

117TH CONGRESS
2D SESSION

S. 4535

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

JULY 14, 2022

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 Simple Reauthorization
6 Act of 2022” or the “FDASRA Act of 2022”.

7 (b) **TABLE OF CONTENTS.**—The table of contents for
8 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. Reauthorization; reporting requirement.
 Sec. 205. Accreditation programs.
 Sec. 206. Sunset dates.
 Sec. 207. Effective date.
 Sec. 208. 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—OTHER REAUTHORIZATIONS

Sec. 501. Reauthorization of the critical path public-private partnership.
 Sec. 502. Reauthorization of the best pharmaceuticals for children program.
 Sec. 503. Reauthorization of the humanitarian device exemption incentive.
 Sec. 504. Reauthorization of the pediatric device consortia program.
 Sec. 505. Reauthorization of provision pertaining to drugs containing single enantiomers.
 Sec. 506. Reauthorization of orphan drug grants.
 Sec. 507. Reauthorization of certain device inspections.

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 and

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

1 be, withdrawn from sale, then, for purposes of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7 product will be withdrawn from sale on a future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9 withdrawn from sale.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16 shall not render a product withdrawn from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

18 (3) by adding at the end the following:

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

20 “(A) means a product—

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

23 “(ii) expected to produce a limited,
24 local reaction at the site of administration
25 (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 striking the period and insert-
2 ing “, and subsection (b)(1)(C) (the dollar
3 amount of the strategic hiring and reten-
4 tion adjustment).”; and

5 (F) in subparagraph (D), as so redesign-
6 dated, 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) CONDITIONS.—Section 738(g) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(g)) is
9 amended—

10 (1) in paragraph (1)(A), by striking
11 “\$320,825,000” and inserting “\$398,566,000”; and

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

14 (e) AUTHORIZATION OF APPROPRIATIONS.—Section
15 738(h)(3) of the Federal Food, Drug, and Cosmetic Act
16 (21 U.S.C. 379j(h)(3)) is amended to read as follows:

17 “(3) AUTHORIZATION OF APPROPRIATIONS.—

18 “(A) IN GENERAL.—For each of the fiscal
19 years 2023 through 2027, there is authorized to
20 be appropriated for fees under this section an
21 amount equal to the revenue amount deter-
22 mined in subparagraph (B), less the amount of
23 reductions determined in subparagraph (C).

1 “(B) REVENUE AMOUNT.—For purposes of
2 this paragraph, the revenue amount for each
3 fiscal year is the sum of—

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

7 “(ii) the performance improvement
8 adjustment amount for the fiscal year
9 under subsection (c)(4)(A), if applicable.

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

13 “(i) the hiring adjustment amount for
14 the fiscal year under subsection (c)(5), if
15 applicable; and

16 “(ii) the operating reserve adjustment
17 amount for the fiscal year under sub-
18 section (c)(6), if applicable.”.

19 **SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENT.**

20 (a) PERFORMANCE REPORTS.—Section 738A(a) of
21 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 379j-1(a)) is amended—

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

1 (2) by striking “Medical Device User Fee
2 Amendments of 2017” each place it appears and in-
3 serting “Medical Device User Fee Amendments of
4 2022”;

5 (3) in paragraph (1)—

6 (A) in subparagraph (A), by redesignating
7 the second clause (iv) (relating to analysis) as
8 clause (v); and

9 (B) in subparagraph (A)(iv) (relating to
10 rationale for MDUFA program changes), by
11 striking “fiscal year 2020” and inserting “fiscal
12 year 2023”; and

13 (4) in paragraph (4), by striking “2018
14 through 2022” and inserting “2023 through 2027”.

15 (b) REAUTHORIZATION.—Section 738A(b) of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
17 1(b)) is amended—

18 (1) in paragraph (1), by striking “2022” and
19 inserting “2027”; and

20 (2) in paragraph (5), by striking “2022” and
21 inserting “2027”.

22 **SEC. 205. ACCREDITATION PROGRAMS.**

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

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

3 (2) in paragraph (1)—

4 (A) in the matter preceding subparagraph
5 (A), by striking “pilot”;

6 (B) in subparagraph (A)—

7 (i) by inserting “meeting criteria spec-
8 ified by the Secretary in guidance” after
9 “testing laboratories”;

10 (ii) by inserting “in guidance” after
11 “by the Secretary”; and

12 (iii) by striking “assess the conform-
13 ance of a device with” and inserting “con-
14 duct testing to support the assessment of
15 the conformance of a device to”; and

16 (C) in subparagraph (B)—

17 (i) by striking “determinations” and
18 inserting “results”;

19 (ii) by inserting “to support” after
20 “so accredited”; and

21 (iii) by striking “a particular such de-
22 termination” and inserting “particular
23 such results”;

24 (3) in paragraph (2)—

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

3 (B) in subparagraph (A)—

4 (i) by striking “determinations by
5 testing laboratories” and all that follows
6 through “such determinations or” and in-
7 serting “results by testing laboratories ac-
8 credited pursuant to this subsection, in-
9 cluding by conducting periodic audits of
10 such results or of the”;

11 (ii) by inserting a comma after “or
12 testing laboratories”;

13 (iii) by inserting “or recognition of an
14 accreditation body” after “accreditation of
15 such testing laboratory”; and

16 (iv) by striking “such device” and in-
17 serting “a device”; and

18 (C) in subparagraph (B)—

19 (i) by striking “by a testing labora-
20 tory so accredited” and inserting “under
21 this subsection”; and

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

25 (4) in paragraph (3)(C)—

1 (A) in the subparagraph heading, by in-
2 serting “AND TRANSITION” after “INITIATION”;
3 and

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

10 (5) by striking paragraph (4).

11 (b) ACCREDITED PERSONS.—Section 523(c) of the
12 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 360m(c)) is amended by striking “2022” and inserting
14 “2027”.

15 **SEC. 206. SUNSET DATES.**

16 (a) AUTHORIZATION.—Sections 737 and 738 of the
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379i;
18 379fj) shall cease to be effective October 1, 2027.

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

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

1 **SEC. 207. EFFECTIVE DATE.**

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

10 **SEC. 208. SAVINGS CLAUSE.**

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

22 **TITLE III—FEES RELATING TO**
23 **GENERIC DRUGS**

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

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

1 (b) FINDING.—The Congress finds that the fees au-
2 thORIZED by the amendments made in this title will be dedi-
3 cated to human generic drug activities, as set forth in the
4 goals identified for purposes of part 7 of subchapter C
5 of chapter VII of the Federal Food, Drug, and Cosmetic
6 Act, 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. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**
13 **NERIC DRUG FEES.**

14 (a) TYPES OF FEES.—Section 744B(a) of the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
16 42(a)) is amended—

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

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

22 (3) in paragraph (3)(B), by striking “fiscal
23 years 2018 through 2022” and inserting “fiscal
24 years 2023 through 2027”;

1 (4) in paragraph (4)(D), by striking “fiscal
2 years 2018 through 2022” and inserting “fiscal
3 years 2023 through 2027”; and

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

7 (b) FEE REVENUE AMOUNTS.—Section 744B(b) of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 379j–42(b)) is amended—

10 (1) in paragraph (1)—

11 (A) in subparagraph (A)—

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

14 (ii) by striking “2018” and inserting
15 “2023”; and

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

18 (B) in subparagraph (B)—

19 (i) in the heading, by striking “2019
20 THROUGH 2022” and inserting “2024
21 THROUGH 2027”;

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

24 “(i) IN GENERAL.—For each”;

1 (iii) by striking “2019 through 2022”
2 and inserting “2024 through 2027”;

3 (iv) by striking “\$493,600,000” and
4 inserting “the base revenue amount under
5 clause (ii)”;

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

7 “(ii) BASE REVENUE AMOUNT.—The
8 base revenue amount for a fiscal year is
9 the total revenue amount established under
10 this paragraph for the previous fiscal year,
11 not including any adjustments made for
12 such previous fiscal year under subsection
13 (c)(3).”; and

14 (2) in paragraph (2)—

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

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

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

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

24 (1) in paragraph (1)—

1 (A) in the matter preceding subparagraph

2 (A)—

3 (i) by striking “2019” and inserting
4 “2024”; and

5 (ii) by striking “the product of the
6 total revenues established in such notice
7 for the prior fiscal year” and inserting
8 “the base revenue amount for the fiscal
9 year determined under subsection
10 (b)(1)(B)(ii)”; and

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

15 (2) by striking paragraph (2) and inserting the
16 following:

17 “(2) CAPACITY PLANNING ADJUSTMENT.—

18 “(A) IN GENERAL.—Beginning with fiscal
19 year 2024, the Secretary shall, in addition to
20 the adjustment under paragraph (1), further in-
21 crease the fee revenue and fees under this sec-
22 tion for a fiscal year, in accordance with this
23 paragraph, to reflect changes in the resource
24 capacity needs of the Secretary for human ge-
25 neric drug activities.

1 “(B) CAPACITY PLANNING METHOD-
2 OLOGY.—The Secretary shall establish a capac-
3 ity planning methodology for purposes of this
4 paragraph, which shall—

5 “(i) be derived from the methodology
6 and recommendations made in the report
7 titled ‘Independent Evaluation of the
8 GDUFA Resource Capacity Planning Ad-
9 justment Methodology: Evaluation and
10 Recommendations’ as announced in the
11 Federal Register on August 3, 2020 (85
12 Fed. Reg. 46658); and

13 “(ii) incorporate approaches and at-
14 tributes determined appropriate by the
15 Secretary, including those made in such re-
16 port recommendations, except the workload
17 categories used in forecasting resources
18 shall only be those specified in section
19 VIII.B.2.e. of the letters described in sec-
20 tion 301(b) of the Generic Drug User Fee
21 Amendments of 2022.

22 “(C) LIMITATIONS.—

23 “(i) IN GENERAL.—Under no cir-
24 cumstances shall an adjustment under this
25 paragraph result in fee revenue for a fiscal

1 year that is less than the sum of the
2 amounts under subsection (b)(1)(B)(ii)
3 (the base revenue amount for the fiscal
4 year) and paragraph (1) (the dollar
5 amount of the inflation adjustment for the
6 fiscal year).

7 “(ii) ADDITIONAL LIMITATION.—An
8 adjustment under this paragraph shall not
9 exceed 3 percent of the sum described in
10 clause (i) for the fiscal year, except that
11 such limitation shall be 4 percent if—

12 “(I) for purposes of an adjust-
13 ment for fiscal year 2024, the Sec-
14 retary determines that, during the pe-
15 riod from April 1, 2021, through
16 March 31, 2023—

17 “(aa) the total number of
18 abbreviated new drug applica-
19 tions submitted was greater than
20 or equal to 2,000; or

21 “(bb) thirty-five percent or
22 more of abbreviated new drug ap-
23 plications submitted related to
24 complex products (as that term is
25 defined in section XI of the let-

1 ters described in section 301(b)
2 of the Generic Drug User Fee
3 Amendments of 2022);

4 “(II) for purposes of an adjust-
5 ment for fiscal year 2025, the Sec-
6 retary determines that, during the pe-
7 riod from April 1, 2022, through
8 March 31, 2024—

9 “(aa) the total number of
10 abbreviated new drug applica-
11 tions submitted was greater than
12 or equal to 2,300; or

13 “(bb) thirty-five percent or
14 more of abbreviated new drug ap-
15 plications submitted related to
16 complex products (as so defined);

17 “(III) for purposes of an adjust-
18 ment for fiscal year 2026, the Sec-
19 retary determines that, during the pe-
20 riod from April 1, 2023, through
21 March 31, 2025—

22 “(aa) the total number of
23 abbreviated new drug applica-
24 tions submitted was greater than
25 or equal to 2,300; or

1 “(bb) thirty-five percent or
2 more of abbreviated new drug ap-
3 plications submitted related to
4 complex products (as so defined);
5 and

6 “(IV) for purposes of an adjust-
7 ment for fiscal year 2027, the Sec-
8 retary determines that, during the pe-
9 riod from April 1, 2024, through
10 March 31, 2026—

11 “(aa) the total number of
12 abbreviated new drug applica-
13 tions submitted was greater than
14 or equal to 2,300; or

15 “(bb) thirty-five percent or
16 more of abbreviated new drug ap-
17 plications submitted related to
18 complex products (as so defined).

19 “(D) PUBLICATION IN FEDERAL REG-
20 ISTER.—The Secretary shall publish in the Fed-
21 eral Register notice under subsection (a), the
22 fee revenue and fees resulting from the adjust-
23 ment and the methodology under this para-
24 graph.

25 “(3) OPERATING RESERVE ADJUSTMENT.—

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

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

12 “(i) 8 weeks for fiscal year 2024;

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

14 “(iii) 10 weeks for each of fiscal year
15 2026 and 2027.

16 “(C) DECREASE.—If the Secretary has
17 carryover balances for human generic drug ac-
18 tivities in excess of 12 weeks of the operating
19 reserves referred to in subparagraph (A), the
20 Secretary shall decrease the fee revenue and
21 fees referred to in such subparagraph to provide
22 for not more than 12 weeks of such operating
23 reserves.

24 “(D) RATIONALE FOR ADJUSTMENT.—If
25 an adjustment under this paragraph is made,

1 the rationale for the amount of the increase or
2 decrease (as applicable) in fee revenue and fees
3 shall be contained in the annual Federal Reg-
4 ister notice under subsection (a) publishing the
5 fee revenue and fees for the fiscal year in-
6 volved.”.

7 (d) ANNUAL FEE SETTING.—Section 744B(d)(1) of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 379j–42(d)(1)) is amended—

10 (1) in the heading, by striking “2018 THROUGH
11 2022” and inserting “2023 THROUGH 2027”;

12 (2) by striking “more” and inserting “later”;
13 and

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

16 (e) EFFECT OF FAILURE TO PAY FEES.—The head-
17 ing of paragraph (3) of section 744B(g) of the Federal
18 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(g)) is
19 amended by striking “AND PRIOR APPROVAL SUPPLEMENT
20 FEE”.

21 (f) CREDITING AND AVAILABILITY OF FEES.—Sec-
22 tion 744B(i)(3) of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 379j–42(i)(3)) is amended by striking
24 “2018 through 2022” and inserting “2023 through
25 2027”.

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

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

4 (1) in subsection (a)—

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

7 (B) by striking “Generic Drug User Fee
8 Amendments of 2017” each place it appears
9 and inserting “Generic Drug User Fee Amend-
10 ments of 2022”;

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

13 (3) in subsection (c)—

14 (A) by striking “2018” and inserting
15 “2023”; and

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

20 (4) in subsection (f)—

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

23 (B) in paragraph (5), by striking “January
24 15, 2022” and inserting “January 15, 2027”.

1 **SEC. 304. SUNSET DATES.**

2 (a) AUTHORIZATION.—Sections 744A and 744B of
3 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 379j–41; 379j–42) shall cease to be effective October 1,
5 2027.

6 (b) REPORTING REQUIREMENTS.—Section 744C of
7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 379j–43) shall cease to be effective January 31, 2028.

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

13 **SEC. 305. EFFECTIVE DATE.**

14 The amendments made by this title shall take effect
15 on October 1, 2022, or the date of the enactment of this
16 Act, whichever is later, except that fees under part 7 of
17 subchapter C of chapter VII of the Federal Food, Drug,
18 and Cosmetic Act (21 U.S.C. 379j–41 et seq.) shall be
19 assessed for all abbreviated new drug applications received
20 on or after October 1, 2022, regardless of the date of the
21 enactment of this Act.

22 **SEC. 306. SAVINGS CLAUSE.**

23 Notwithstanding the amendments made by this title,
24 part 7 of subchapter C of chapter VII of the Federal Food,
25 Drug, and Cosmetic Act, as in effect on the day before
26 the date of the enactment of this title, shall continue to

1 be in effect with respect to abbreviated new drug applica-
2 tions (as defined in such part as of such day) that were
3 received by the Food and Drug Administration within the
4 meaning of section 505(j)(5)(A) of such Act (21 U.S.C.
5 355(j)(5)(A)), prior approval supplements that were sub-
6 mitted, and drug master files for Type II active pharma-
7 ceutical ingredients that were first referenced on or after
8 October 1, 2017, but before October 1, 2022, with respect
9 to assessing and collecting any fee required by such part
10 for a fiscal year prior to fiscal year 2023.

11 **TITLE IV—FEES RELATING TO**
12 **BIOSIMILAR BIOLOGICAL**
13 **PRODUCTS**

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

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

17 (b) **FINDING.**—Congress finds that the fees author-
18 ized by the amendments made in this title will be dedi-
19 cated to expediting the process for the review of biosimilar
20 biological product applications, including postmarket safe-
21 ty activities, as set forth in the goals identified for pur-
22 poses of part 8 of subchapter C of chapter VII of the Fed-
23 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51
24 et seq.), in the letters from the Secretary of Health and
25 Human Services to the Chairman of the Committee on

1 Health, Education, Labor, and Pensions of the Senate and
2 the Chairman of the Committee on Energy and Commerce
3 of the House of Representatives, as set forth in the Con-
4 gressional Record.

5 **SEC. 402. DEFINITIONS.**

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

8 (1) in paragraph (1)—

9 (A) by striking “Washington-Baltimore,
10 DC–MD–VA–WV” and inserting “Washington–
11 Arlington–Alexandria, DC–VA–MD–WV”;

12 (B) by striking “October of” and inserting
13 “September of”; and

14 (C) by striking “October 2011” and insert-
15 ing “September 2011”; and

16 (2) in paragraph (4)(B)(iii)—

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

18 (B) by redesignating subclauses (III) and
19 (IV) as subclauses (II) and (III), respectively.

20 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR BIO-**
21 **LOGICAL PRODUCT FEES.**

22 (a) TYPES OF FEES.—Section 744H(a) of the Fed-
23 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
24 52(a)) is amended—

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

3 (2) in paragraph (1)—

4 (A) in subparagraph (A)—

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

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

9 (B) in subparagraph (B)—

10 (i) in clause (i), by inserting “, except
11 that, in the case that such product (includ-
12 ing, where applicable, ownership of the rel-
13 evant investigational new drug application)
14 is transferred to a licensee, assignee, or
15 successor of such person, and written no-
16 tice of such transfer is provided to the Sec-
17 retary, such licensee, assignee or successor
18 shall pay the annual biosimilar biological
19 product development fee” before the pe-
20 riod;

21 (ii) in clause (iii)—

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

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

1 (III) by adding at the end the
2 following:

3 “(III) been administratively re-
4 moved from the biosimilar biological
5 product development program for the
6 product under subparagraph (E)(v).”;
7 and

8 (iii) in clause (iv), by striking “accept-
9 ed for filing on or after October 1 of such
10 fiscal year” and inserting “subsequently
11 accepted for filing”;

12 (C) in subparagraph (D)—

13 (i) in clause (i)—

14 (I) in the matter preceding sub-
15 clause (I), by striking “shall, if the
16 person seeks to resume participation
17 in such program, pay” and inserting
18 “or who has been administratively re-
19 moved from such program for a prod-
20 uct under subparagraph (E)(v) shall,
21 if the person seeks to resume partici-
22 pation in such program, pay all an-
23 nual biosimilar biological product de-
24 velopment fees previously assessed for
25 such product and still owed and”;

- 1 (II) in subclause (I)—
- 2 (aa) by striking “5 days”
- 3 and inserting “7 days”; and
- 4 (bb) by inserting “or the
- 5 date of administrative removal,
- 6 as applicable” after “discon-
- 7 tinued”; and
- 8 (III) in subclause (II), by insert-
- 9 ing “or the date of administrative re-
- 10 moval, as applicable” after “discon-
- 11 tinued”; and
- 12 (ii) in clause (ii), by inserting “, ex-
- 13 cept that, in the case that such product
- 14 (including, where applicable, ownership of
- 15 the relevant investigational new drug appli-
- 16 cation) is transferred to a licensee, as-
- 17 signee, or successor of such person, and
- 18 written notice of such transfer is provided
- 19 to the Secretary, such licensee, assignee or
- 20 successor shall pay the annual biosimilar
- 21 biological product development fee” before
- 22 the period at the end; and
- 23 (D) in subparagraph (E), by adding at the
- 24 end the following:

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

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

20 (4) in paragraph (3)—

21 (A) in subparagraph (A)—

22 (i) in clause (i), by striking “; and”
23 and inserting a semicolon;

24 (ii) by redesignating clause (ii) as
25 clause (iii); and

1 (iii) by inserting the following after
2 clause (i):

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

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

7 “(E) MOVEMENT TO DISCONTINUED
8 LIST.—

9 “(i) WRITTEN REQUEST TO PLACE ON
10 DISCONTINUED LIST.—

11 “(I) IN GENERAL.—If a written
12 request to place a product on the list
13 of discontinued biosimilar biological
14 products referred to in subparagraph
15 (A)(iii) is submitted to the Secretary
16 on behalf of an applicant, and the re-
17 quest identifies the date the product
18 is, or will be, withdrawn from sale,
19 then for purposes of assessing the bio-
20 similar biological product program fee,
21 the Secretary shall consider such
22 product to have been included on such
23 list on the later of—

24 “(aa) the date such request
25 was received; or

1 “(bb) if the product will be
2 withdrawn from sale on a future
3 date, such future date when the
4 product is withdrawn from sale.

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

16 “(ii) PRODUCTS REMOVED FROM DIS-
17 CONTINUED LIST.—If a biosimilar biologi-
18 cal product that is identified in a bio-
19 similar biological product application ap-
20 proved as of October 1 of a fiscal year ap-
21 pears, as of October 1 of such fiscal year,
22 on the list of discontinued biosimilar bio-
23 logical products referred to in subpara-
24 graph (A)(iii), and on any subsequent day
25 during such fiscal year the biosimilar bio-

1 logical product does not appear on such
2 list, except as provided in subparagraph
3 (D), each person who is named as the ap-
4 plicant in the biosimilar biological product
5 application shall pay the annual biosimilar
6 biological product program fee established
7 for a fiscal year under subsection (c)(5) for
8 such biosimilar biological product. Not-
9 withstanding subparagraph (B), such fee
10 shall be due on the last business day of
11 such fiscal year and shall be paid only once
12 for each product for each fiscal year.”; and

13 (5) by striking paragraph (4).

14 (b) FEE REVENUE AMOUNTS.—Section 744H(b) of
15 the Federal Food, Drug, and Cosmetic Act ((21 U.S.C.
16 379j–52(b)) is amended—

17 (1) by striking paragraph (1);

18 (2) by redesignating paragraphs (2) through
19 (4) as paragraphs (1) through (3), respectively;

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

21 (A) in the paragraph heading, by striking
22 “SUBSEQUENT FISCAL YEARS” and inserting
23 “IN GENERAL”;

1 (B) in the matter preceding subparagraph
2 (A), by striking “2019 through 2022” and in-
3 serting “2023 through 2027”;

4 (C) in subparagraph (A), by striking
5 “paragraph (4)” and inserting “paragraph
6 (3)”;

7 (D) by redesignating subparagraphs (C)
8 and (D) as subparagraphs (D) and (E), respec-
9 tively;

10 (E) by inserting after subparagraph (B)
11 the following:

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

15 (F) in subparagraph (D), as so redesign-
16 ated, by striking “subsection (c)(2); and” and
17 inserting “subsection (c)(3));”;

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

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

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

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

25 and

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

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

3 (A) in the paragraph heading, by striking

4 “; LIMITATIONS ON FEE AMOUNTS”;

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

6 (C) by redesignating subparagraphs (C)

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

8 tively; and

9 (5) by amending paragraph (3), as so redesignated, to read as follows:

11 “(3) ANNUAL BASE REVENUE.—For purposes
12 of paragraph (1), the dollar amount of the annual
13 base revenue for a fiscal year shall be—

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

15 and

16 “(B) for fiscal years 2024 through 2027,
17 the dollar amount of the total revenue amount
18 established under paragraph (1) for the pre-
19 vious fiscal year, excluding any adjustments to
20 such revenue amount under subsection (c)(4).”.

21 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section
22 744H(e) of the Federal Food, Drug, and Cosmetic Act
23 ((21 U.S.C. 379j–52(e)) is amended—

24 (1) in paragraph (1)—

25 (A) in subparagraph (A)—

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

4 (ii) in clause (i), by striking “sub-
5 section (b)” and inserting “subsection
6 (b)(1)(A)”; and

7 (B) in subparagraph (B)(ii), by striking
8 “Washington-Baltimore, DC–MD–VA–WV”
9 and inserting “Washington–Arlington–Alexan-
10 dria, DC–VA–MD–WV”;

11 (2) by striking paragraph (4);

12 (3) by redesignating paragraphs (2) and (3) as
13 paragraphs (3) and (4), respectively;

14 (4) by inserting after paragraph (1) the fol-
15 lowing:

16 “(2) STRATEGIC HIRING AND RETENTION AD-
17 JUSTMENT.—For each fiscal year beginning in fiscal
18 year 2023, after the annual base revenue under sub-
19 section (b)(1)(A) is adjusted for inflation in accord-
20 ance with paragraph (1), the Secretary shall further
21 increase the fee revenue and fees by \$150,000.”;

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

23 (A) in subparagraph (A)—

24 (i) by striking “Beginning with the
25 fiscal year described in subparagraph

1 (B)(ii)(II)” and inserting “For each fiscal
2 year”; and

3 (ii) by striking “adjustment under
4 paragraph (1), further increase” and in-
5 sserting “adjustments under paragraphs (1)
6 and (2), further adjust”;

7 (B) by amending subparagraph (B) to read
8 as follows:

9 “(B) METHODOLOGY.—For purposes of
10 this paragraph, the Secretary shall employ the
11 capacity planning methodology utilized by the
12 Secretary in setting fees for fiscal year 2021, as
13 described in the notice titled ‘Biosimilar User
14 Fee Rates for Fiscal Year 2021’ (85 Fed. Reg.
15 47220; August 4, 2020). The workload cat-
16 egories used in forecasting shall include only
17 the activities described in such notice and, as
18 feasible, additional activities that are also di-
19 rectly related to the direct review of biosimilar
20 biological product applications and supplements,
21 including additional formal meeting types and
22 the direct review of postmarketing commitments
23 and requirements, the direct review of risk eval-
24 uation and mitigation strategies, and the direct
25 review of annual reports for approved biosimilar

1 biological products. Subject to the exceptions in
2 the preceding sentence, the Secretary shall not
3 include as workload categories in forecasting
4 any non-core review activities, including any ac-
5 tivities that the Secretary referenced for poten-
6 tial future use in such notice but did not utilize
7 in setting fees for fiscal year 2021.”; and

8 (C) in subparagraph (C)—

9 (i) by striking “subsections (b)(2)(A)”
10 and inserting “subsections (b)(1)(A)”;

11 (ii) by striking “and (b)(2)(B)” and
12 inserting “, (b)(1)(B)”;

13 (iii) by inserting “, and (b)(1)(C) (the
14 dollar amount of the strategic hiring and
15 retention adjustment)” before the period at
16 the end;

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

19 “(4) OPERATING RESERVE ADJUSTMENT.—

20 “(A) INCREASE.—For fiscal year 2023 and
21 subsequent fiscal years, the Secretary shall, in
22 addition to adjustments under paragraphs (1),
23 (2), and (3), further increase the fee revenue
24 and fees if such an adjustment is necessary to
25 provide for at least 10 weeks of operating re-

1 serves of carryover user fees for the process for
2 the review of biosimilar biological product appli-
3 cations.

4 “(B) DECREASE.—

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

14 “(ii) FISCAL YEAR 2024.—For fiscal
15 year 2024, if the Secretary has carryover
16 balances for the process for the review of
17 biosimilar biological product applications in
18 excess of 27 weeks of such operating re-
19 serves, the Secretary shall decrease such
20 fee revenue and fees to provide for not
21 more than 27 weeks of such operating re-
22 serves.

23 “(iii) FISCAL YEAR 2025 AND SUBSE-
24 QUENT FISCAL YEARS.—For fiscal year
25 2025 and subsequent fiscal years, if the

1 Secretary has carryover balances for the
2 process for the review of biosimilar biological
3 product applications in excess of 21
4 weeks of such operating reserves, the Secretary shall decrease such fee revenue and
5 fees to provide for not more than 21 weeks
6 of such operating reserves.
7

8 “(C) FEDERAL REGISTER NOTICE.—If an
9 adjustment under subparagraph (A) or (B) is
10 made, the rationale for the amount of the increase or decrease (as applicable) in fee revenue
11 and fees shall be contained in the annual Federal Register notice under paragraph (5)(B) establishing
12 fee revenue and fees for the fiscal
13 year involved.”; and
14

15
16 (7) in paragraph (5), in the matter preceding
17 subparagraph (A), by striking “2018” and inserting
18 “2023”.

19 (d) CREDITING AND AVAILABILITY OF FEES.—Section 744H(f)(3) of the Federal Food, Drug, and Cosmetic
20 Act ((21 U.S.C. 379j–52(f)(3)) is amended by striking
21 “2018 through 2022” and inserting “2023 through
22 2027”.

23
24 (e) WRITTEN REQUESTS FOR WAIVERS AND RE-
25 FUNDS.—Subsection (h) of section 744H of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52) is
2 amended to read as follows:

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

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

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

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

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

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

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

1 **SEC. 405. SUNSET DATES.**

2 (a) AUTHORIZATION.—Sections 744G and 744H of
3 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 379j–51, 379j–52) shall cease to be effective October 1,
5 2027.

6 (b) REPORTING REQUIREMENTS.—Section 744I of
7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 379j–53) shall cease to be effective January 31, 2028.

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

13 **SEC. 406. EFFECTIVE DATE.**

14 The amendments made by this title shall take effect
15 on October 1, 2022, or the date of the enactment of this
16 Act, whichever is later, except that fees under part 8 of
17 subchapter C of chapter VII of the Federal Food, Drug,
18 and Cosmetic Act (21 U.S.C. 379j–51 et seq.) shall be
19 assessed for all biosimilar biological product applications
20 received on or after October 1, 2022, regardless of the
21 date of the enactment of this Act.

22 **SEC. 407. SAVINGS CLAUSE.**

23 Notwithstanding the amendments made by this title,
24 part 8 of subchapter C of chapter VII of the Federal Food,
25 Drug, and Cosmetic Act (21 U.S.C. 379j–51 et seq.), as
26 in effect on the day before the date of the enactment of

1 this title, shall continue to be in effect with respect to bio-
2 similar biological product applications and supplements
3 (as defined in such part as of such day) that were accepted
4 by the Food and Drug Administration for filing on or after
5 October 1, 2017, but before October 1, 2022, with respect
6 to assessing and collecting any fee required by such part
7 for a fiscal year prior to fiscal year 2023.

8 **TITLE V—OTHER** 9 **REAUTHORIZATIONS**

10 **SEC. 501. REAUTHORIZATION OF THE CRITICAL PATH PUB-** 11 **LIC-PRIVATE PARTNERSHIP.**

12 Section 566(f) of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 360bbb–5(f)) is amended by striking
14 “2018 through 2022” and inserting “2023 through
15 2027”.

16 **SEC. 502. REAUTHORIZATION OF THE BEST PHARMA-** 17 **CEUTICALS FOR CHILDREN PROGRAM.**

18 Section 409I(d)(1) of the Public Health Service Act
19 (42 U.S.C. 284m(d)(1)) is amended by striking “2018
20 through 2022” and inserting “2023 through 2027”.

21 **SEC. 503. REAUTHORIZATION OF THE HUMANITARIAN DE-** 22 **VICE EXEMPTION INCENTIVE.**

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

1 **SEC. 504. REAUTHORIZATION OF THE PEDIATRIC DEVICE**
2 **CONSORTIA PROGRAM.**

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

8 **SEC. 505. REAUTHORIZATION OF PROVISION PERTAINING**
9 **TO DRUGS CONTAINING SINGLE**
10 **ENANTIOMERS.**

11 Section 505(u)(4) of the Federal Food, Drug, and
12 Cosmetic Act (21 U.S.C. 355(u)(4)) is amended by strik-
13 ing “October 1, 2022” and inserting “October 1, 2027”.

14 **SEC. 506. REAUTHORIZATION OF ORPHAN DRUG GRANTS.**

15 Section 5(c) of the Orphan Drug Act (21 U.S.C.
16 360ee(c)) is amended by striking “2018 through 2022”
17 and inserting “2023 through 2027”.

18 **SEC. 507. REAUTHORIZATION OF CERTAIN DEVICE INSPEC-**
19 **TIONS.**

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

○