

Calendar No. 152

119TH CONGRESS
1ST SESSION**S. 2292**

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user fee program for over-the-counter monograph drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 15, 2025

Mr. BANKS (for himself, Mr. KAINE, Mr. KIM, and Mr. HUSTED) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

SEPTEMBER 8, 2025

Reported by Mr. CASSIDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user fee program for over-the-counter monograph drugs, 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.**

4 This Act may be cited as the “Over-the-Counter
5 Monograph Drug User Fee Amendments”.

1 **SEC. 2. FINDING.**

2 Congress finds that the fees authorized by the
 3 amendments made in this Act will be dedicated to OTC
 4 monograph drug activities, as set forth in the goals identi-
 5 fied for purposes of part 10 of subchapter C of chapter
 6 VII of the Federal Food, Drug, and Cosmetic Act (21
 7 U.S.C. 379j–71 et seq.), in the letters from the Secretary
 8 of Health and Human Services to the Chairman of the
 9 Committee on Energy and Commerce of the House of
 10 Representatives and the Chairman of the Committee on
 11 Health, Education, Labor, and Pensions of the Senate, as
 12 set forth in the Congressional Record.

13 **SEC. 3. DEFINITIONS.**

14 Section 744L(9)(A) of the Federal Food, Drug, and
 15 Cosmetic Act (21 U.S.C. 379j–71(9)(A)) is amended—

16 (1) in clause (v), by striking “; or” and insert-
 17 ing a semicolon;

18 (2) in clause (vi)—

19 (A) by striking “addition” and inserting
 20 “the addition”; and

21 (B) by striking the period and inserting “;
 22 or”; and

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

24 “(vii) the addition or modification of a
 25 testing procedure applicable to one or more
 26 OTC monograph drugs, provided that such ad-

ditional or modified testing procedure reflects a
voluntary consensus standard with respect to
pharmaceutical quality that is—

“(I) established by a national or inter-
national standards development organiza-
tion; and

“(II) recognized by the Secretary
through a process described in guidance
for industry, initially published in July
2023, or any successor guidance, publicly
available on the website of the Food and
Drug Administration, which addresses vol-
untary consensus standards for pharma-
ceutical quality.”.

**SEC. 4. AUTHORITY TO ASSESS AND USE OTC MONOGRAPH
FEES.**

(a) TYPES OF FEES.—Section 744M(a)(1) of the
Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
72(a)(1)) is amended—

(1) in subparagraph (A)—

(A) by striking “on December 31 of the
fiscal year or at any time during the preceding
12-month period” and inserting “at any time
during the applicable period specified in clause
(ii) for a fiscal year”;

(B) by striking “Each person” and inserting the following:

“(i) ASSESSMENT OF FEES.—Each person”; and

(C) by adding at the end the following:

“(ii) APPLICABLE PERIOD.—For purposes of clause (i), the applicable period is—

“(I) for fiscal year 2026, the 12-month period ending on December 31, 2025;

“(II) for fiscal year 2027, the 9-month period ending on September 30, 2026; and

“(III) for fiscal year 2028 and each subsequent fiscal year, the 12-month period ending on September 30 of the preceding fiscal year.”;

(2) in subparagraph (B)(i), by amending subclause (I) to read as follows:

“(I) has ceased all activities related to OTC monograph drugs prior to—

“(aa) for purposes of fiscal year 2026, January 1, 2025;

1 “(bb) for purposes of fiscal
 2 year 2027, January 1, 2026; and
 3 “(cc) for purposes of fiscal
 4 year 2028 and each subsequent
 5 fiscal year, October 1 of the pre-
 6 ceding fiscal year; and”;

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

9 “(D) DUE DATE.—

10 “(i) FISCAL YEAR 2026.—For fiscal
 11 year 2026, the facility fees required under
 12 subparagraph (A) shall be due on the later
 13 of—

14 “(I) the first business day of
 15 June of such year; or

16 “(H) the first business day after
 17 the enactment of an appropriations
 18 Act providing for the collection and
 19 obligation of fees under this section
 20 for such year.

21 “(ii) FISCAL YEAR 2027.—For fiscal
 22 year 2027, the facility fees required under
 23 subparagraph (A) shall be due—

1 ~~“(I) in a first installment rep-~~
 2 ~~resenting 50 percent of such fee, on~~
 3 ~~the later of—~~

4 ~~“(aa) October 1, 2026; or~~

5 ~~“(bb) the first business day~~
 6 ~~after the enactment of an appro-~~
 7 ~~priations Act providing for the~~
 8 ~~collection and obligation of fees~~
 9 ~~under this section for such year;~~
 10 ~~and~~

11 ~~“(II) in a second installment rep-~~
 12 ~~resenting the remaining 50 percent of~~
 13 ~~such fee, on—~~

14 ~~“(aa) February 1, 2027; or~~

15 ~~“(bb) if an appropriations~~
 16 ~~Act described in subclause~~
 17 ~~(I)(bb) is not in effect on Feb-~~
 18 ~~ruary 1, 2027, the first business~~
 19 ~~day after enactment of such an~~
 20 ~~appropriations Act.~~

21 ~~“(iii) SUBSEQUENT FISCAL YEARS.—~~

22 ~~For fiscal year 2028 and each subsequent~~
 23 ~~fiscal year, the facility fees required under~~
 24 ~~subparagraph (A) shall be due on the later~~
 25 ~~of—~~

1 “(I) the first business day on or
 2 after October 1 of the fiscal year; or
 3 “(H) the first business day after
 4 the date of enactment of an appro-
 5 priations Act providing for the collec-
 6 tion and obligation of fees under this
 7 section for the fiscal year.”.

8 (b) FEE REVENUE AMOUNTS.—Section 744M(b) of
 9 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 10 379j–72(b)) is amended to read as follows:

11 “(b) FEE REVENUE AMOUNTS.—

12 “(1) IN GENERAL.—For each of the fiscal years
 13 2026 through 2030, fees under subsection (a)(1)
 14 shall be established to generate a total facility fee
 15 revenue amount equal to the sum of—

16 “(A) the annual base revenue for the fiscal
 17 year (as determined under paragraph (2));

18 “(B) the dollar amount equal to the infla-
 19 tion adjustment for the fiscal year (as deter-
 20 mined under subsection (c)(1));

21 “(C) the dollar amount equal to the oper-
 22 ating reserve adjustment for the fiscal year, if
 23 applicable (as determined under subsection
 24 (c)(2));

1 “(D) additional direct cost adjustments (as
2 determined under subsection (c)(3));

3 “(E) an additional dollar amount equal
4 to—

5 “(i) \$2,373,000 for fiscal year 2026;

6 “(ii) \$1,233,000 for fiscal year 2027;

7 and

8 “(iii) \$854,000 for fiscal year 2028;

9 and

10 “(F) in the case of a fiscal year for which
11 the Secretary applies the one-time facility fee
12 workload adjustment under subsection (c)(4),
13 the dollar amount equal to such adjustment.

14 “(2) ANNUAL BASE REVENUE.—For purposes
15 of paragraph (1), the dollar amount of the annual
16 base revenue for a fiscal year shall be—

17 “(A) for fiscal year 2026, the dollar
18 amount of the total revenue amount established
19 for fiscal year 2025 under this subsection as in
20 effect on the day before the date of enactment
21 of the Over-the-Counter Monograph Drug User
22 Fee Amendments, not including any adjust-
23 ments made for such fiscal year 2025 under
24 subsection (c)(2), as so in effect; and

1 “(B) for fiscal years 2027 through 2030,
 2 the dollar amount of the total revenue amount
 3 established under this subsection for the pre-
 4 vious fiscal year, not including any adjustments
 5 made for such previous fiscal year under sub-
 6 section (c)(2) or (c)(3).”.

7 (c) ~~ADJUSTMENTS; ANNUAL FEE SETTING.~~—Section
 8 744M(e) of the Federal Food, Drug, and Cosmetic Act
 9 (21 U.S.C. 379j-72) is amended—

10 (1) in paragraph (1)—

11 (A) in subparagraph (A), in the matter
 12 preceding clause (i)—

13 (i) by striking “subsection (b)(2)(B)”
 14 and inserting “subsection (b)(1)(B)”; and
 15 (ii) by striking “fiscal year 2022 and
 16 each subsequent fiscal year” and inserting
 17 “each fiscal year”;

18 (B) in subparagraph (B), by striking “fis-
 19 cal year 2022” and all that follows through the
 20 period at the end and inserting the following:
 21 “a fiscal year shall be equal to the product of—

22 “(i) for fiscal year 2026—

23 “(I) the fee for fiscal year 2025
 24 under subsection (a)(2); and

1 “(H) the inflation adjustment
2 percentage under subparagraph (C);
3 and

4 “(ii) for each of fiscal years 2027
5 through 2030—

6 “(I) the applicable fee under sub-
7 section (a)(2) for the preceding fiscal
8 year; and

9 “(H) the inflation adjustment
10 percentage under subparagraph (C).”;
11 and

12 (C) in subparagraph (C)—

13 (i) in the matter preceding clause (i);
14 by inserting “the sum of” after “is equal
15 to”;

16 (ii) by striking clause (i);

17 (iii) by redesignating subclauses (I)
18 and (H) of clause (ii) as clauses (i) and
19 (ii), respectively, and adjusting the mar-
20 gins accordingly;

21 (iv) by striking “(ii) for each of fiscal
22 years 2024 and 2025, the sum of—”; and

23 (v) in clause (ii), as so redesignated,
24 by striking “Washington-Baltimore, DC—

1 ~~MD-VA-WV~~ and inserting “Washington-
 2 ~~Arlington-Alexandria-DC-VA-MD-WV~~”;
 3 ~~(2)~~ in paragraph ~~(2)~~—
 4 ~~(A)~~ in subparagraph ~~(A)~~—
 5 (i) by striking “fiscal year 2021 and
 6 subsequent fiscal years” and inserting
 7 “each fiscal year”;
 8 (ii) by striking “subsections (b)(1)(B)
 9 and (b)(2)(C)” and inserting “subsection
 10 (b)(1)(C)”; and
 11 (iii) by striking “the number of weeks
 12 specified in subparagraph (B)” and insert-
 13 ing “10 weeks”;
 14 (B) by striking subparagraph (B);
 15 (C) by redesignating subparagraphs (C)
 16 and (D) as subparagraphs (B) and (C), respec-
 17 tively; and
 18 ~~(D)~~ in subparagraph ~~(C)~~, as so redesign-
 19 ated, by striking “paragraph (4) establishing”
 20 and inserting “paragraph (5) publishing”;
 21 ~~(3)~~ in paragraph ~~(3)~~—
 22 ~~(A)~~ in the matter preceding subparagraph
 23 ~~(A)~~, by striking “subsection (b)(2)(D)” and in-
 24 serting “subsection (b)(1)(D)”; and

1 (B) by striking subparagraphs (A) through
2 (E) and inserting the following:

3 “(A) \$135,000 for fiscal year 2026;

4 “(B) \$300,000 for fiscal year 2027;

5 “(C) \$55,000 for fiscal year 2028;

6 “(D) \$30,000 for fiscal year 2029; and

7 “(E) \$0 for fiscal year 2030.”; and

8 (4) by striking paragraph (4) and inserting the
9 following:

10 “(4) ONE-TIME FACILITY FEE WORKLOAD AD-
11 JUSTMENT.—

12 “(A) IN GENERAL.—In addition to the ad-
13 justments under paragraphs (1), (2), and (3),
14 the Secretary may further increase the fee reve-
15 nues and fees through a one-time adjustment
16 made for fiscal year 2028, 2029, or 2030, in
17 accordance with this paragraph.

18 “(B) ADJUSTMENT DESCRIBED.—

19 “(i) CONDITIONS FOR ADJUST-
20 MENT.—An adjustment under this para-
21 graph may be made for a fiscal year only
22 if—

23 “(I) an adjustment under this
24 paragraph had not been made for any
25 prior fiscal year;

1 “(H) the average number of OTC
 2 monograph drug facilities subject to a
 3 facility fee under subsection (a)(1)
 4 over the period of the preceding 3 fis-
 5 cal years exceeds 1,625; and

6 “(III) with respect to facilities
 7 described in subclause (H), the aver-
 8 age number of such facilities (ex-
 9 pressed as a percentage) that ap-
 10 peared on the arrears lists pursuant
 11 to subsection (c)(1)(A)(i) over the pe-
 12 riod of the preceding 3 fiscal years is
 13 less than 30 percent.

14 “(ii) AMOUNT OF ADJUSTMENT.—An
 15 adjustment under this paragraph for a fis-
 16 cal year shall equal the product of—

17 “(I) the total facility revenue
 18 amount determined under subsection
 19 (b) for the fiscal year, exclusive of the
 20 adjustment under this paragraph for
 21 such fiscal year; and

22 “(II) the excess facility percent-
 23 age described in clause (iii).

1 “(iii) ~~EXCESS FACILITY PERCENT-~~
 2 ~~AGE.~~—The excess facility percentage de-
 3 scribed in this clause is—

4 “(I) the amount by which the av-
 5 erage number of OTC monograph
 6 drug facilities subject to a facility fee
 7 under subsection (a)(1) over the pre-
 8 ceding 3 fiscal years exceeds 1,625;
 9 divided by

10 “(H) ~~1,625.~~

11 “(5) ~~ANNUAL FEE SETTING.~~—The Secretary
 12 shall, not later than 60 days before the first day of
 13 each fiscal year—

14 “(A) establish for such fiscal year, based
 15 on the revenue amounts under subsection (b)
 16 and the adjustments provided under this sub-
 17 section—

18 “(i) OTC monograph drug facility fees
 19 under subsection (a)(1); and

20 “(ii) OTC monograph order request
 21 fees under subsection (a)(2); and

22 “(B) publish such fee revenue amounts, fa-
 23 cility fees, and OTC monograph order request
 24 fees in the Federal Register.”.

1 (d) CREDITING AND AVAILABILITY OF FEES.—Sec-
 2 tion 744M(f) of the Federal Food, Drug, and Cosmetic
 3 Act (21 U.S.C. 379j–72(f)) is amended—

4 (1) in paragraph (2)(D)—

5 (A) in the subparagraph heading, by strik-
 6 ing “IN SUBSEQUENT YEARS”; and

7 (B) by striking “(after fiscal year 2021)”;
 8 and

9 (2) in paragraph (3), by striking “2021
 10 through 2025” and inserting “2026 through 2030”.

11 **SEC. 5. REAUTHORIZATION; REPORTING REQUIREMENTS.**

12 Section 744N of the Federal Food, Drug, and Cos-
 13 metic Act (21 U.S.C. 379j–73) is amended—

14 (1) in subsection (a)—

15 (A) by striking “Beginning with fiscal year
 16 2021, and not later than 120 calendar days
 17 after the end of each fiscal year thereafter” and
 18 inserting “Not later than 120 calendar days
 19 after the end of each fiscal year”; and

20 (B) by striking “section 3861(b) of the
 21 CARES Act” and inserting “section 2 of the
 22 Over-the-Counter Monograph Drug User Fee
 23 Amendments”;

1 (2) in subsection (b), by striking “fiscal year
2 2021 and each subsequent fiscal year” and inserting
3 “each fiscal year”; and

4 (3) in subsection (d), by striking “2025” each
5 place it appears and inserting “2030”.

6 **SEC. 6. SUNSET DATES.**

7 (a) **AUTHORIZATION.**—Sections 744L and 744M of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 379j–71; 379j–72) shall cease to be effective October 1,
10 2030.

11 (b) **REPORTING REQUIREMENTS.**—Section 744N of
12 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 379j–73) shall cease to be effective January 31, 2031.

14 **SEC. 7. EFFECTIVE DATE.**

15 The amendments made by this Act shall take effect
16 on October 1, 2025, or the date of the enactment of this
17 Act, whichever is later, except that fees under part 10 of
18 subchapter C of chapter VII of the Federal Food, Drug,
19 and Cosmetic Act (21 U.S.C. 379j–71 et seq.) shall be
20 assessed beginning October 1, 2025, regardless of the date
21 of the enactment of this Act.

22 **SEC. 8. SAVINGS CLAUSE.**

23 Notwithstanding the amendments made by this Act,
24 part 10 of subchapter C of chapter VII of the Federal
25 Food, Drug, and Cosmetic Act (21 U.S.C. 379j–71 et

1 seq.); as in effect on the day before the date of enactment
 2 of this Act, shall continue to be in effect with respect to
 3 assessing and collecting any fee required by such part for
 4 a fiscal year prior to fiscal year 2026.

5 **SECTION 1. SHORT TITLE.**

6 *This Act may be cited as the “Over-the-Counter Mono-*
 7 *graph Drug User Fee Amendments”.*

8 **SEC. 2. FINDING.**

9 *Congress finds that the fees authorized by the amend-*
 10 *ments made in this Act will be dedicated to OTC mono-*
 11 *graph drug activities, as set forth in the goals identified*
 12 *for purposes of part 10 of subchapter C of chapter VII of*
 13 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
 14 *71 et seq.) in the letters from the Secretary of Health and*
 15 *Human Services to the Chairman of the Committee on En-*
 16 *ergy and Commerce of the House of Representatives and*
 17 *the Chairman of the Committee on Health, Education,*
 18 *Labor, and Pensions of the Senate, as set forth in the Con-*
 19 *gressional Record.*

20 **SEC. 3. DEFINITIONS.**

21 *Section 744L(9)(A) of the Federal Food, Drug, and*
 22 *Cosmetic Act (21 U.S.C. 379j–71(9)(A)) is amended—*

23 *(1) in clause (v), by striking “; or” and inserting*
 24 *a semicolon;*

25 *(2) in clause (vi)—*

1 (A) by striking “addition” and inserting
2 “the addition”; and

3 (B) by striking the period and inserting “;
4 or”; and

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

6 “(vii) the addition or modification of a test-
7 ing procedure applicable to one or more OTC
8 monograph drugs, provided that such additional
9 or modified testing procedure reflects a voluntary
10 consensus standard with respect to pharma-
11 ceutical quality that is—

12 “(I) established by a national or inter-
13 national standards development organiza-
14 tion; and

15 “(II) recognized by the Secretary
16 through a process described in guidance for
17 industry, initially published in July 2023,
18 or any successor guidance, publicly avail-
19 able on the website of the Food and Drug
20 Administration, which addresses voluntary
21 consensus standards for pharmaceutical
22 quality.”.

1 **SEC. 4. AUTHORITY TO ASSESS AND USE OTC MONOGRAPH**

2 **FEEES.**

3 (a) *TYPES OF FEEES.*—Section 744M(a)(1) of the Fed-
 4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
 5 72(a)(1)) is amended—

6 (1) in subparagraph (A)—

7 (A) by striking “on December 31 of the fis-
 8 cal year or at any time during the preceding 12-
 9 month period” and inserting “at any time dur-
 10 ing the applicable period specified in clause (ii)
 11 for a fiscal year”;

12 (B) by striking “Each person” and insert-
 13 ing the following:

14 “(i) *ASSESSMENT OF FEEES.*—Each
 15 person”; and

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

17 “(ii) *APPLICABLE PERIOD.*—For pur-
 18 poses of clause (i), the applicable period
 19 is—

20 “(I) for fiscal year 2026, the 12-
 21 month period ending on December 31,
 22 2025;

23 “(II) for fiscal year 2027, the 9-
 24 month period ending on September 30,
 25 2026; and

1 “(III) for fiscal year 2028 and
 2 each subsequent fiscal year, the 12-
 3 month period ending on September 30
 4 of the preceding fiscal year.”;

5 (2) in subparagraph (B)(i), by amending sub-
 6 clause (I) to read as follows:

7 “(I) has ceased all activities re-
 8 lated to OTC monograph drugs prior
 9 to—

10 “(aa) for purposes of fiscal
 11 year 2026, January 1, 2025;

12 “(bb) for purposes of fiscal
 13 year 2027, January 1, 2026; and

14 “(cc) for purposes of fiscal
 15 year 2028 and each subsequent
 16 fiscal year, October 1 of the pre-
 17 ceding fiscal year; and”;

18 (3) by amending subparagraph (D) to read as
 19 follows:

20 “(D) DUE DATE.—

21 “(i) FISCAL YEAR 2026.—For fiscal
 22 year 2026, the facility fees required under
 23 subparagraph (A) shall be due on the later
 24 of—

1 “(I) the first business day of June
2 of such year; or

3 “(II) the first business day after
4 the enactment of an appropriations
5 Act providing for the collection and ob-
6 ligation of fees under this section for
7 such year.

8 “(ii) FISCAL YEAR 2027.—For fiscal
9 year 2027, the facility fees required under
10 subparagraph (A) shall be due—

11 “(I) in a first installment rep-
12 resenting 50 percent of such fee, on the
13 later of—

14 “(aa) October 1, 2026; or

15 “(bb) the first business day
16 after the enactment of an appro-
17 priations Act providing for the
18 collection and obligation of fees
19 under this section for such year;
20 and

21 “(II) in a second installment rep-
22 resenting the remaining 50 percent of
23 such fee, on—

24 “(aa) February 1, 2027; or

1 “(bb) if an appropriations
 2 Act described in subclause (I)(bb)
 3 is not in effect on February 1,
 4 2027, the first business day after
 5 enactment of such an appropria-
 6 tions Act.

7 “(iii) *SUBSEQUENT FISCAL YEARS.*—
 8 For fiscal year 2028 and each subsequent
 9 fiscal year, the facility fees required under
 10 subparagraph (A) shall be due on the later
 11 of—

12 “(I) the first business day on or
 13 after October 1 of the fiscal year; or

14 “(II) the first business day after
 15 the date of enactment of an appropria-
 16 tions Act providing for the collection
 17 and obligation of fees under this sec-
 18 tion for the fiscal year.”.

19 (b) *FEE REVENUE AMOUNTS.*—Section 744M(b) of the
 20 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
 21 72(b)) is amended to read as follows:

22 “(b) *FEE REVENUE AMOUNTS.*—

23 “(1) *IN GENERAL.*—For each of the fiscal years
 24 2026 through 2030, fees under subsection (a)(1) shall

1 *be established to generate a total facility fee revenue*
 2 *amount equal to the sum of—*

3 “(A) *the annual base revenue for the fiscal*
 4 *year (as determined under paragraph (2));*

5 “(B) *the dollar amount equal to the infla-*
 6 *tion adjustment for the fiscal year (as deter-*
 7 *mined under subsection (c)(1));*

8 “(C) *the dollar amount equal to the oper-*
 9 *ating reserve adjustment for the fiscal year, if*
 10 *applicable (as determined under subsection*
 11 *(c)(2));*

12 “(D) *additional direct cost adjustments (as*
 13 *determined under subsection (c)(3));*

14 “(E) *an additional dollar amount equal*
 15 *to—*

16 “(i) *\$2,373,000 for fiscal year 2026;*

17 “(ii) *\$1,233,000 for fiscal year 2027;*

18 *and*

19 “(iii) *\$854,000 for fiscal year 2028;*

20 *and*

21 “(F) *in the case of a fiscal year for which*
 22 *the Secretary applies the one-time facility fee*
 23 *workload adjustment under subsection (c)(4), the*
 24 *dollar amount equal to such adjustment.*

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

4 “(A) *for fiscal year 2026, the dollar amount*
 5 *of the total revenue amount established for fiscal*
 6 *year 2025 under this subsection as in effect on*
 7 *the day before the date of enactment of the Over-*
 8 *the-Counter Monograph Drug User Fee Amend-*
 9 *ments, not including any adjustments made for*
 10 *such fiscal year 2025 under subsection (c)(2), as*
 11 *so in effect; and*

12 “(B) *for fiscal years 2027 through 2030, the*
 13 *dollar amount of the total revenue amount estab-*
 14 *lished under this subsection for the previous fis-*
 15 *cal year, not including any adjustments made*
 16 *for such previous fiscal year under subsection*
 17 *(c)(2) or (c)(3).”.*

18 (c) *ADJUSTMENTS; ANNUAL FEE SETTING*.—Section
 19 744M(c) of the Federal Food, Drug, and Cosmetic Act (21
 20 U.S.C. 379j–72) is amended—

21 (1) *in paragraph (1)—*

22 (A) *in subparagraph (A), in the matter pre-*
 23 *ceding clause (i)—*

24 (i) *by striking “subsection (b)(2)(B)”*
 25 *and inserting “subsection (b)(1)(B)”;* and

1 (ii) by striking “fiscal year 2022 and
2 each subsequent fiscal year” and inserting
3 “each fiscal year”;

4 (B) in subparagraph (B), by striking “fis-
5 cal year 2022” and all that follows through the
6 period at the end and inserting the following: “a
7 fiscal year shall be equal to the product of—

8 “(i) for fiscal year 2026—

9 “(I) the fee for fiscal year 2025
10 under subsection (a)(2); and

11 “(II) the inflation adjustment per-
12 centage under subparagraph (C); and

13 “(ii) for each of fiscal years 2027
14 through 2030—

15 “(I) the applicable fee under sub-
16 section (a)(2) for the preceding fiscal
17 year; and

18 “(II) the inflation adjustment per-
19 centage under subparagraph (C).”; and
20 (C) in subparagraph (C)—

21 (i) in the matter preceding clause (i),
22 by inserting “the sum of” after “is equal
23 to”;

24 (ii) by striking clause (i);

1 (iii) by redesignating subclauses (I)
2 and (II) of clause (ii) as clauses (i) and
3 (ii), respectively, and adjusting the margins
4 accordingly;

5 (iv) by striking “(ii) for each of fiscal
6 years 2024 and 2025, the sum of—”; and

7 (v) in clause (ii), as so redesignated,
8 by striking “Washington-Baltimore, DC–
9 MD–VA–WV” and inserting “Washington–
10 Arlington–Alexandria–DC–VA–MD–WV”;

11 (2) in paragraph (2)—

12 (A) in subparagraph (A)—

13 (i) by striking “fiscal year 2021 and
14 subsequent fiscal years” and inserting “each
15 fiscal year”;

16 (ii) by striking “subsections (b)(1)(B)
17 and (b)(2)(C)” and inserting “subsection
18 (b)(1)(C)”; and

19 (iii) by striking “the number of weeks
20 specified in subparagraph (B)” and insert-
21 ing “10 weeks”;

22 (B) by striking subparagraph (B);

23 (C) by redesignating subparagraphs (C)
24 and (D) as subparagraphs (B) and (C), respec-
25 tively; and

(D) in subparagraph (C), as so redesignated, by striking “paragraph (4) establishing” and inserting “paragraph (5) publishing”;
(3) in paragraph (3)—

(A) in the matter preceding subparagraph (A), by striking “subsection (b)(2)(D)” and inserting “subsection (b)(1)(D)”; and

(B) by striking subparagraphs (A) through (E) and inserting the following:

“(A) \$135,000 for fiscal year 2026;

“(B) \$300,000 for fiscal year 2027;

“(C) \$55,000 for fiscal year 2028;

“(D) \$30,000 for fiscal year 2029; and

“(E) \$0 for fiscal year 2030.”; and

(4) by striking paragraph (4) and inserting the following:

“(4) ONE-TIME FACILITY FEE WORKLOAD ADJUSTMENT.—

“(A) IN GENERAL.—In addition to the adjustments under paragraphs (1), (2), and (3), the Secretary may further increase the fee revenues and fees through a one-time adjustment made for fiscal year 2028, 2029, or 2030, in accordance with this paragraph.

“(B) ADJUSTMENT DESCRIBED.—

1 “(i) *CONDITIONS FOR ADJUSTMENT.*—

2 *An adjustment under this paragraph may*
 3 *be made for a fiscal year only if—*

4 “(I) *an adjustment under this*
 5 *paragraph had not been made for any*
 6 *prior fiscal year;*

7 “(II) *the average number of OTC*
 8 *monograph drug facilities subject to a*
 9 *facility fee under subsection (a)(1) over*
 10 *the period of the preceding 3 fiscal*
 11 *years exceeds 1,625; and*

12 “(III) *with respect to facilities de-*
 13 *scribed in subclause (II), the average*
 14 *number of such facilities (expressed as*
 15 *a percentage) that appeared on the ar-*
 16 *rears lists pursuant to subsection*
 17 *(e)(1)(A)(i) over the period of the pre-*
 18 *ceding 3 fiscal years is less than 30*
 19 *percent.*

20 “(ii) *AMOUNT OF ADJUSTMENT.*—*An*
 21 *adjustment under this paragraph for a fis-*
 22 *cal year shall equal the product of—*

23 “(I) *the total facility revenue*
 24 *amount determined under subsection*
 25 *(b) for the fiscal year, exclusive of the*

1 *adjustment under this paragraph for*
 2 *such fiscal year; and*

3 “(II) *the excess facility percentage*
 4 *described in clause (iii).*

5 “(iii) *EXCESS FACILITY PERCENT-*
 6 *AGE.—The excess facility percentage de-*
 7 *scribed in this clause is—*

8 “(I) *the amount by which the av-*
 9 *erage number of OTC monograph drug*
 10 *facilities subject to a facility fee under*
 11 *subsection (a)(1) over the preceding 3*
 12 *fiscal years exceeds 1,625; divided by*

13 “(II) *1,625.*

14 “(5) *ANNUAL FEE SETTING.—The Secretary*
 15 *shall, not later than 60 days before the first day of*
 16 *each fiscal year—*

17 “(A) *establish for such fiscal year, based on*
 18 *the revenue amounts under subsection (b) and*
 19 *the adjustments provided under this subsection—*

20 “(i) *OTC monograph drug facility fees*
 21 *under subsection (a)(1); and*

22 “(ii) *OTC monograph order request*
 23 *fees under subsection (a)(2); and*

1 “(B) publish such fee revenue amounts, fa-
 2 cility fees, and OTC monograph order request
 3 fees in the Federal Register.”.

4 (d) *CREDITING AND AVAILABILITY OF FEES.*—Section
 5 744M(f) of the Federal Food, Drug, and Cosmetic Act (21
 6 U.S.C. 379j–72(f)) is amended—

7 (1) in paragraph (2)(D)—

8 (A) in the subparagraph heading, by strik-
 9 ing “IN SUBSEQUENT YEARS”; and

10 (B) by striking “(after fiscal year 2021)”;
 11 and

12 (2) in paragraph (3), by striking “2021 through
 13 2025” and inserting “2026 through 2030”.

14 **SEC. 5. REAUTHORIZATION; REPORTING REQUIREMENTS.**

15 (a) *PERFORMANCE REPORT.*—Section 744N of the
 16 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
 17 73) is amended—

18 (1) in subsection (a)—

19 (A) by striking “Beginning with fiscal year
 20 2021, and not later than 120 calendar days after
 21 the end of each fiscal year thereafter” and insert-
 22 ing the following:

23 “(1) *IN GENERAL.*—Not later than 120 calendar
 24 days after the end of each fiscal year”;

1 (B) by striking “section 3861(b) of the
 2 CARES Act” and inserting “section 2 of the
 3 Over-the-Counter Monograph Drug User Fee
 4 Amendments”; and

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

6 “(2) *ADDITIONAL INFORMATION.—Beginning*
 7 *with fiscal year 2026, the annual report under this*
 8 *subsection shall include—*

9 “(A) *the progress of the Food and Drug Ad-*
 10 *ministration in achieving the goals, and future*
 11 *plans for meeting the goals, including—*

12 “(i) *the number of Tier 1 OTC mono-*
 13 *graph order requests for which a proposed*
 14 *order was issued, and the number of such*
 15 *requests for which a final order was issued,*
 16 *in the previous fiscal year;*

17 “(ii) *the number of Tier 2 OTC mono-*
 18 *graph order requests for which a proposed*
 19 *order was issued, and the number of such*
 20 *requests for which a final order was issued,*
 21 *in the previous fiscal year;*

22 “(iii) *the number of specified safety*
 23 *OTC monograph order requests for which a*
 24 *proposed order was issued, and the number*

1 *of such requests for which a final order was*
2 *issued, in the previous fiscal year;*

3 *“(iv) the number of generally recog-*
4 *nized as safe and effective finalization OTC*
5 *monograph order requests for which a pro-*
6 *posed order was issued, and the number of*
7 *such requests for which a final order was*
8 *issued, in the previous fiscal year;*

9 *“(v) the average timeline for processing*
10 *OTC monograph order requests, in the ag-*
11 *gregate and by submission type, in the pre-*
12 *vious fiscal year; and*

13 *“(vi) postmarket safety activities with*
14 *respect to OTC monograph drugs, includ-*
15 *ing—*

16 *“(I) collecting, developing, and re-*
17 *viewing safety information on OTC*
18 *monograph drugs, including adverse*
19 *event reports;*

20 *“(II) developing and using im-*
21 *proved analytical tools, adverse event*
22 *data-collection systems, including in-*
23 *formation technology systems, to assess*
24 *potential safety problems, including*
25 *access to external databases; and*

1 “(III) activities under section
2 760;

3 “(B) information regarding registration of
4 OTC monograph drug facilities and contract
5 manufacturing organization facilities and pay-
6 ment of registration fees by such facilities, in-
7 cluding—

8 “(i) the OTC monograph drug facilities
9 and contract manufacturing organization
10 facilities that were first registered under
11 section 510(c) or 510(i) in the fiscal year;
12 and

13 “(ii) for each OTC monograph drug fa-
14 cility and contract manufacturing organi-
15 zation facility that was assessed a facility
16 fee under section 744M(a) in the fiscal year,
17 whether the facility paid such fee;

18 “(C) the status of implementation of evi-
19 dence and testing standards for nonprescription
20 drugs intended for topical administration, in-
21 cluding—

22 “(i) the application of evidence or test-
23 ing standards; and

24 “(ii) the number of active ingredient
25 requests for nonprescription drugs intended

1 *for topical administration reviewed using*
 2 *the standards under section 505G(b); and*
 3 “(D) *the progress of the Food and Drug Ad-*
 4 *ministration in allowing nonclinical testing al-*
 5 *ternatives to animal testing for the consideration*
 6 *of sunscreen active ingredients.*

7 “(3) *CONFIDENTIALITY.—Nothing in paragraph*
 8 *(2) shall be construed to authorize the disclosure of in-*
 9 *formation that is prohibited from disclosure under*
 10 *section 301(j) of this Act or section 1905 of title 18,*
 11 *United States Code, or that is subject to withholding*
 12 *under section 552(b)(4) of title 5, United States*
 13 *Code.”;*

14 (2) *in subsection (b), by striking “fiscal year*
 15 *2021 and each subsequent fiscal year” and inserting*
 16 *“each fiscal year”; and*

17 (3) *in subsection (d)—*

18 (A) *by striking “2025” each place it ap-*
 19 *pears and inserting “2030”; and*

20 (B) *by adding at the end the following:*

21 “(4) *MINUTES OF NEGOTIATION MEETINGS.—*

22 “(A) *PUBLIC AVAILABILITY.—The Secretary*
 23 *shall make publicly available, on the public*
 24 *website of the Food and Drug Administration,*
 25 *robust written minutes of all negotiation meet-*

ings conducted under this subsection between the Food and Drug Administration and the regulated industry, not later than 30 days after each such negotiation meeting.

“(B) *CONTENT.*—The robust written minutes described under subparagraph (A) shall contain, in detail, any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.”.

(b) *GAO REPORT.*—

(1) *IN GENERAL.*—Not later than September 30, 2027, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report assessing the supply chain of over-the-counter monograph drugs.

(2) *CONTENTS.*—The report required under paragraph (1) shall include an assessment of—

(A) the overall stability of the supply chain of over-the-counter monograph drugs;

(B) what information is collected by the Food and Drug Administration with respect to

1 *the supply chain of over-the-counter monograph*
 2 *drugs;*

3 *(C) how the Food and Drug Administration*
 4 *uses information collected on the supply chain of*
 5 *over-the-counter monograph drugs to inform reg-*
 6 *ulatory decisions;*

7 *(D) how the Food and Drug Administration*
 8 *coordinates with other Federal agencies to mon-*
 9 *itor and mitigate disruptions to the supply*
 10 *chain of over-the-counter monograph drugs; and*

11 *(E) the unique characteristics of the over-*
 12 *the-counter monograph drug marketplace and*
 13 *what additional authorities or information the*
 14 *Food and Drug Administration may need to en-*
 15 *sure the stability of the supply chain of over-the-*
 16 *counter monograph drugs.*

17 **SEC. 6. TREATMENT OF ACTIVE INGREDIENTS FOR TOPICAL**
 18 **ADMINISTRATION.**

19 *(a) IN GENERAL.—Section 505G of the Federal Food,*
 20 *Drug, and Cosmetic Act (21 U.S.C. 355h) is amended by*
 21 *adding at the end the following:*

22 “(r) *EVIDENCE AND TESTING STANDARDS FOR ACTIVE*
 23 *INGREDIENTS FOR TOPICAL ADMINISTRATION.—*

1 “(1) *EVIDENCE AND TESTING STANDARDS FOR*
2 *ACTIVE INGREDIENTS FOR TOPICAL ADMINISTRA-*
3 *TION.—The Secretary shall—*

4 “(A) *in evaluating the generally recognized*
5 *as safe and effective status of active ingredients*
6 *used in nonprescription drugs intended for top-*
7 *ical administration for purposes of subsection*
8 *(a), utilize standards that allow for the use of*
9 *real world evidence (as defined in section*
10 *505F(b)), as appropriate, as part of a com-*
11 *prehensive evaluation of scientific evidence to*
12 *demonstrate the safety and effectiveness of such*
13 *active ingredients, to supplement evidence from*
14 *traditional clinical trials, provided that such*
15 *standards allow the Secretary to evaluate wheth-*
16 *er the benefits of such active ingredients outweigh*
17 *the risks; and*

18 “(B) *apply subsection (b)(6)(C) to the regu-*
19 *lation of active ingredients used in drugs in-*
20 *tended for topical administration.*

21 “(2) *NON-ANIMAL TESTING METHODS FOR TOP-*
22 *ICAL ACTIVE INGREDIENTS.—*

23 “(A) *IN GENERAL.—The Secretary shall*
24 *consider the types of nonclinical tests described*
25 *in paragraphs (1) through (4) of the first sub-*

1 *section (z) of section 505 (as inserted by section*
 2 *3209(a)(2) of the Health Extenders, Improving*
 3 *Access to Medicare, Medicaid, and CHIP, and*
 4 *Strengthening Public Health Act of 2022 (divi-*
 5 *sion FF of Public Law 117–328)), or any other*
 6 *alternative to animal testing that the Secretary*
 7 *determines appropriate, in the consideration of*
 8 *drugs intended for topical administration under*
 9 *this section.*

10 “(B) *GUIDANCE.*—Not later than 1 year
 11 *after the date of enactment of this subsection, the*
 12 *Secretary shall issue new draft guidance on how*
 13 *sponsors can use nonclinical testing alternatives*
 14 *to animal testing, as appropriate, to meet safety*
 15 *and efficacy standards under this section for*
 16 *drugs intended for topical administration.*

17 “(3) *CLARIFICATION.*—Nothing in this subsection
 18 *shall be construed to alter, supersede, or limit the*
 19 *standards for making determinations of whether a*
 20 *drug is generally recognized as safe and effective*
 21 *under section 201(p) or the standards set forth under*
 22 *section 505 for determining the safety and effective-*
 23 *ness of drugs.”.*

24 (b) *SUNSCREEN FINAL ADMINISTRATIVE ORDER.*—A
 25 *final administrative order on nonprescription sunscreen ac-*

1 *tive ingredients issued under section 3854 of the*
 2 *Coronavirus Aid, Relief, and Economic Security Act (Pub-*
 3 *lic Law 116–136; 21 U.S.C. 360fff–3 note) shall—*

4 *(1) account for historical data regarding the*
 5 *safety of sunscreen active ingredients that have pre-*
 6 *viously been accepted for marketing in the United*
 7 *States;*

8 *(2) account for the role of broad spectrum sun-*
 9 *screens with a Sun Protection Factor of 15 or higher*
 10 *in effective skin cancer prevention; and*

11 *(3) incorporate the evidence and testing stand-*
 12 *ards for sunscreen active ingredients detailed in sec-*
 13 *tion 505G(r) of the Federal Food, Drug, and Cosmetic*
 14 *Act (21 U.S.C. 355h) (as added by subsection (a)).*

15 **SEC. 7. INCREASING THE CLARITY AND PREDICTABILITY OF**
 16 **THE PROCESS FOR DEVELOPING APPLICA-**
 17 **TIONS FOR RX-TO-NONPRESCRIPTION**
 18 **SWITCHES.**

19 *(a) IN GENERAL.—Section 505(b) of the Federal Food,*
 20 *Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended by*
 21 *adding at the end the following:*

22 *“(7) RX-TO-NONPRESCRIPTION SWITCHES.—*

23 *“(A) MEETINGS.—Any person planning to*
 24 *submit an application for an Rx-to-nonprescrip-*
 25 *tion switch may submit to the Secretary a writ-*

1 *ten request for a meeting, for purposes of devel-*
2 *oping a plan for such application that addresses*
3 *the potential risks to public health of such switch*
4 *and the evidence necessary to support such ap-*
5 *plication, including the design of any necessary*
6 *studies, and the format and content of the*
7 *planned application. The Secretary may grant*
8 *such a meeting, as appropriate, consistent with*
9 *established procedures for granting meetings*
10 *with, and providing written responses to, spon-*
11 *sors of applications under this section. Each*
12 *such meeting shall be documented in meeting*
13 *minutes.*

14 *“(B) GUIDANCE.—*

15 *“(i) IN GENERAL.—Not later than 18*
16 *months after the date of enactment of this*
17 *paragraph, the Secretary shall issue guid-*
18 *ance to increase the clarity and predict-*
19 *ability of the process and standards for ap-*
20 *proval of applications for nonprescription*
21 *drugs under this section, including in the*
22 *case of applications for an Rx-to-non-*
23 *prescription switch, especially with respect*
24 *to prescription drugs with well-established*

1 *safety profiles for which an applicant may*
2 *seek approval for nonprescription use.*

3 “(ii) *CONTENTS.—The guidance under*
4 *clause (i) shall—*

5 “(I) *describe how published re-*
6 *ports in medical literature, any pre-*
7 *vious finding of safety or effectiveness*
8 *for the drug under this section, the re-*
9 *sults of significant human experience*
10 *with the drug, unpublished studies and*
11 *other data, and other sources of infor-*
12 *mation may be used to support an ap-*
13 *plication for a nonprescription drug,*
14 *including in the context of an applica-*
15 *tion for an Rx-to-nonprescription*
16 *switch;*

17 “(II) *set forth procedures for*
18 *sponsors to request meetings described*
19 *in subparagraph (A) and document the*
20 *recommendations made in such meet-*
21 *ings;*

22 “(III) *describe evidentiary expec-*
23 *tations to support approval of an ap-*
24 *plication for a nonprescription drug,*
25 *including in the context of an applica-*

1 *tion for an Rx-to-nonprescription*
 2 *switch, including how sponsors can*
 3 *demonstrate that consumers can appro-*
 4 *priately self-select and use the drug*
 5 *and comprehend the nonprescription*
 6 *drug label; and*

7 “(IV) provide recommendations
 8 *for how mechanisms, in addition to the*
 9 *required Drug Facts Label, such as*
 10 *mobile applications and decision aids,*
 11 *can be incorporated into the informa-*
 12 *tion submitted in support of an appli-*
 13 *cation for an Rx-to-nonprescription*
 14 *switch.*

15 “(C) PLAN TO ENGAGE WITH STAKE-
 16 *HOLDERS.—Not later than 1 year after the date*
 17 *of enactment of this paragraph, the Secretary*
 18 *shall develop and make publicly available on the*
 19 *website of the Food and Drug Administration a*
 20 *plan to engage stakeholders on steps and factors*
 21 *for application holders and other stakeholders to*
 22 *consider in identifying approved prescription*
 23 *drugs that may be promising candidates for ap-*
 24 *plications for an Rx-to-nonprescription switch.*

1 “(D) *DEFINITION.*—*The term ‘Rx-to-non-*
 2 *prescription switch’ means the approval of an*
 3 *application, or supplemental application, as ap-*
 4 *plicable, submitted under this section by the*
 5 *holder of an approved application for a prescrip-*
 6 *tion drug seeking approval to market such drug*
 7 *as a nonprescription drug, including for—*

8 “(i) *a full Rx-to-nonprescription*
 9 *switch, under which a drug previously ap-*
 10 *proved for prescription use only is—*

11 “(I) *approved for nonprescription*
 12 *use under the same conditions of use as*
 13 *applied to the drug when approved for*
 14 *prescription use; or*

15 “(II) *approved for nonprescrip-*
 16 *tion use subject to one or more addi-*
 17 *tional conditions for nonprescription*
 18 *use; and*

19 “(ii) *a partial Rx-to-nonprescription*
 20 *switch, under which the drug is approved*
 21 *for nonprescription use only under certain*
 22 *conditions of use described in the approved*
 23 *labeling, while the drug otherwise remains*
 24 *approved for prescription use only.*

1 “(E) *RULE OF CONSTRUCTION.*—*Nothing in*
 2 *this paragraph shall be construed to—*

3 “(i) *supersede or modify the authority*
 4 *of the Secretary under section 505G with re-*
 5 *spect to the regulation of OTC monograph*
 6 *drugs; or*

7 “(ii) *authorize the disclosure by the*
 8 *Secretary of confidential commercial infor-*
 9 *mation or trade secrets.”.*

10 (b) *GAO REPORT.*—

11 (1) *IN GENERAL.*—*Not later than 1 year after*
 12 *the date of enactment of this Act, the Comptroller*
 13 *General of the United States shall submit to the Com-*
 14 *mittee on Health, Education, Labor, and Pensions of*
 15 *the Senate and the Committee on Energy and Com-*
 16 *merce of the House of Representatives a report that*
 17 *evaluates—*

18 (A) *the number of applications for an Rx-*
 19 *to-nonprescription switch approved during the*
 20 *period beginning on October 1, 2022, and ending*
 21 *on the date of the report;*

22 (B) *the number of drugs for which an ap-*
 23 *plication for an Rx-to-nonprescription switch*
 24 *was approved during such period subject to an*
 25 *additional condition for nonprescription use;*

1 (C) among the drugs for which an applica-
2 tion for a full or partial Rx-to-nonprescription
3 switch was approved during such period, the av-
4 erage length of time from receipt by the Food
5 and Drug Administration of the application to
6 the approval of such application;

7 (D) the number of partial Rx-to-non-
8 prescription switch applications approved dur-
9 ing such period, and the number of applications
10 for such a partial switch was not approved;

11 (E) any barriers to timely and predictable
12 review of applications for an Rx-to-nonprescrip-
13 tion switch;

14 (F) engagement by the Food and Drug Ad-
15 ministration with public stakeholders, including
16 public meetings or additional activities, to sup-
17 port review of applications for an Rx-to-non-
18 prescription switch; and

19 (G) opportunities for collaboration between
20 the Center for Drug Evaluation and Research
21 and the Centers for Medicare & Medicaid Serv-
22 ices for the purpose of analyzing health insur-
23 ance claims data for commonly prescribed drugs
24 that appear to be suitable for an Rx-to-non-
25 prescription switch.

1 (2) *DEFINITION.*—*In this subsection, the term*
 2 *“Rx-to-nonprescription switch” has the meaning*
 3 *given such term in paragraph (7) of section 505(b) of*
 4 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 5 *244(b)), as added by subsection (a).*

6 **SEC. 8. SUNSET DATES.**

7 (a) *AUTHORIZATION.*—*Sections 744L and 744M of the*
 8 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
 9 *71; 379j–72) shall cease to be effective October 1, 2030.*

10 (b) *REPORTING REQUIREMENTS.*—*Section 744N of the*
 11 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
 12 *73) shall cease to be effective January 31, 2031.*

13 **SEC. 9. EFFECTIVE DATE.**

14 *The amendments made by this Act shall take effect on*
 15 *October 1, 2025, or the date of the enactment of this Act,*
 16 *whichever is later, except that fees under part 10 of sub-*
 17 *chapter C of chapter VII of the Federal Food, Drug, and*
 18 *Cosmetic Act (21 U.S.C. 379j–71 et seq.) shall be assessed*
 19 *beginning October 1, 2025, regardless of the date of the en-*
 20 *actment of this Act.*

21 **SEC. 10. SAVINGS CLAUSE.**

22 *Notwithstanding the amendments made by this Act,*
 23 *part 10 of subchapter C of chapter VII of the Federal Food,*
 24 *Drug, and Cosmetic Act (21 U.S.C. 379j–71 et seq.), as in*
 25 *effect on the day before the date of enactment of this Act,*

- 1 *shall continue to be in effect with respect to assessing and*
- 2 *collecting any fee required by such part for a fiscal year*
- 3 *prior to fiscal year 2026.*

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S. 2292

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user fee program for over-the-counter monograph drugs, and for other purposes.

SEPTEMBER 8, 2025

Reported with an amendment