cosmetic Act, as added by section 822) with a
22 premarket approval under section 515 of the
23 Federal Food, Drug, and Cosmetic Act (21
24 U.S.C. 360e) or a licensure under section 351
25 of the Public Health Service Act (42 U.S.C.

1 262) is deemed to be approved pursuant to an
2 application under section 587B(c) of the Fed-
3 eral Food, Drug, and Cosmetic Act, as added
4 by this Act; and

5 (B) any in vitro clinical test (as so defined)
6 that was cleared under section 510(k) of the
7 Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 360(k)) or authorized under section
9 513(f)(2) of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 360c(f)(2)) is deemed to
11 be approved pursuant to an application under
12 section 587B(d) of the Federal Food, Drug,
13 and Cosmetic Act, as added by this Act.

14 (2) DEEMED INVESTIGATIONAL USE EXEMP-
15 TION.—Any in vitro clinical test (as defined in sec-
16 tion 201(ss) of the Federal Food, Drug, and Cos-
17 metic Act, as added by section 822) that has an in-
18 vestigational device exemption in effect under section
19 520(g) of the Federal Food, Drug, and Cosmetic Act
20 (21 U.S.C. 360j(g)) is deemed to have an investiga-
21 tional use exemption in effect under section 587S of
22 such Act, as added by this Act, beginning on the ef-
23 fective date of this Act.

24 (3) DEEMED HUMANITARIAN DEVICE EXEMP-
25 TION.—Any in vitro clinical test (as defined in sec-

1 tion 201(ss) of the Federal Food, Drug, and Cos-
2 metic Act, as added by section 822) that has an ap-
3 proved humanitarian device exemption under section
4 520(m) of such Act is deemed to have a humani-
5 tarian test exemption under section 587A(g) of such
6 Act, as added by this Act, beginning on the effective
7 date of this Act.

8 (4) DEEMED DESIGNATED BREAKTHROUGH.—
9 Any in vitro clinical test (as defined in section
10 201(gg) of the Federal Food, Drug, and Cosmetic
11 Act, as added by section 822) that has received a
12 breakthrough device designation under section
13 515B(e)(1)(D) of such Act (21 U.S.C. 360e–
14 3(e)(1)(D)) is deemed to have a breakthrough in
15 vitro clinical test designation under section 587C of
16 such Act, as added by this Act, beginning on the ef-
17 fective date of this Act.

18 (5) DEEMED REQUEST FOR INFORMAL FEED-
19 BACK.—With regard to any in vitro clinical test that
20 is the subject of a pre-submission request described
21 in the guidance, “Requests for Feedback and Meet-
22 ings for Medical Device Submissions: The Q-Submis-
23 sion Program”, issued by the Food and Drug Ad-
24 ministration on January 6, 2021, such request is
25 deemed to constitute a request for informal feedback

1 under section 587F of the Federal Food, Drug, and
2 Cosmetic Act, as added by section 823, beginning on
3 the effective date of this Act.

4 (e) PREVIOUSLY CLASSIFIED DEVICES.—Notwith-
5 standing section 587 of the Federal Food, Drug, and Cos-
6 metic Act, as added by section 823, for purposes of sub-
7 chapter J of chapter V of such Act, as added by section
8 823, the following apply:

9 (1) In the case of an in vitro clinical test type
10 that has been classified by the Secretary as a class
11 I device pursuant to section 513 of such Act (21
12 U.S.C. 360e), such in vitro clinical test shall be low-
13 risk, unless the in vitro clinical test is a test de-
14 scribed in section 510(l) or the test is redesignated
15 by the Secretary pursuant to section 587F of such
16 Act.

17 (2) In the case of an in vitro clinical test type
18 that has been classified by the Secretary as a class
19 II device pursuant to section 513 of such Act (21
20 U.S.C. 360e), such in vitro clinical test shall be
21 moderate-risk, unless inaccurate results from the
22 test would be immediately life threatening or the test
23 is redesignated by the Secretary pursuant to section
24 587F of such Act.

1 (3) In the case of an in vitro clinical test type
2 that is a class III device pursuant to section 513 of
3 such Act (21 U.S.C. 360c), such in vitro clinical test
4 shall be high-risk, unless redesignated by the Sec-
5 retary pursuant to section 587F of such Act.

6 **SEC. 826. EMERGENCY USE AUTHORIZATION.**

7 (a) IN GENERAL.—Section 564 of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amend-
9 ed—

10 (1) in subsection (a)—

11 (A) in paragraphs (1) and (4)(C), by in-
12 serting “in vitro clinical test,” before “or bio-
13 logical product” each place such term appears;
14 and

15 (B) in paragraph (2)(A), by striking “or
16 515” and inserting “515, or 587B”;

17 (2) in subsection (e)—

18 (A) in paragraph (3)—

19 (i) in subparagraph (B), by striking
20 “and” at the end;

21 (ii) in subparagraph (C), by striking
22 the period and inserting “; and”; and

23 (iii) by adding at the end the fol-
24 lowing:

1 “(D) quality requirements (with respect to
2 in vitro clinical tests) under section 587K.”;
3 and

4 (B) in paragraph (4)—

5 (i) in subparagraph (A), by striking “;
6 or” and inserting a semicolon;

7 (ii) in subparagraph (B), by striking
8 the period and inserting “; or”; and

9 (iii) by adding at the end the fol-
10 lowing:

11 “(C) with respect to in vitro clinical tests,
12 requirements applicable to restricted in vitro
13 clinical tests pursuant to section 587O.”;

14 (3) in subsection (m)—

15 (A) in the subsection heading, by striking
16 “LABORATORY TESTS ASSOCIATED WITH DE-
17 VICES” inserting “IN VITRO CLINICAL TESTS”
18 after “DEVICES”; and

19 (B) in paragraph (1)—

20 (i) by striking “to a device” and in-
21 serting “to an in vitro clinical test”; and

22 (ii) by striking “such device” and in-
23 serting “such in vitro clinical test”.

24 (b) EMERGENCY USE OF MEDICAL PRODUCTS.—Sec-
25 tion 564A(a)(2) of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 360bbb–3a(a)(2)) is amended by inserting
2 “in vitro clinical test,” after “device,”.

3 (c) PRODUCTS HELD FOR EMERGENCY USE.—Sec-
4 tion 564B(2) of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 360bbb–3b(2)) is amended—

6 (1) in subparagraph (A), by striking “or 515”
7 and inserting “515, or 587B”; and

8 (2) in subparagraph (B), by striking “or 520”
9 and inserting 520, or 587S.

10 **SEC. 827. ANTIMICROBIAL SUSCEPTIBILITY TESTS.**

11 Section 511A of the Federal Food, Drug, and Cos-
12 metic Act (21 U.S.C. 360a–2) is amended—

13 (1) in subsection (a)(1)(C)—

14 (A) by striking “clear under section
15 510(k), classify under section 513(f)(2), or ap-
16 prove under section 515” and inserting “ap-
17 prove under section 587B, exempt from pre-
18 market review under section 587C, or grant a
19 technology certification order under section
20 587D”; and

21 (B) by striking “testing devices” and in-
22 serting “in vitro clinical tests”;

23 (2) in subsection (c)(5), by striking “drug or
24 device” each place it appears and inserting “drug,
25 device, or in vitro clinical test”;

1 (3) in subsection (e)—

2 (A) in the heading, by striking “TESTING
3 DEVICES” and inserting “IN VITRO CLINICAL
4 TESTS”;

5 (B) in paragraph (1)—

6 (i) by striking “510, 513, and 515,”
7 and inserting “587B, and 587D”;

8 (ii) by striking “antimicrobial suscep-
9 tibility testing device” and inserting “anti-
10 microbial susceptibility in vitro clinical
11 test”; and

12 (iii) by striking “such device” and in-
13 serting “such in vitro clinical test”; and

14 (C) in paragraph (2)—

15 (i) in the heading, by striking “TEST-
16 ING DEVICES” and inserting “IN VITRO
17 CLINICAL TESTS”;

18 (ii) in subparagraphs (A) and (B)
19 (other than clause (iii) of such subpara-
20 graph (B)), by striking “device” each place
21 it appears and inserting “in vitro clinical
22 test”;

23 (iii) in subparagraph (B)(iii), by strik-
24 ing “a device” and inserting “an in vitro
25 clinical test”; and

1 (iv) by amending subparagraph (C) to
2 read as follows:

3 “(C) The antimicrobial susceptibility in
4 vitro clinical test meets all other requirements
5 to be approved under section 587B, exempted
6 from premarket review under section 587C, or
7 offered under a technology certification order
8 under section 587D.”;

9 (4) in subsection (f), by amending paragraph
10 (1) to read as follows:

11 “(1) The term ‘antimicrobial susceptibility in
12 vitro clinical test’ means an in vitro clinical test that
13 utilizes susceptibility test interpretive criteria to de-
14 termine and report the in vitro susceptibility of cer-
15 tain microorganisms to a drug (or drugs).”; and

16 (5) in subsection (g)(2)—

17 (A) by amending the matter preceding sub-
18 paragraph (A) to read as follows:

19 “(2) with respect to approving an application
20 under section 587B or granting a technology certifi-
21 cation order under section 587D—”; and

22 (B) in subparagraph (A)—

23 (i) by striking “device” and inserting
24 “in vitro clinical test”; and

1 (ii) by striking “antimicrobial suscep-
2 tibility testing device” and inserting “anti-
3 microbial susceptibility in vitro clinical
4 test”.

5 **SEC. 828. COMBINATION PRODUCTS.**

6 (a) IN GENERAL.—Section 503(g) of the Federal
7 Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is
8 amended—

9 (1) in paragraph (1)—

10 (A) in subparagraph (A), by striking “or
11 biological product” and inserting “in vitro clin-
12 ical test, or biological product (except for a
13 product constituted of a device and an in vitro
14 clinical test)”;

15 (B) in subparagraph (B), by adding at the
16 end the following: “For purposes of this Act, a
17 product that constitutes a combination of a
18 drug and an in vitro clinical test is not a com-
19 bination product within the meaning of this
20 subsection.”; and

21 (C) in subparagraph (D)(ii)—

22 (i) by inserting “or in vitro clinical
23 test” after “device”; and

24 (ii) by inserting “and in vitro clinical
25 tests” before “shall”;

1 (2) in paragraph (3), by striking “safety and
2 effectiveness or substantial equivalence” and insert-
3 ing “safety and effectiveness, substantial equiva-
4 lence, or analytical validity and clinical validity” be-
5 fore “for the approved constituent part”;

6 (3) in paragraph (4)—

7 (A) in subparagraph (A), by striking “or
8 513(f)(2) (submitted in accordance with para-
9 graph (5))” and inserting “513(f)(2) (sub-
10 mitted in accordance with paragraph (5)),
11 587B, or 587D, or an exempt test under sec-
12 tion 587C, as applicable”; and

13 (B) in subparagraph (B), by inserting “,
14 587B, or 587D” after “section 515”;

15 (4) in paragraph (5)(A), by striking “or
16 510(k)” and inserting “, 510(k), 587B, or 587D”;

17 (5) in paragraph (7), by striking “or substan-
18 tial equivalence” and inserting “, substantial equiva-
19 lence, or analytical validity and clinical validity”;

20 (6) in paragraph (8), by adding at the end the
21 following:

22 “(I) This paragraph shall not apply to a
23 product constituted of a device and an in vitro
24 clinical test.”; and

25 (7) in paragraph (9)—

1 (A) in subparagraph (C)(i), by striking “or
2 520(g)” and inserting “520(g), 587B, or
3 587D”; and

4 (B) in subparagraph (D), by striking “or
5 520” and inserting “520, 587B, or 587D”.

6 (b) CLASSIFICATION OF PRODUCTS.—Section 563 of
7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 360bbb–2) is amended by adding at the end the following:
9 “(d) EXEMPTION.—This section shall not apply to a
10 product constituted of a device and an in vitro clinical
11 test.”.

12 **SEC. 829. RESOURCES.**

13 (a) FINDINGS.—Congress finds that the fees author-
14 ized by this section will be dedicated to meeting the goals
15 identified in the letters from the Secretary of Health and
16 Human Services to the Committee on Health, Education,
17 Labor, and Pensions of the Senate and the Committee on
18 Energy and Commerce of the House of Representatives,
19 as set forth in the Congressional Record.

20 (b) AUTHORIZATION OF APPROPRIATIONS.—For pur-
21 poses of funding implementation of subchapter J of title
22 V of the Federal Food, Drug, and Cosmetic Act, as added
23 by this Act, including undertaking activities for the devel-
24 opment of regulations and guidances, hiring of necessary
25 staff, and the development of technology systems to imple-

1 ment this subchapter in a timely, effective, and efficient
2 manner there is authorized to be appropriated
3 \$480,000,000.

4 (c) ESTABLISHMENT OF USER FEE PROGRAM.—

5 (1) DEVELOPMENT OF USER FEES FOR IN
6 VITRO CLINICAL TESTS.—

7 (A) IN GENERAL.—Beginning not later
8 than October 1, 2021, the Secretary of Health
9 and Human Services (in this section referred to
10 as the “Secretary”) shall develop recommenda-
11 tions to present to Congress with respect to the
12 goals, and plans for meeting the goals, for the
13 process for the review of in vitro clinical test
14 submissions and applications under subchapter
15 J of chapter V of the Federal Food, Drug, and
16 Cosmetic Act, as added by this Act, for the first
17 5 fiscal years after fiscal year 2022. In devel-
18 oping such recommendations, the Secretary
19 shall consult with—

20 (i) the Committee on Health, Edu-
21 cation, Labor, and Pensions of the Senate;

22 (ii) the Committee on Energy and
23 Commerce of the House of Representa-
24 tives;

25 (iii) scientific and academic experts;

1 (iv) health care professionals;

2 (v) representatives of patient and con-
3 sumer advocacy groups; and

4 (vi) the regulated industry.

5 (B) PRIOR PUBLIC INPUT.—Prior to begin-
6 ning negotiations with the regulated industry
7 on the authorization of such subchapter J, the
8 Secretary shall—

9 (i) publish a notice in the Federal
10 Register requesting public input on the au-
11 thorization of user fees;

12 (ii) hold a public meeting at which the
13 public may present its views on the author-
14 ization, including specific suggestions for
15 the recommendations submitted under sub-
16 paragraph (E);

17 (iii) provide a period of 30 days after
18 the public meeting to obtain written com-
19 ments from the public suggesting changes
20 to such subchapter J; and

21 (iv) publish any comments received
22 under clause (iii) on the website of the
23 Food and Drug Administration.

24 (C) PERIODIC CONSULTATION.—Not less
25 frequently than once every month during nego-

1 tiations with the regulated industry, the Sec-
2 retary shall hold discussions with representa-
3 tives of patient and consumer advocacy groups
4 to continue discussions of the authorization
5 under such subchapter J and to solicit sugges-
6 tions to be included in the recommendations
7 transmitted to Congress under subparagraph
8 (E).

9 (D) PUBLIC REVIEW OF RECOMMENDA-
10 TIONS.—After negotiations with the regulated
11 industry, the Secretary shall—

12 (i) present the recommendations de-
13 veloped under subparagraph (A) to the
14 Committee on Health, Education, Labor,
15 and Pensions of the Senate and the Com-
16 mittee on Energy and Commerce of the
17 House of Representatives;

18 (ii) publish such recommendations in
19 the Federal Register;

20 (iii) provide for a period of 30 days
21 for the public to provide written comments
22 on such recommendations;

23 (iv) hold a meeting at which the pub-
24 lic may present its views on such rec-
25 ommendations; and

1 (v) after consideration of such public
2 views and comments, revise such rec-
3 ommendations as necessary.

4 (E) TRANSMITTAL OF RECOMMENDA-
5 TIONS.—

6 (i) IN GENERAL.—Not later than Jan-
7 uary 15, 2027, the Secretary shall trans-
8 mit to Congress the revised recommenda-
9 tions under subparagraph (A), a summary
10 of the views and comments received under
11 such subparagraph, and any changes made
12 to the recommendations in response to
13 such views and comments.

14 (ii) RECOMMENDATION REQUIRE-
15 MENTS.—The recommendations trans-
16 mitted under this subparagraph shall—

17 (I) include the number of full-
18 time equivalent employees per fiscal
19 year that are agreed to be hired to
20 carry out the goals included in such
21 recommendations for each year of the
22 5-year period;

23 (II) provide that the amount of
24 operating reserve balance in the user
25 fee program established under this

1 section is not more than the equiva-
2 lent of 10 weeks of operating reserve;

3 (III) require the development of
4 a strategic plan for any surplus within
5 the operating reserve account above
6 the 10-week operating reserve within
7 2 years of the establishment of the
8 program;

9 (IV) include an operating reserve
10 adjustment such that, if the Secretary
11 has an operating reserve balance in
12 excess of 10 weeks of such operating
13 reserves, the Secretary shall decrease
14 such fee revenue and fees to provide
15 for not more than 10 weeks of such
16 operating reserves;

17 (V) if an adjustment is made as
18 described in subelause (IV), provide
19 the rationale for the amount of the
20 decrease in fee revenue and fees shall
21 be contained in the Federal Register;
22 and

23 (VI) provide that the fees as-
24 sessed and collected for the full-time
25 equivalent employees at the Center for

1 Devices and Radiological Health, with
2 respect to which the majority of time
3 reporting data indicates are dedicated
4 to the process for the review of in
5 vitro clinical test submissions and ap-
6 plications under paragraph (5), are
7 not supported by the funds authorized
8 to be collected and assessed under sec-
9 tion 738 of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 379j).

11 (F) PUBLICATION OF RECOMMENDA-
12 TIONS.—The Secretary shall publish on the
13 website of the Food and Drug Administration
14 the revised recommendations under subpara-
15 graph (A), a summary of the views and com-
16 ments received under subparagraphs (B)
17 through (D), and any changes made to the rec-
18 ommendations originally proposed by the Sec-
19 retary in response to such views and comments.

20 (G) MINUTES OF NEGOTIATION MEET-
21 INGS.—

22 (i) PUBLIC AVAILABILITY.—The Sec-
23 retary shall make publicly available, on the
24 website of the Food and Drug Administra-
25 tion, minutes of all negotiation meetings

1 conducted under this subsection between
2 the Food and Drug Administration and the
3 regulated industry not later than 30 days
4 after such meeting.

5 (ii) CONTENT.—The minutes de-
6 scribed under clause (i) shall summarize
7 any substantive proposal made by any
8 party to the negotiations, any significant
9 controversies or differences of opinion dur-
10 ing the negotiations, and the resolution of
11 any such controversy or difference of opin-
12 ion.

13 (2) ESTABLISHMENT OF USER FEE PRO-
14 GRAM.—Effective on October 1, 2027, provided that
15 the Secretary transmits the recommendations under
16 paragraph (1)(E), the Secretary is authorized to col-
17 lect user fees relating to the review of in vitro clin-
18 ical test submissions and applications under sub-
19 chapter J of chapter V of the Federal Food, Drug,
20 and Cosmetic Act, as added by this Act. Fees under
21 such program shall be assessed and collected only if
22 the requirements under paragraph (4) are met.

23 (3) AUDIT.—

24 (A) IN GENERAL.—On the date that is 2
25 years after first receiving a user fee applicable

1 to submission of an in vitro clinical test applica-
2 tion submitted under subchapter J of chapter V
3 of the Federal Food, Drug, and Cosmetic Act,
4 as added by this Act, and on a biennial basis
5 thereafter, the Secretary shall perform an audit
6 of the costs of reviewing such applications
7 under such subchapter J. Such an audit shall
8 compare the costs of reviewing such applica-
9 tions under such subchapter J to the amount of
10 the user fee applicable to such applications.

11 (B) ALTERATION OF USER FEE.—If the
12 audit performed under subparagraph (A) indi-
13 cates that the user fees applicable to applica-
14 tions submitted under such subchapter J exceed
15 49 percent of the costs of reviewing such appli-
16 cations, the Secretary shall alter the user fees
17 applicable to applications submitted under such
18 subchapter J such that the user fees do not ex-
19 ceed such percentage.

20 (C) ACCOUNTING STANDARDS.—The Sec-
21 retary shall perform an audit under subpara-
22 graph (A) in conformance with the accounting
23 principles, standards, and requirements pre-
24 scribed by the Comptroller General of the
25 United States under section 3511 of title 31,

1 United States Code, to ensure the validity of
2 any potential variability.

3 (4) CONDITIONS.—The user fee program de-
4 scribed in this subsection shall take effect only if the
5 Food and Drug Administration issues draft guidance
6 related to the review requirements for in vitro diag-
7 nostic tests that would be subject to premarket re-
8 view under section 587B of the Federal Food, Drug,
9 and Cosmetic Act, as added by section 823, the re-
10 view requirements for test categories eligible for
11 technology certification under section 587D of such
12 Act, as added by section 823, and the parameters
13 for the test categories that would be exempt from
14 any review under subchapter J of chapter V of such
15 Act.

16 (5) USER FEE PROGRAM DEFINITIONS AND RE-
17 SOURCE REQUIREMENTS.—

18 (A) IN GENERAL.—The term “process for
19 the review of in vitro clinical test submissions
20 and applications” means the following activities
21 of the Secretary with respect to the review of in
22 vitro clinical test premarket and technology cer-
23 tification applications including supplements for
24 such applications:

1 (i) The activities necessary for the re-
2 view of premarket applications, premarket
3 reports, technology certification applica-
4 tions, and supplements to such applica-
5 tions.

6 (ii) Actions related to submissions in
7 connection with in vitro clinical test devel-
8 opment, the issuance of action letters that
9 allow the marketing of in vitro clinical
10 tests or which set forth in detail the spe-
11 cific deficiencies in such applications, re-
12 ports, supplements, or submissions and,
13 where appropriate, the actions necessary to
14 support the development of in vitro clinical
15 tests.

16 (iii) The inspection of manufacturing
17 establishments and other facilities under-
18 taken as part of the Secretary's review of
19 pending premarket applications, technology
20 certifications, and supplements.

21 (iv) Monitoring of research conducted
22 in connection with the review of such appli-
23 cations, supplements, and submissions.

24 (v) Review of in vitro clinical test ap-
25 plications subject to section 351 of the

1 Public Health Service Act (42 U.S.C. 262)
2 and activities conducted in anticipation of
3 the submission of such applications for in-
4 vestigational use under section 587S of the
5 Federal Food, Drug, and Cosmetic Act (as
6 added by section 823).

7 (vi) The development of guidance, pol-
8 icy documents, or regulations to improve
9 the process for the review of premarket ap-
10 plications, technology certification applica-
11 tions, and supplements.

12 (vii) The development of voluntary
13 test methods, consensus standards, or
14 mandatory performance standards in con-
15 nection with the review of such applica-
16 tions, supplements, or submissions and re-
17 lated activities.

18 (viii) The provision of technical assist-
19 ance to in vitro clinical test developers in
20 connection with the submission of such ap-
21 plications, reports, supplements, or submis-
22 sions.

23 (ix) Any activity undertaken in con-
24 nection with the initial classification or re-
25 classification of an in vitro clinical test in

1 connection with any requirement for ap-
2 proval or eligibility for an exemption from
3 premarket review of an in vitro clinical
4 test.

5 (x) Any activity undertaken in connec-
6 tion with making a pathway determination
7 of an in vitro clinical test, including the
8 identification, establishment, and imple-
9 mentation of mitigation measures.

10 (xi) Evaluation of postmarket studies
11 required as a condition of an approval of
12 a premarket application of an in vitro clin-
13 ical test and ensuring such studies are con-
14 ducted as required.

15 (xii) Any activity undertaken in con-
16 nection with ensuring in vitro clinical tests
17 marketed under an exemption from pre-
18 market review pursuant to section 587C or
19 587G meet the criteria for such exemption
20 and the applicable standard.

21 (xiii) Compiling, developing, and re-
22 viewing information on in vitro clinical
23 tests necessary to identify issues with the
24 ability of in vitro clinical tests to meet the
25 applicable standard, as applicable.

1 (B) RESOURCE REQUIREMENTS.—Fees col-
2 lected and assessed under this section shall be
3 used for the process for the review of in vitro
4 clinical test applications, as described in sub-
5 paragraph (A), and shall—

6 (i) be subject to the limitation under
7 section 738(g)(3) of the Federal Food,
8 Drug, and Cosmetic Act (21 U.S.C.
9 379j(g)(3)), in the same manner that fees
10 collected and assessed under section
11 737(9)(C) of such Act (21 U.S.C.
12 379i(9)(C)) are subject to such limitation;

13 (ii) include travel expenses for officers
14 and employees of the Food and Drug Ad-
15 ministration only if the Secretary deter-
16 mines that such travel is directly related to
17 an activity described in subparagraph (A);
18 and

19 (iii) not be allocated to purposes de-
20 scribed under section 722(a) of the Con-
21 solidated Appropriations Act, 2018 (Public
22 Law 115–141).

23 (d) REPORTS.—

24 (1) PERFORMANCE REPORT.—

25 (A) IN GENERAL.—

1 (i) GENERAL REQUIREMENTS.—Be-
2 ginning with fiscal year 2027, for each fis-
3 cal year for which fees are collected under
4 this section, the Secretary shall prepare
5 and submit to the Committee on Health,
6 Education, Labor, and Pensions of the
7 Senate and the Committee on Energy and
8 Commerce of the House of Representatives
9 annual reports concerning the progress of
10 the Food and Drug Administration in
11 achieving the goals identified in the rec-
12 ommendations transmitted to Congress by
13 the Secretary pursuant to subsection
14 (b)(1)(E) during such fiscal year and the
15 future plans of the Food and Drug Admin-
16 istration for meeting the goals.

17 (ii) ADDITIONAL INFORMATION.—Be-
18 ginning with fiscal year 2021, the annual
19 report under this subparagraph shall in-
20 clude the progress of the Food and Drug
21 Administration in achieving the goals, and
22 future plans for meeting the goals, includ-
23 ing—

24 (I) the number of premarket ap-
25 plications filed under section 587B of

1 the Federal Food, Drug, and Cos-
2 metic Act during the applicable fiscal
3 year;

4 (II) the number of technology
5 certification applications submitted
6 under section 587D of the Federal
7 Food, Drug, and Cosmetic Act during
8 the applicable fiscal year for each re-
9 view division;

10 (III) the number of breakthrough
11 designations under section 587I of the
12 Federal Food, Drug, and Cosmetic
13 Act during the applicable fiscal year;
14 and

15 (IV) the number of information
16 requests requested by the Secretary
17 pursuant to section 587G(d) of such
18 Act.

19 (iii) REAL-TIME REPORTING.—

20 (I) IN GENERAL.—Not later than
21 30 calendar days after the end of the
22 second quarter of fiscal year 2027,
23 and not later than 30 calendar days
24 after the end of each quarter of each
25 fiscal year thereafter, the Secretary

1 shall post the data described in sub-
2 clause (II) on the website of the Food
3 and Drug Administration for such
4 quarter and on a cumulative basis for
5 such fiscal year, and may remove du-
6 plicative data from the annual report
7 under this subparagraph.

8 (II) DATA.—The Secretary shall
9 post the following data in accordance
10 with subclause (I):

11 (aa) The number and titles
12 of draft and final regulations on
13 topics related to the process for
14 the review of in vitro clinical test
15 submissions and applications,
16 and whether such guidances were
17 required by statute or pursuant
18 to the recommendations trans-
19 mitted to Congress by the Sec-
20 retary pursuant to subsection
21 (b)(1)(E).

22 (bb) The number and titles
23 of draft and final guidance on
24 topics related to the process for
25 the review of in vitro clinical test

1 submissions and applications,
2 and whether such guidances were
3 issued as required by statute or
4 pursuant to the recommendations
5 transmitted to Congress by the
6 Secretary pursuant to subsection
7 (c)(1)(E).

8 (cc) The number and titles
9 of public meetings held on topics
10 related to the process for the re-
11 view of in vitro clinical tests, and
12 if such meetings were required by
13 statute or pursuant to the rec-
14 ommendations transmitted to
15 Congress by the Secretary pursu-
16 ant to subsection (c)(1)(E).

17 (iv) RATIONALE FOR IVCT USER FEE
18 PROGRAM CHANGES.—Beginning with fis-
19 cal year 2027, the Secretary shall include
20 in the annual performance report under
21 paragraph (1)—

22 (I) data, analysis, and discussion
23 of the changes in the number of full-
24 time equivalents hired as agreed upon
25 in the recommendations transmitted

1 to Congress by the Secretary pursuant
2 to subsection (b)(1)(E) and the num-
3 ber of full-time equivalents funded by
4 budget authority at the Food and
5 Drug Administration by each division
6 within the Center for Devices and Ra-
7 diological Health, the Center for Bio-
8 logics Evaluation and Research, the
9 Office of Regulatory Affairs, and the
10 Office of the Commissioner;

11 (II) data, analysis, and discus-
12 sion of the changes in the fee revenue
13 amounts and costs for the process for
14 the review of in vitro clinical test sub-
15 missions and applications, including
16 identifying drivers of such changes;
17 and

18 (III) for each of the Center for
19 Devices and Radiological Health, the
20 Center for Biologics Evaluation and
21 Research, the Office of Regulatory Af-
22 fairs, and the Office of the Commis-
23 sioner, the number of employees for
24 whom time reporting is required and

1 the number of employees for whom
2 time reporting is not required.

3 (v) ANALYSIS.—For each fiscal year,
4 the Secretary shall include in the report
5 under clause (i) an analysis of the fol-
6 lowing:

7 (I) The difference between the
8 aggregate number of premarket appli-
9 cations filed under section 587B or
10 section 587D of the Federal Food,
11 Drug, and Cosmetic Act and the ag-
12 gregate number of major deficiency
13 letters, not approvable letters, and de-
14 nials for such applications issued by
15 the agency, accounting for—

16 (aa) the number of applica-
17 tions filed under each of sections
18 587B and 587D of the Federal
19 Food, Drug, and Cosmetic Act
20 during one fiscal year for which a
21 decision is not scheduled to be
22 made until the following fiscal
23 year; and

24 (bb) the aggregate number
25 of applications under each of sec-

1 tions 587B and 587D of the
2 Federal Food, Drug, and Cos-
3 metic Act for each fiscal year
4 that did not meet the goals as
5 identified by the recommenda-
6 tions transmitted to Congress by
7 the Secretary pursuant to sub-
8 section (b)(1)(E).

9 (II) Relevant data to determine
10 whether the Center for Devices and
11 Radiological Health has met perform-
12 ance enhancement goals identified by
13 the recommendations transmitted to
14 Congress by the Secretary pursuant to
15 subsection (b)(1)(E).

16 (III) The most common causes
17 and trends for external or other cir-
18 cumstances affecting the ability of the
19 Food and Drug Administration to
20 meet review time and performance en-
21 hancement goals identified by the rec-
22 ommendations transmitted to Con-
23 gress by the Secretary pursuant to
24 subsection (b)(1)(E).

1 (B) PUBLICATION.—With regard to infor-
2 mation to be reported by the Food and Drug
3 Administration to industry on a quarterly and
4 annual basis pursuant to recommendations
5 transmitted to Congress by the Secretary pur-
6 suant to subsection (b)(1)(E), the Secretary
7 shall make such information publicly available
8 on the website of the Food and Drug Adminis-
9 tration not later than 60 days after the end of
10 each quarter or 120 days after the end of each
11 fiscal year, respectively, to which such informa-
12 tion applies.

13 (C) UPDATES.—The Secretary shall in-
14 clude in each report under subparagraph (A)
15 information on all previous cohorts for which
16 the Secretary has not given a complete response
17 on all in vitro clinical test premarket applica-
18 tions and technology certification orders and
19 supplements, premarket, and technology certifi-
20 cation notifications in the cohort.

21 (2) CORRECTIVE ACTION REPORT.—Beginning
22 with fiscal year 2022, for each fiscal year for which
23 fees are collected under this section, the Secretary
24 shall prepare and submit a corrective action report
25 to the Committee on Health, Education, Labor, and

1 Pensions and the Committee on Appropriations of
2 the Senate and the Committee on Energy and Com-
3 merce and the Committee on Appropriations of the
4 House of Representatives. The report shall include
5 the following information, as applicable:

6 (A) GOALS MET.—For each fiscal year, if
7 the Secretary determines, based on the analysis
8 under paragraph (1)(A)(v), that each of the
9 goals identified by the recommendations trans-
10 mitted to Congress by the Secretary pursuant
11 to subsection (b)(1)(E) for the applicable fiscal
12 year have been met, the corrective action report
13 shall include recommendations on ways in which
14 the Secretary can improve and streamline the in
15 vitro clinical test premarket application and
16 technology certification review process.

17 (B) GOALS MISSED.—For each of the goals
18 identified by the letters described in rec-
19 ommendations transmitted to Congress by the
20 Secretary pursuant to subsection (b)(1)(E) for
21 the applicable fiscal year that the Secretary de-
22 termines to not have been met, the corrective
23 action report shall include—

24 (i) a justification for such determina-
25 tion;

1 (ii) a description of the types of cir-
2 cumstances, in the aggregate, under which
3 applications or reports submitted under
4 sections 587B and 587D of the Federal
5 Food, Drug, and Cosmetic Act missed the
6 review goal times but were approved dur-
7 ing the first cycle review, as applicable;

8 (iii) a summary and any trends with
9 regard to the circumstances for which a re-
10 view goal was missed; and

11 (iv) the performance enhancement
12 goals that were not achieved during the
13 previous fiscal year and a description of ef-
14 forts the Food and Drug Administration
15 has put in place for the fiscal year in
16 which the report is submitted to improve
17 the ability of such agency to meet each
18 such goal for the such fiscal year.

19 (3) FISCAL REPORT.—For fiscal years 2027
20 and annually thereafter, not later than 120 days
21 after the end of each fiscal year during which fees
22 are collected under this subpart, the Secretary shall
23 prepare and submit to the Committee on Health,
24 Education, Labor, and Pensions of the Senate and
25 the Committee on Energy and Commerce of the

1 House of Representatives, a report on the implemen-
2 tation of the authority for such fees during such fis-
3 cal year and the use, by the Food and Drug Admin-
4 istration, of the fees collected during such fiscal year
5 for which the report is made.

6 (A) CONTENTS.—Such report shall include
7 expenditures delineated by budget authority and
8 user fee dollars related to administrative ex-
9 penses and information technology infrastruc-
10 ture contracts and expenditures.

11 (B) OPERATING RESERVE.—Such report
12 shall provide the amount of operating reserve
13 balance available each year, and any planned al-
14 locations or obligations of such balance that is
15 above 10 weeks of operating reserve for the pro-
16 gram.

17 (4) PUBLIC AVAILABILITY.—The Secretary
18 shall make the reports required under paragraphs
19 (1) through (3) available to the public on the website
20 of the Food and Drug Administration.

21 (5) ENHANCED COMMUNICATION.—

22 (A) COMMUNICATIONS WITH CONGRESS.—
23 Each fiscal year, as applicable and requested,
24 representatives from the Centers with expertise
25 in the review of in vitro clinical tests shall meet

1 with representatives from the Committee on
2 Health, Education, Labor, and Pensions of the
3 Senate and the Committee on Energy and Com-
4 merce of the House of Representatives to report
5 on the contents described in the reports under
6 this section.

7 (B) PARTICIPATION IN CONGRESSIONAL
8 HEARING.—Each fiscal year, as applicable and
9 requested, representatives from the Food and
10 Drug Administration shall participate in a pub-
11 lic hearing before the Committee on Health,
12 Education, Labor, and Pensions of the Senate
13 and the Committee on Energy and Commerce
14 of the House of Representatives, to report on
15 the contents described in the reports under this
16 section. Such hearing shall occur not later than
17 120 days after the end of each fiscal year for
18 which fees are collected under this section.

19 **SEC. 830. AUTHORIZATION OF APPROPRIATIONS.**

20 For purposes of funding implementation of this sub-
21 title (including the amendments made by this subtitle), in-
22 cluding undertaking activities for the development of regu-
23 lations and guidances, hiring of necessary staff, and the
24 development of technology systems to implement this sub-
25 title (including the amendments made by this subtitle) in

1 a timely, effective, and efficient manner, there is author-
2 ized to be appropriated not more than \$480,000,000, to
3 remain available through the end of fiscal year 2027.

4 **TITLE IX—OTHER PROVISIONS**

5 **SEC. 901. FACILITIES MANAGEMENT.**

6 (a) PDUFA AUTHORITY.—Section 736(g)(2) of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 379h(g)(2))—

9 (1) in subparagraph (A)(ii)—

10 (A) by striking “shall be available to de-
11 fray” and inserting the following: “shall be
12 available—

13 “(I) for fiscal year 2023, to de-
14 fray”;

15 (B) by striking the period and inserting “;
16 and”; and

17 (C) by adding at the end the following:

18 “(II) for fiscal year 2024 and
19 each subsequent fiscal year, to defray
20 the costs of the resources allocated for
21 the process for the review of human
22 drug applications (including such
23 costs for an additional number of full-
24 time equivalent positions in the De-
25 partment of Health and Human Serv-

1 ices to be engaged in such process),
2 only if the sum of the amounts allo-
3 cated by the Secretary for such costs,
4 excluding costs paid from fees col-
5 lected under this section, plus other
6 costs for the maintenance, renovation,
7 and repair of facilities and acquisition,
8 maintenance, and repair of fixtures,
9 furniture, and other necessary mate-
10 rials and supplies in connection with
11 the process for the review of human
12 drug applications, is no less than the
13 amount allocated for such costs, ex-
14 cluding any such costs paid from fees
15 collected under this section, for fiscal
16 year 1997, multiplied by the adjust-
17 ment factor.”; and

18 (2) in subparagraph (B), by striking “for the
19 process for the review of human drug applications”
20 and inserting “as described in subclause (I) or (II)
21 of such subparagraph, as applicable”.

22 (b) BSUFA AUTHORITY.—Section 744H(f)(2) of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
24 52(f)(2)) is amended—

25 (1) in subparagraph (B)(i)—

1 (A) by striking “available for a fiscal year
2 beginning after fiscal year 2012” and inserting
3 the following: “available—

4 “(I) for fiscal year 2023”;

5 (B) by striking “the fiscal year involved.”
6 and inserting “such fiscal year; and”; and

7 (C) by adding at the end the following:

8 “(II) for fiscal year 2024 and
9 each subsequent fiscal year, to defray
10 the costs of the process for the review
11 of biosimilar biological product appli-
12 cations (including such costs for an
13 additional number of full-time equiva-
14 lent positions in the Department of
15 Health and Human Services to be en-
16 gaged in such process), only if the
17 sum of the amounts allocated by the
18 Secretary for such costs, excluding
19 costs paid from fees collected under
20 this section, plus other costs for the
21 maintenance, renovation, and repair
22 of facilities and acquisition, mainte-
23 nance, and repair of fixtures, fur-
24 niture, and other necessary materials
25 and supplies in connection with the

1 process for the review of biosimilar bi-
 2 ological product applications, is no
 3 less than \$20,000,000, multiplied by
 4 the adjustment factor applicable to
 5 the fiscal year involved.”; and

6 (2) in subparagraph (C), by striking “subpara-
 7 graph (B) in any fiscal year if the costs described
 8 in such subparagraph” and inserting “subparagraph
 9 (B)(i) in any fiscal year if the costs allocated as de-
 10 scribed in subclause (I) or (II) of such subpara-
 11 graph, as applicable,”.

12 (c) GDUFA AUTHORITY.—Section 744B of the Fed-
 13 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42)
 14 is amended—

15 (1) in subsection (e)(2), by striking
 16 “744A(11)(C)” and inserting “744A(12)(C)”;

17 (2) in subsection (i)(2)—

18 (A) in subparagraph (A)(ii)—

19 (i) by striking “available for a fiscal
 20 year beginning after fiscal year 2012” and
 21 inserting the following: “available—

22 “(I) for fiscal year 2023; and”;

23 (ii) by striking “the fiscal year in-
 24 volved.” and inserting “such fiscal year;
 25 and”;

1 (iii) by adding at the end the fol-
2 lowing:

3 “(II) for fiscal year 2024 and
4 each subsequent fiscal year, to defray
5 the costs of human generic drug ac-
6 tivities (including such costs for an
7 additional number of full-time equiva-
8 lent positions in the Department of
9 Health and Human Services to be en-
10 gaged in such activities), only if the
11 sum of the amounts allocated by the
12 Secretary for such costs, excluding
13 costs paid from fees collected under
14 this section, plus other costs for the
15 maintenance, renovation, and repair
16 of facilities and acquisition, mainte-
17 nance, and repair of fixtures, fur-
18 niture, and other necessary materials
19 and supplies in connection with
20 human generic drug activities, is no
21 less than \$97,000,000 multiplied by
22 the adjustment factor defined in sec-
23 tion 744A(3) applicable to the fiscal
24 year involved.”; and

1 (B) in subparagraph (B), by striking “for
2 human generic activities” and inserting “as de-
3 scribed in subclause (I) or (II) of such subpara-
4 graph, as applicable”.

5 (d) MDUFA AUTHORITY.—Section 738 of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is
7 amended—

8 (1) in subsection (h)(2)—

9 (A) in subparagraph (A)(ii)—

10 (i) by striking “shall be available to
11 defray” and inserting the following: “shall
12 be available—

13 “(I) for fiscal year 2023, to de-
14 fray”;

15 (ii) by striking the period and insert-
16 ing “; and”; and

17 (iii) by adding at the end the fol-
18 lowing:

19 “(II) for fiscal year 2024 and
20 each subsequent fiscal year, to defray
21 the costs of the resources allocated for
22 the process for the review of device
23 applications (including such costs for
24 an additional number of full-time
25 equivalent positions in the Depart-

1 ment of Health and Human Services
2 to be engaged in such process), only if
3 the sum of the amounts allocated by
4 the Secretary for such costs, excluding
5 costs paid from fees collected under
6 this section, plus other costs for the
7 maintenance, renovation, and repair
8 of facilities and acquisition, mainte-
9 nance, and repair of fixtures, fur-
10 niture and other necessary materials
11 and supplies in connection with the
12 process for the review of device appli-
13 cations, is no less than the amount al-
14 located for such costs, excluding any
15 such costs paid from fees collected
16 under this section, for fiscal year
17 2009 multiplied by the adjustment
18 factor.”; and

19 (B) in subparagraph (B)(i), in the matter
20 preceding subclause (I), by striking “for the
21 process for the review of device applications”
22 and inserting “as described in subclause (I) or
23 (II) of such subparagraph, as applicable”; and
24 (2) in subsection (g)(3), by striking
25 “737(9)(C)” and inserting “737(10)(C)”.

1 (e) TECHNICAL CORRECTION.—

2 (1) IN GENERAL.—Section 905(b)(2) of the
3 FDA Reauthorization Act of 2017 (Public Law 115–
4 52) is amended by striking “Section 738(h) of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 379j(h)) is amended” and inserting “Subsection (g)
7 of section 738 of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 379j), as so redesignated by
9 section 203(f)(2)(B)(i), is amended”.

10 (2) EFFECTIVE DATE.—The amendment made
11 by paragraph (1) shall take effect as though in-
12 cluded in the enactment of section 905 of the FDA
13 Reauthorization Act of 2017 (Public Law 115–52).

14 **SEC. 902. ANNUAL REPORT ON INSPECTIONS.**

15 Section 902 of the FDA Reauthorization Act of 2017
16 (Public Law 115–52) is amended, in the matter preceding
17 paragraph (1)—

18 (1) by striking “March 1 of each year” and in-
19 serting “120 days after the end of each fiscal year”;
20 and

21 (2) by striking “previous calendar year” and in-
22 serting “previous fiscal year”.

23 **SEC. 903. USER FEE PROGRAM TRANSPARENCY AND AC-**
24 **COUNTABILITY.**

25 (a) PDUFA.—

1 (1) REAUTHORIZATION; REPORTING REQUIRE-
2 MENTS.—

3 (A) PERFORMANCE REPORT.—Section
4 736B(a) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 379h-2(a)) is amended—

6 (i) in paragraph (1)—

7 (I) in subparagraph (B)—

8 (aa) in clause (vii), by strik-
9 ing “; and” and inserting a semi-
10 colon;

11 (bb) in clause (viii), by strik-
12 ing the period and inserting “;
13 and”; and

14 (cc) by adding at the end
15 the following:

16 “(ix) the number of investigational
17 new drug applications submitted per fiscal
18 year, including for each review division.”;

19 and

20 (II) by adding at the end the fol-
21 lowing flush text:

22 “Nothing in subparagraph (B) shall be construed to
23 authorize the disclosure of confidential commercial
24 information or other information considered propri-
25 etary or trade secret, as prohibited under section

1 301(j) of this Act of section 1905 of title 18, United
2 States Code.”; and

3 (ii) in paragraph (4)—

4 (I) by amending subparagraph

5 (A) to read as follows:

6 “(A) data, analysis, and discussion of the
7 changes in the number of individuals hired as
8 agreed upon in the letters described in section
9 101(b) of the Prescription Drug User Fee
10 Amendments of 2022 and the number of re-
11 maining vacancies, the number of full-time
12 equivalents funded by fees collected pursuant to
13 section 736, and the number of full-time
14 equivalents funded by budget authority at the
15 Food and Drug Administration by each division
16 within the Center for Drug Evaluation and Re-
17 search, the Center for Biologics Evaluation and
18 Research, the Office of Regulatory Affairs, and
19 the Office of the Commissioner;”;

20 (II) by amending subparagraph

21 (B) to read as follows:

22 “(B) data, analysis, and discussion of the
23 changes in the fee revenue amounts and costs
24 for the process for the review of human drug
25 applications, including identifying—

1 “(i) drivers of such changes; and

2 “(ii) changes in the average total cost
3 per full-time equivalent in the prescription
4 drug review program;”;

5 (III) in subparagraph (C), by
6 striking the period and inserting “;
7 and”; and

8 (IV) by adding at the end the fol-
9 lowing:

10 “(D) data, analysis, and discussion of the
11 changes in the average full-time equivalent
12 hours required to complete review of each type
13 of human drug application.”.

14 (2) REAUTHORIZATION.—Section 736B(f) of
15 the Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 379h–2(f)) is amended—

17 (A) by redesignating paragraphs (4)
18 through (6) as paragraphs (5) through (7), re-
19 spectively;

20 (B) by inserting after paragraph (3) the
21 following:

22 “(4) UPDATES TO CONGRESS.—The Secretary,
23 in consultation with regulated industry, shall provide
24 regular updates on negotiations on the reauthoriza-
25 tion of this part to the Committee on Health, Edu-

1 cation, Labor, and Pensions of the Senate and the
 2 Committee on Energy and Commerce of the House
 3 of Representatives.”; and

4 (C) in paragraph (7), as so redesignated—

5 (i) in subparagraph (A)—

6 (I) by striking “Before pre-
 7 senting the recommendations devel-
 8 oped under paragraphs (1) through
 9 (5) to the Congress, the” and insert-
 10 ing “The”; and

11 (II) by inserting “, not later than
 12 30 days after each such negotiation
 13 meeting” before the period at the end;
 14 and

15 (ii) in subparagraph (B), by inserting
 16 “, in sufficient detail,” after “shall sum-
 17 marize”.

18 (b) MDUFA.—

19 (1) REAUTHORIZATION; REPORTING REQUIRE-
 20 MENTS.—

21 (A) REPORTS.—Section 738A(a)(1)(A) of
 22 the Federal Food, Drug, and Cosmetic Act (21
 23 U.S.C. 379j–1(a)(1)(A)) is amended—

24 (i) in clause (ii)—

1 (I) in subclause (II), by striking
2 “; and” and inserting a semicolon;

3 (II) in subclause (III), by strik-
4 ing the period and inserting a semi-
5 colon;

6 (III) by adding at the end the
7 following:

8 “(IV) the number of investiga-
9 tional device exemption applications
10 submitted under section 520(g) per
11 fiscal year, including for each review
12 division; and

13 “(V) the number of expedited de-
14 velopment and priority review requests
15 and designations under section 515B
16 per fiscal year, including for each re-
17 view division.”; and

18 (IV) by adding at the end the fol-
19 lowing flush text:

20 “Nothing in this clause shall be construed
21 to authorize the disclosure of confidential
22 commercial information or other informa-
23 tion considered proprietary or trade secret,
24 as prohibited under section 301(j) of this

1 Act or section 1905 of title 18, United
2 States Code.”;

3 (ii) in the first clause (iv) (relating to
4 rationale for MDUFA program changes)—

5 (I) by amending subclause (I) to
6 read as follows:

7 “(I) data, analysis, and discus-
8 sion of the changes in the number of
9 individuals hired as agreed upon in
10 the letters described in section 201(b)
11 of the Medical Device User Fee
12 Amendments of 2022 and the number
13 of remaining vacancies, the number of
14 full-time equivalents funded by fees
15 collected pursuant to section 738, and
16 the number of full time equivalents
17 funded by budget authority at the
18 Food and Drug Administration by
19 each division within the Center for
20 Devices and Radiological Health, the
21 Center for Biologics Evaluation and
22 Research, the Office of Regulatory Af-
23 fairs, and the Office of the Commis-
24 sioner;”;

1 (II) by amending subclause (II)
2 to read as follows:

3 “(II) data, analysis, and discus-
4 sion of the changes in the fee revenue
5 amounts and costs for the process for
6 the review of device applications, in-
7 cluding identifying—

8 “(aa) drivers of such
9 changes; and

10 “(bb) changes in the average
11 total cost per full-time equivalent
12 in the medical device review pro-
13 gram;”;

14 (III) in subclause (III), by strik-
15 ing the period and inserting “; and”;
16 and

17 (IV) by adding at the end the fol-
18 lowing:

19 “(IV) data, analysis, and discus-
20 sion of the changes in the average
21 full-time equivalent hours required to
22 complete review of medical device ap-
23 plication types.”; and

1 (iii) by redesignating the second
2 clause (iv) (relating to analysis) as clause
3 (v).

4 (2) REAUTHORIZATION.—Section 738A(b) of
5 the Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 379j–1(b)) is amended—

7 (A) by redesignating paragraphs (4)
8 through (6) as paragraphs (5) through (7), re-
9 spectively;

10 (B) by inserting after paragraph (3) the
11 following:

12 “(4) UPDATES TO CONGRESS.—The Secretary,
13 in consultation with regulated industry, shall provide
14 regular updates on negotiations on the reauthoriza-
15 tion of this part to the Committee on Health, Edu-
16 cation, Labor, and Pensions of the Senate and the
17 Committee on Energy and Commerce of the House
18 of Representatives.”; and

19 (C) in paragraph (7), as so redesignated—

20 (i) in subparagraph (A)—

21 (I) by striking “Before pre-
22 senting the recommendations devel-
23 oped under paragraphs (1) through
24 (5) to the Congress, the” and insert-
25 ing “The”; and

1 (II) by inserting “, not later than
2 30 days after each such negotiation
3 meeting” before the period at the end;
4 and

5 (ii) in subparagraph (B), by inserting
6 “, in sufficient detail,” after “shall sum-
7 marize”.

8 (c) GDUFA.—

9 (1) REAUTHORIZATION; REPORTING REQUIRE-
10 MENTS.—

11 (A) PERFORMANCE REPORT.—Section
12 744C(a)(3) of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 379j-43(a)(3)) is
14 amended—

15 (i) by amending subparagraph (A) to
16 read as follows:

17 “(A) data, analysis, and discussion of the
18 changes in the number of individuals hired as
19 agreed upon in the letters described in section
20 301(b) of the Generic Drug User Fee Amend-
21 ments of 2022 and the number of remaining va-
22 cancies, the number of full-time equivalents
23 funded by fees collected pursuant to section
24 744B, and the number of full time equivalents
25 funded by budget authority at the Food and

1 Drug Administration by each division within
2 the Center for Drug Evaluation and Research,
3 the Center for Biologics Evaluation and Re-
4 search, the Office of Regulatory Affairs, and
5 the Office of the Commissioner;”;

6 (ii) by amending subparagraph (B) to
7 read as follows:

8 “(B) data, analysis, and discussion of the
9 changes in the fee revenue amounts and costs
10 for human generic drug activities, including—

11 “(i) identifying drivers of such
12 changes; and

13 “(ii) changes in the total average cost
14 per full-time equivalent in the generic drug
15 review program;”;

16 (iii) in subparagraph (C), by striking
17 the period at the end and inserting “;
18 and”; and

19 (iv) by adding at the end the fol-
20 lowing:

21 “(D) data, analysis, and discussion of the
22 changes in the average full-time equivalent
23 hours required to complete review of each type
24 of abbreviated new drug application.”.

1 (2) REAUTHORIZATION.—Section 744C(f) of
2 the Federal Food, Drug, and Cosmetic Act (21
3 U.S.C. 379j-43(f)) is amended—

4 (A) by redesignating paragraphs (4)
5 through (6) as paragraphs (5) through (7), re-
6 spectively;

7 (B) by inserting after paragraph (3) the
8 following:

9 “(4) UPDATES TO CONGRESS.—The Secretary,
10 in consultation with regulated industry, shall provide
11 regular updates on negotiations on the reauthoriza-
12 tion of this part to the Committee on Health, Edu-
13 cation, Labor, and Pensions of the Senate and the
14 Committee on Energy and Commerce of the House
15 of Representatives.”; and

16 (C) in paragraph (7), as so redesignated—

17 (i) in subparagraph (A)—

18 (I) by striking “Before pre-
19 senting the recommendations devel-
20 oped under paragraphs (1) through
21 (5) to the Congress, the” and insert-
22 ing “The”; and

23 (II) by inserting “, not later than
24 30 days after each such negotiation

1 meeting” before the period at the end;

2 and

3 (ii) in subparagraph (B), by inserting

4 “, in sufficient detail,” after “shall sum-
5 marize”.

6 (d) BSUFA.—

7 (1) REAUTHORIZATION; REPORTING REQUIRE-
8 MENTS.—Section 744I(a)(4) of the Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 379j–53(a)(4))
10 is amended—

11 (A) by amending subparagraph (A) to read
12 as follows:

13 “(A) data, analysis, and discussion of the
14 changes in the number of individuals hired as
15 agreed upon in the letters described in section
16 401(b) of the Biosimilar User Fee Amendments
17 of 2022 and the number of remaining vacan-
18 cies, the number of full-time equivalents funded
19 by fees collected pursuant to section 744H, and
20 the number of full time equivalents funded by
21 budget authority at the Food and Drug Admin-
22 istration by each division within the Center for
23 Drug Evaluation and Research, the Center for
24 Biologics Evaluation and Research, the Office

1 of Regulatory Affairs, and the Office of the
2 Commissioner;”;

3 (B) by amending subparagraph (B) to read
4 as follows:

5 “(B) data, analysis, and discussion of the
6 changes in the fee revenue amounts and costs
7 for the process for the review of biosimilar bio-
8 logical product applications, including identi-
9 fying—

10 “(i) drivers of such changes; and

11 “(ii) changes in the average total cost
12 per full-time equivalent in the biosimilar
13 biological product review program;”;

14 (C) in subparagraph (C), by striking the
15 period at the end and inserting “; and”; and

16 (D) by adding at the end the following:

17 “(D) data, analysis, and discussion of the
18 changes in the average full-time equivalent
19 hours required to complete review of each type
20 of biosimilar biological product application.”.

21 (2) REAUTHORIZATION.—Section 744I(f) of the
22 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
23 379j–53(f)) is amended—

24 (A) by redesignating paragraphs (2) and
25 (3) as paragraphs (5) and (6), respectively;

1 (B) by inserting after paragraph (1) the
2 following:

3 “(2) PRIOR PUBLIC INPUT.—Prior to beginning
4 negotiations with the regulated industry on the reau-
5 thorization of this part, the Secretary shall—

6 “(A) publish a notice in the Federal Reg-
7 ister requesting public input on the reauthoriza-
8 tion;

9 “(B) hold a public meeting at which the
10 public may present its views on the reauthoriza-
11 tion;

12 “(C) provide a period of 30 days after the
13 public meeting to obtain written comments from
14 the public suggesting changes to this part; and

15 “(D) publish the comments on the Food
16 and Drug Administration’s website.

17 “(3) PERIODIC CONSULTATION.—Not less fre-
18 quently than once every month during negotiations
19 with the regulated industry, the Secretary shall hold
20 discussions with representatives of patient and con-
21 sumer advocacy groups to continue discussions of
22 their views on the reauthorization and their sugges-
23 tions for changes to this part as expressed under
24 paragraph (2).

1 “(4) UPDATES TO CONGRESS.—The Secretary,
2 in consultation with regulated industry, shall provide
3 regular updates on negotiations on the reauthoriza-
4 tion of this part to the Committee on Health, Edu-
5 cation, Labor, and Pensions of the Senate and the
6 Committee on Energy and Commerce of the House
7 of Representatives.”; and

8 (C) by adding at the end the following:

9 “(7) MINUTES OF NEGOTIATION MEETINGS.—

10 “(A) PUBLIC AVAILABILITY.—The Sec-
11 retary shall make publicly available, on the pub-
12 lic website of the Food and Drug Administra-
13 tion, minutes of all negotiation meetings con-
14 ducted under this subsection between the Food
15 and Drug Administration and the regulated in-
16 dustry, not later than 30 days after each such
17 negotiation meeting.

18 “(B) CONTENT.—The minutes described
19 under subparagraph (A) shall summarize, in
20 sufficient detail, any substantive proposal made
21 by any party to the negotiations as well as sig-
22 nificant controversies or differences of opinion
23 during the negotiations and their resolution.”.

1 **SEC. 904. OTC HEARING AIDS FINAL RULE.**

2 Not later than 30 days after the date of enactment
3 of this Act, the Secretary of Health and Human Services
4 shall issue a final rule to establish a category of over-the-
5 counter hearing aids, as defined in subsection (q) of sec-
6 tion 520 of the Federal Food, Drug, and Cosmetic Act
7 (21 U.S.C. 360j), as described in section 709(b) of the
8 FDA Reauthorization Act of 2017 (Public Law 115–52).

9 **SEC. 905. ENHANCE INTRA-AGENCY COORDINATION AND**
10 **PUBLIC HEALTH ASSESSMENT WITH REGARD**
11 **TO COMPLIANCE ACTIVITIES.**

12 (a) COORDINATION.—Section 506D of the Federal
13 Food, Drug, and Cosmetic Act (21 U.S.C. 356d) is
14 amended—

15 (1) by adding at the end the following:

16 “(g) COORDINATION.—The Secretary shall ensure
17 timely and effective internal coordination and alignment
18 among the field investigators of the Food and Drug Ad-
19 ministration and the staff of the Center for Drug Evalua-
20 tion and Research’s Office of Compliance and Drug Short-
21 age Program regarding the reviews of reports shared pur-
22 suant to section 704(b)(2), and any feedback or corrective
23 or preventive actions in response to such reports.”; and

24 (2) by amending subsection (f) to read as fol-
25 lows:

1 “(f) TEMPORARY SUNSET.—Subsection (a) shall
2 cease to be effective on the date that is 5 years after the
3 date of enactment of the Food and Drug Administration
4 Safety and Innovation Act. Subsections (b), (c), and (e)
5 shall not be in effect during the period beginning 5 years
6 after the date of enactment of the Food and Drug Admin-
7 istration Safety and Innovation Act and ending on the
8 date of enactment of the Food and Drug Administration
9 Safety and Landmark Advancements Act of 2022. Sub-
10 sections (b), (c), and (e) shall be in effect beginning on
11 the date of enactment of the Food and Drug Administra-
12 tion Safety and Landmark Advancements Act of 2022.”.

13 (b) REPORTING.—Section 506C–1(a) of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 356c–1(a)) is
15 amended—

16 (1) by redesignating paragraphs (3) through
17 (7) as paragraphs (4) through (8), respectively;

18 (2) by inserting after paragraph (2) the fol-
19 lowing:

20 “(3) provides the number of reports that were
21 required under section 704(b)(2) to be sent to the
22 appropriate offices of the Food and Drug Adminis-
23 tration with expertise regarding drug shortages, and
24 the number of such reports that were sent;”;

1 (3) in paragraph (3)(A), by striking “paragraph
2 (7)” and inserting “paragraph (8)”.

3 (c) APPLICABILITY.—

4 (1) SUBSECTION (a).—The amendments made
5 by subsection (a) shall apply beginning on the date
6 of enactment of this Act.

7 (2) SUBSECTION (b).—The amendments made
8 by subsection (b) shall apply beginning on the date
9 that is 1 year after the date of enactment of this
10 Act.

11 (d) REPORTING OF MUTUAL RECOGNITION AGREE-
12 MENTS FOR INSPECTIONS AND REVIEW ACTIVITIES.—
13 Section 510(h) of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 360(h)) is amended—

15 (1) in paragraph (6)—

16 (A) in subparagraph (A), by striking
17 clause (ii) and inserting the following:

18 “(ii) the number of such registered estab-
19 lishments in each region of interest;

20 “(iii) the number of such domestic estab-
21 lishments and the number of such foreign es-
22 tablishments, including the number of establish-
23 ments in each region of interest, that the Sec-
24 retary inspected in the previous calendar year;

1 “(iv) the number of inspections to support
2 actions by the Secretary on applications under
3 section 505 of this Act or section 351 of the
4 Public Health Service Act, including the num-
5 ber of inspections to support actions by the Sec-
6 retary on supplemental applications, including
7 changes to manufacturing processes, the Sec-
8 retary conducted in the previous fiscal year;

9 “(v) the number of routine surveillance in-
10 spections the Secretary conducted in the pre-
11 vious fiscal year;

12 “(vi) the number of for-cause inspections
13 the Secretary conducted in the previous fiscal
14 year, not including inspections described in
15 clause (iv); and

16 “(vii) the number of inspections the Sec-
17 retary has recognized pursuant to an agreement
18 entered into pursuant to section 809, or other-
19 wise recognized, for each of the types of inspec-
20 tions described in clauses (v) and (vi);”;

21 (B) in subparagraph (B), by striking “;
22 and” and inserting a semicolon;

23 (C) in subparagraph (C), by striking the
24 period and inserting “; and”; and

25 (D) by adding at the end the following:

1 “(D) the status of the efforts of the Food
2 and Drug Administration to expand its recogni-
3 tion of inspections conducted or recognized by
4 foreign regulatory authorities under section
5 809, including any obstacles to expanding the
6 use of such recognition.”; and

7 (2) by adding at the end the following:

8 “(7) REGION OF INTEREST.—For purposes of
9 paragraph (6)(A), the term ‘region of interest’
10 means a foreign geographic region or country, in-
11 cluding the People’s Republic of China, India, the
12 European Union, the United Kingdom, and any
13 other country or geographic region, as the Secretary
14 determines appropriate.”.

15 (e) ENHANCING TRANSPARENCY OF DRUG FACILITY
16 INSPECTION TIMELINES.—Section 902 of the FDA Reau-
17 thorization Act of 2017 (21 U.S.C. 355 note) is amended
18 to read as follows:

19 “**SEC. 902. ANNUAL REPORT ON INSPECTIONS.**

20 “Not later than March 1 of each year, the Secretary
21 of Health and Human Services shall post on the website
22 of the Food and Drug Administration information related
23 to inspections of facilities necessary for approval of a drug
24 under subsection (c) or (j) of section 505 of the Federal
25 Food, Drug, and Cosmetic Act (21 U.S.C. 355), approval

1 of a device under section 515 of such Act (21 U.S.C.
2 360e), or clearance of a device under section 510(k) of
3 such Act (21 U.S.C. 360(k)) that were conducted during
4 the previous calendar year. Such information shall include
5 the following:

6 “(1) The median time following a request from
7 staff of the Food and Drug Administration review-
8 ing an application or report to the beginning of the
9 inspection, including—

10 “(A) the median time for drugs described
11 in 505(j)(11)(A)(i) of the Federal Food, Drug,
12 and Cosmetic Act (21 U.S.C. 355(j)(11)(A)(i));

13 “(B) the median time for drugs described
14 in section 506C(a) of such Act (21 U.S.C.
15 356c(a)) only; and

16 “(C) the median time for drugs on the
17 drug shortage list in effect under section 506E
18 of such Act (21 U.S.C. 356f).

19 “(2) The median time from the issuance of a
20 report pursuant to section 704(b) of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 374(b))
22 to the sending of a warning letter, issuance of an
23 import alert, or holding of a regulatory meeting for
24 inspections for which the Secretary concluded that
25 regulatory or enforcement action was indicated, in-

1 including the median time for each category of drugs
2 listed in subparagraphs (A) through (C) of para-
3 graph (1).

4 “(3) The median time from the sending of a
5 warning letter, issuance of an import alert, or hold-
6 ing of a regulatory meeting related to conditions ob-
7 served by the Secretary during an inspection, to the
8 time at which the Secretary concludes that corrective
9 actions to resolve such conditions have been taken.

10 “(4) The median time spent by staff of the
11 Food and Drug Administration at a facility during
12 an inspection, including—

13 “(A) the median time when records were
14 provided remotely in accordance with a request
15 under section 704(a)(4) of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 374(a)(4))
17 in advance of the inspection; and

18 “(B) the median time when a request for
19 records pursuant to such section 704(a)(4) was
20 not issued, or complied with, in advance of the
21 inspection.

22 “(5) The number and type of violations identi-
23 fied during inspections when a request for records
24 pursuant to such section 704(a)(4) was issued and
25 complied with in advance of the inspection, versus

1 when a request for records pursuant to such section
2 704(a)(4) was not issued or complied with.

3 “(6) The number of facilities that did not im-
4 plement requested corrective or preventive actions
5 following a report issued pursuant to such section
6 704(b), resulting in a withhold recommendation, in-
7 cluding the number of such times for each category
8 of drugs listed in subparagraphs (A) through (C) of
9 paragraph (1).”.

○