

Union Calendar No. 254

119TH CONGRESS
1ST SESSION

H. R. 4273

[Report No. 119–300]

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 HOUSE OF REPRESENTATIVES

JULY 2, 2025

Mr. LATTA (for himself, Ms. DEGETTE, Mr. CRENSHAW, and Mrs. DINGELL) introduced the following bill; which was referred to the Committee on Energy and Commerce

SEPTEMBER 17, 2025

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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

[For text of introduced bill, see copy of bill as introduced on July 2, 2025]

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 Mono-*
 5 *graph Drug User Fee Amendments”.*

6 **SEC. 2. FINDING.**

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

18 **SEC. 3. DEFINITIONS.**

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

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

23 *(2) in clause (vi)—*

24 *(A) by striking “addition” and inserting*
 25 *“the addition”; and*

1 (B) by striking the period and inserting “;
2 or”; and

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

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

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

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

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

23 (a) *TYPES OF FEES.*—Section 744M(a)(1) of the Fed-
24 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j-
25 72(a)(1)) is amended—

1 (1) in subparagraph (A)—

2 (A) by striking “on December 31 of the fis-
3 cal year or at any time during the preceding 12-
4 month period” and inserting “at any time dur-
5 ing the applicable period specified in clause (ii)
6 for a fiscal year”;

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

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

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

12 “(ii) APPLICABLE PERIOD.—For pur-
13 poses of clause (i), the applicable period
14 is—

15 “(I) for fiscal year 2026, the 12-
16 month period ending on December 31,
17 2025;

18 “(II) for fiscal year 2027, the 9-
19 month period ending on September 30,
20 2026; and

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

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

3 “(I) has ceased all activities re-
 4 lated to OTC monograph drugs prior
 5 to—

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

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

10 “(cc) for purposes of fiscal
 11 year 2028 and each subsequent
 12 fiscal year, October 1 of the pre-
 13 ceding fiscal year; and”;

14 (3) by amending subparagraph (D) to read as
 15 follows:

16 “(D) DUE DATE.—

17 “(i) FISCAL YEAR 2026.—For fiscal
 18 year 2026, the facility fees required under
 19 subparagraph (A) shall be due on the later
 20 of—

21 “(I) the first business day of June
 22 of such year; or

23 “(II) the first business day after
 24 the enactment of an appropriations
 25 Act providing for the collection and ob-

1 *ligation of fees under this section for*
2 *such year.*

3 “(ii) *FISCAL YEAR 2027.—For fiscal*
4 *year 2027, the facility fees required under*
5 *subparagraph (A) shall be due—*

6 “(I) *in a first installment rep-*
7 *resenting 50 percent of such fee, on the*
8 *later of—*

9 “(aa) *October 1, 2026; or*

10 “(bb) *the first business day*
11 *after the enactment of an appro-*
12 *priations Act providing for the*
13 *collection and obligation of fees*
14 *under this section for such year;*
15 *and*

16 “(II) *in a second installment rep-*
17 *resenting the remaining 50 percent of*
18 *such fee, on—*

19 “(aa) *February 1, 2027; or*

20 “(bb) *if an appropriations*
21 *Act described in subclause (I)(bb)*
22 *is not in effect on February 1,*
23 *2027, the first business day after*
24 *enactment of such an appropria-*
25 *tions Act.*

1 “(iii) *SUBSEQUENT FISCAL YEARS.*—
 2 *For fiscal year 2028 and each subsequent*
 3 *fiscal year, the facility fees required under*
 4 *subparagraph (A) shall be due on the later*
 5 *of—*

6 “(I) *the first business day on or*
 7 *after October 1 of the fiscal year; or*

8 “(II) *the first business day after*
 9 *the date of enactment of an appropria-*
 10 *tions Act providing for the collection*
 11 *and obligation of fees under this sec-*
 12 *tion for the fiscal year.”.*

13 (b) *FEE REVENUE AMOUNTS.*—Section 744M(b) of the
 14 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–*
 15 *72(b)) is amended to read as follows:*

16 “(b) *FEE REVENUE AMOUNTS.*—

17 “(1) *IN GENERAL.*—*For each of the fiscal years*
 18 *2026 through 2030, fees under subsection (a)(1) shall*
 19 *be established to generate a total facility fee revenue*
 20 *amount equal to the sum of—*

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

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

“(C) the dollar amount equal to the operating reserve adjustment for the fiscal year, if applicable (as determined under subsection (c)(2));

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

“(E) an additional dollar amount equal to—

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

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

and

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

and

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

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

“(A) for fiscal year 2026, the dollar amount of the total revenue amount established for fiscal year 2025 under this subsection as in effect on the day before the date of enactment of the Over-the-Counter Monograph Drug User Fee Amend-

ments, not including any adjustments made for such fiscal year 2025 under subsection (c)(2), as so in effect; and

“(B) for fiscal years 2027 through 2030, the dollar amount of the total revenue amount established under this subsection for the previous fiscal year, not including any adjustments made for such previous fiscal year under subsection (c)(2) or (c)(3).”.

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

(1) in paragraph (1)—

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

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

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

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

“(i) for fiscal year 2026—

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

3 “(II) the inflation adjustment per-
4 centage under subparagraph (C); and

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

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

10 “(II) the inflation adjustment per-
11 centage under subparagraph (C).”; 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 (II) of clause (ii) as clauses (i) and
19 (ii), respectively, and adjusting the margins
20 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 “each*
 7 *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), the
14 Secretary may further increase the fee revenues
15 and fees through a one-time adjustment made for
16 fiscal year 2028, 2029, or 2030, in accordance
17 with this paragraph.

18 “(B) ADJUSTMENT DESCRIBED.—

19 “(i) CONDITIONS FOR ADJUSTMENT.—
20 An adjustment under this paragraph may
21 be made for a fiscal year only if—

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

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

6 “(III) with respect to facilities de-
7 scribed in subclause (II), the average
8 number of such facilities (expressed as
9 a percentage) that appeared on the ar-
10 rears lists pursuant to subsection
11 (e)(1)(A)(i) over the period of the pre-
12 ceding 3 fiscal years is less than 30
13 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 percentage
23 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 drug*
 6 *facilities subject to a facility fee under*
 7 *subsection (a)(1) over the preceding 3*
 8 *fiscal years exceeds 1,625; divided by*
 9 “(II) *1,625.*

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

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

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

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

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

23 “(d) *CREDITING AND AVAILABILITY OF FEES.—Section*
 24 *744M(f) of the Federal Food, Drug, and Cosmetic Act (21*
 25 *U.S.C. 379j–72(f)) is amended—*

1 (1) in paragraph (2)(D)—

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

4 (B) by striking “(after fiscal year 2021”;
5 and

6 (2) in paragraph (3), by striking “2021 through
7 2025” and inserting “2026 through 2030”.

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

9 Section 744N of the Federal Food, Drug, and Cosmetic
10 Act (21 U.S.C. 379j–73) is amended—

11 (1) in subsection (a)—

12 (A) by striking “Beginning with fiscal year
13 2021, and not later than 120 calendar days after
14 the end of each fiscal year thereafter” and insert-
15 ing “Not later than 120 calendar days after the
16 end of each fiscal year”; and

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

21 (2) in subsection (b), by striking “fiscal year
22 2021 and each subsequent fiscal year” and inserting
23 “each fiscal year”; and

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

1 **SEC. 6. REGULATION OF CERTAIN NONPRESCRIPTION**
 2 **DRUGS THAT ARE MARKETING WITHOUT AN**
 3 **APPROVED DRUG APPLICATION.**

4 (a) *DEVELOPMENT ADVICE TO SPONSORS OR REQUESTORS.*—Section 505G(h) of the Federal Food, Drug, and
 5 *Cosmetic Act (21 U.S.C. 355h(h))* is amended by striking
 6 “sponsors or requestors” and inserting “sponsors, requestors, or organizations nominated by sponsors or requestors
 7 to represent their interests in a proceeding”.

10 (b) *TECHNICAL CORRECTION.*—Section
 11 505G(b)(2)(A)(iv)(III) of the Federal Food, Drug, and Cos-
 12 *metic Act (21 U.S.C. 355h(b)(2)(A)(iv)(III))* is amended by
 13 striking “requestors” and inserting “sponsors or requestors”.

15 **SEC. 7. SUNSET DATES.**

16 (a) *AUTHORIZATION.*—Sections 744L and 744M of the
 17 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
 18 71; 379j–72) shall cease to be effective October 1, 2030.

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

22 **SEC. 8. EFFECTIVE DATE.**

23 The amendments made by this Act shall take effect on
 24 October 1, 2025, or the date of the enactment of this Act,
 25 whichever is later, except that fees under part 10 of sub-
 26 chapter C of chapter VII of the Federal Food, Drug, and

1 *Cosmetic Act (21 U.S.C. 379j–71 et seq.) shall be assessed*
2 *beginning October 1, 2025, regardless of the date of the en-*
3 *actment of this Act.*

4 **SEC. 9. SAVINGS CLAUSE.**

5 *Notwithstanding the amendments made by this Act,*
6 *part 10 of subchapter C of chapter VII of the Federal Food,*
7 *Drug, and Cosmetic Act (21 U.S.C. 379j–71 et seq.), as in*
8 *effect on the day before the date of enactment of this Act,*
9 *shall continue to be in effect with respect to assessing and*
10 *collecting any fee required by such part for a fiscal year*
11 *prior to fiscal year 2026.*

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