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(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. 4273

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

M____ introduced the following bill; which was referred to the
Committee on _____

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”.

6 **SEC. 2. FINDING.**

7 Congress finds that the fees authorized by the
8 amendments made in this Act will be dedicated to OTC

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

10 **SEC. 3. DEFINITIONS.**

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

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

15 (2) in clause (vi)—

16 (A) by striking “addition” and inserting
17 “the addition”; and

18 (B) by striking the period and inserting “;
19 or”; and

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

21 “(vii) the addition or modification of a
22 testing procedure applicable to one or more
23 OTC monograph drugs, provided that such ad-
24 ditional or modified testing procedure reflects a

1 voluntary consensus standard with respect to
2 pharmaceutical quality that is—

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

6 “(II) recognized by the Secretary
7 through a process described in guidance
8 for industry, initially published in July
9 2023, or any successor guidance, publicly
10 available on the agency website, which ad-
11 dresses voluntary consensus standards for
12 pharmaceutical quality.”.

13 **SEC. 4. AUTHORITY TO ASSESS AND USE OTC MONOGRAPH**
14 **FEEES.**

15 (a) TYPES OF FEEES.—Section 744M(a)(1) of the
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–
17 72(a)(1)) is amended—

18 (1) in subparagraph (A)—

19 (A) by striking “on December 31 of the
20 fiscal year or at any time during the preceding
21 12-month period” and inserting “at any time
22 during the applicable period specified in clause
23 (ii) for a fiscal year”;

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

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

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

4 “(ii) APPLICABLE PERIOD.—For pur-
5 poses of clause (i), the applicable period
6 is—

7 “(I) for fiscal year 2026, the 12-
8 month period ending on December 31,
9 2025;

10 “(II) for fiscal year 2027, the 9-
11 month period ending on September
12 30, 2026; and

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

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

19 “(I) has ceased all activities re-
20 lated to OTC monograph drugs prior
21 to—

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

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

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

5 (3) by amending subparagraph (D) to read as
6 follows:

7 “(D) DUE DATE.—

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

12 “(I) the first business day of
13 June of such year; or

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

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

22 “(I) in a first installment rep-
23 resenting 50 percent of such fee, on
24 the later of—

25 “(aa) October 1, 2026; or

1 “(bb) the first business day
2 after the enactment of an appro-
3 priations Act providing for the
4 collection and obligation of fees
5 under this section for such year;
6 and

7 “(II) in a second installment rep-
8 resenting the remaining 50 percent of
9 such fee, on—

10 “(aa) February 1, 2027; or

11 “(bb) if an appropriations
12 Act described in subclause
13 (I)(bb) is not in effect on Feb-
14 ruary 1, 2027, the first business
15 day after enactment of such an
16 appropriations Act.

17 “(iii) SUBSEQUENT FISCAL YEARS.—
18 For fiscal year 2028 and each subsequent
19 fiscal year, the facility fees required under
20 subparagraph (A) shall be due on the later
21 of—

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

24 “(II) the first business day after
25 the date of enactment of an appro-

1 priations Act providing for the collec-
2 tion and obligation of fees under this
3 section for the fiscal year.”.

4 (b) FEE REVENUE AMOUNTS.—Section 744M(b) of
5 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 379j–72(b)) is amended to read as follows:

7 “(b) FEE REVENUE AMOUNTS.—

8 “(1) IN GENERAL.—For each of the fiscal years
9 2026 through 2030, fees under subsection (a)(1)
10 shall be established to generate a total facility fee
11 revenue amount equal to the sum of—

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

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

17 “(C) the dollar amount equal to the oper-
18 ating reserve adjustment for the fiscal year, if
19 applicable (as determined under subsection
20 (c)(2));

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

23 “(E) an additional dollar amount equal
24 to—

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

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

2 and

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

4 and

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

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

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

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

1 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section
2 744M(c) of the Federal Food, Drug, and Cosmetic Act
3 (21 U.S.C. 379j–72) is amended—

4 (1) in paragraph (1)—

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

7 (i) by striking “subsection (b)(2)(B)”

8 and inserting “subsection (b)(1)(B)”; and

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

12 (B) in subparagraph (B), by striking “fis-
13 cal year 2022” and all that follows through the
14 period at the end and inserting the following:

15 “a fiscal year shall be equal to the product of—

16 “(i) for fiscal year 2026—

17 “(I) the fee for fiscal year 2025

18 under subsection (a)(2); and

19 “(II) the inflation adjustment

20 percentage under subparagraph (C);

21 and

22 “(ii) for each of fiscal years 2027

23 through 2030—

1 “(I) the applicable fee under sub-
2 section (a)(2) for the preceding fiscal
3 year; and

4 “(II) the inflation adjustment
5 percentage under subparagraph (C).”;
6 and

7 (C) in subparagraph (C)—

8 (i) in the matter preceding clause (i),
9 by inserting “the sum of” after “is equal
10 to”;

11 (ii) by striking clause (i);

12 (iii) by redesignating subclauses (I)
13 and (II) as clauses (i) and (ii), respec-
14 tively, and adjusting the margins accord-
15 ingly; and

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

18 (v) in clause (ii), as so redesignated,
19 by striking “Washington-Baltimore, DC-
20 MD-VA-WV” and inserting “Washington-
21 Arlington-Alexandria-DC-VA-MD-WV”;

22 (2) in paragraph (2)—

23 (A) in subparagraph (A)—

1 (i) by striking “fiscal year 2021 and
2 subsequent fiscal years” and inserting
3 “each fiscal year”;

4 (ii) by striking “subsections (b)(1)(B)
5 and (b)(2)(C)” and inserting “subsection
6 (b)(1)(C)”; and

7 (iii) by striking “the number of weeks
8 specified in subparagraph (B)” and insert-
9 ing “10 weeks”;

10 (B) by striking subparagraph (B);

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

14 (D) in subparagraph (C), as so redesign-
15 ated, by striking “paragraph (4) establishing”
16 and inserting “paragraph (5) publishing”;
17 (3) in paragraph (3)—

18 (A) in the matter preceding subparagraph
19 (A), by striking “subsection (b)(2)(D)” and in-
20 serting “subsection (b)(1)(D)”; and

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

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

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

25 “(C) \$55,000 for fiscal year 2028;

1 “(D) \$0 for fiscal year 2029; and

2 “(E) \$30,000 for fiscal year 2030.”; and

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

5 “(4) ONE-TIME FACILITY FEE WORKLOAD AD-
6 JUSTMENT.—

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

13 “(B) ADJUSTMENT DESCRIBED.—

14 “(i) CONDITIONS FOR ADJUST-
15 MENT.—An adjustment under this para-
16 graph may be made for a fiscal year only
17 if—

18 “(I) an adjustment under this
19 paragraph had not been made for any
20 prior fiscal year;

21 “(II) the average number of OTC
22 monograph drug facilities subject to a
23 facility fee under subsection (a)(1)
24 over the period of the preceding 3 fis-
25 cal years exceeds 1,625; and

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

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

12 “(I) the total facility revenue
13 amount determined under subsection
14 (b) for the fiscal year, exclusive of the
15 adjustment under this paragraph for
16 such fiscal year; and

17 “(II) the excess facility percent-
18 age described in clause (iii).

19 “(iii) EXCESS FACILITY PERCENT-
20 AGE.—The excess facility percentage de-
21 scribed in this clause is—

22 “(I) the amount by which the av-
23 erage number of OTC monograph
24 drug facilities subject to a facility fee
25 under subsection (a)(1) over the pre-

1 ceding 3 fiscal years exceeds 1,625;
2 divided by
3 “(II) 1,625.

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

7 “(A) establish for such fiscal year, based
8 on the revenue amounts under subsection (b)
9 and the adjustments provided under this sub-
10 section—

11 “(i) OTC monograph drug facility fees
12 under subsection (a)(1); and

13 “(ii) OTC monograph order request
14 fees under subsection (a)(2); and

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

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

21 (1) in paragraph (2)(D)—

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

24 (B) by striking “(after fiscal year 2021)”;
25 and

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

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

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

6 (1) in subsection (a)—

7 (A) by striking “Beginning with fiscal year
8 2021, and not later than 120 calendar days
9 after the end of each fiscal year thereafter” and
10 inserting “Not later than 120 calendar days
11 after the end of each fiscal year”; and

12 (B) by striking “section 3861(b) of the
13 CARES Act” and inserting “section 2 of the
14 Over-the-Counter Monograph Drug User Fee
15 Amendments”;

16 (2) in subsection (b), by striking “fiscal year
17 2021 and each subsequent fiscal year” and inserting
18 “each fiscal year”; and

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

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

22 (a) AUTHORIZATION.—Sections 744L and 744M of
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 379j–71; 379j–72) shall cease to be effective October 1,
25 2030.

1 (b) REPORTING REQUIREMENTS.—Section 744N of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 379j–73) shall cease to be effective January 31, 2031.

4 **SEC. 7. EFFECTIVE DATE.**

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

12 **SEC. 8. SAVINGS CLAUSE.**

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