HR 4273

Over-the-Counter Monograph Drug User Fee Amendments

Congress: 119 (2025–2027, Current)
Chamber: House
Policy Area: Health
Introduced: Jul 2, 2025
Current Status: Placed on the Union Calendar, Calendar No. 254.
Latest Action: Placed on the Union Calendar, Calendar No. 254. (Sep 17, 2025)
Official Text: https://www.congress.gov/bill/119th-congress/house-bill/4273

Sponsor

Name: Rep. Latta, Robert E. [R-OH-5]
Party: Republican • **State:** OH • **Chamber:** House

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Crenshaw, Dan [R-TX-2]	R · TX		Jul 2, 2025
Rep. DeGette, Diana [D-CO-1]	D · CO		Jul 2, 2025
Rep. Dingell, Debbie [D-MI-6]	D · MI		Jul 2, 2025

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Reported By	Sep 17, 2025

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
119 HR 5371	Related bill	**Nov 12, 2025:** Became Public Law No: 119-37.
119 S 2292	Related bill	**Sep 8, 2025:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 152.

Summary (as of Jul 2, 2025)

Over-the-Counter Monograph Drug User Fee Amendments

This bill reauthorizes the Over-the-Counter (OTC) Monograph Drug User Fee Program (OMUFA) through FY2030 and revises certain aspects of the program, including total fees to be collected and fee due dates.

Under current law, many OTC drugs are marketed through compliance with an OTC monograph issued by the Food and Drug Administration (FDA), rather than through an approved new drug application. Monographs establish the conditions under which OTC drugs are generally recognized as safe and effective, and include ingredients, dosages, and other requirements. OMUFA permits the FDA to collect fees from OTC drug facilities and entities requesting changes to a monograph.

The bill makes certain changes to OMUFA, including by

- revising the total facility fee revenue amount to be collected for FY2026-FY2030,
- revising due dates for facility fees,
- permitting the FDA to implement a one-time adjustment to facility fees if certain conditions exist, and
- requiring the FDA to publish facility and order request fee amounts at least 60 days before the start of each fiscal year.

Finally, the bill adds as a *Tier 2 OTC monograph order request* a request for the addition or modification of a testing procedure applicable to a monograph drug, provided the testing procedure reflects a voluntary consensus standard with respect to pharmaceutical quality. (Requestors seeking certain kinds of changes to a monograph are awarded a period of market exclusivity if the FDA makes the requested changes; tier 2 requests are not eligible for market exclusivity.)

Actions Timeline

- **Sep 17, 2025:** Reported (Amended) by the Committee on Energy and Commerce. H. Rept. 119-300.
- **Sep 17, 2025:** Placed on the Union Calendar, Calendar No. 254.
- **Jul 23, 2025:** Committee Consideration and Mark-up Session Held
- **Jul 23, 2025:** Ordered to be Reported (Amended) by the Yeas and Nays: 51 - 0.
- **Jul 2, 2025:** Introduced in House
- **Jul 2, 2025:** Referred to the House Committee on Energy and Commerce.

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