

119TH CONGRESS
2D SESSION

H. R. 9774

To amend the Federal Food, Drug, and Cosmetic Act to provide for expedited approval of priority nonprescription drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 20, 2026

Mr. LATTA (for himself and Mr. LANDSMAN) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for expedited approval of priority nonprescription 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. PRIORITY NONPRESCRIPTION DRUGS.**

4 (a) IN GENERAL.—The Federal Food, Drug, and
5 Cosmetic Act is amended by inserting after section 506L
6 (21 U.S.C. 356l) the following:

7 **“SEC. 506M. PRIORITY NONPRESCRIPTION DRUGS.**

8 “(a) IN GENERAL.—

9 “(1) DESIGNATION.—The Secretary may, at the
10 request of the sponsor of a nonprescription drug,

1 designate as a priority nonprescription drug under
2 this section a drug intended for nonprescription use
3 that is subject to an application submitted (or to be
4 submitted) under section 505(b), if the Secretary de-
5 termines that the drug meets the criteria specified in
6 subsection (d).

7 “(2) NONPRESCRIPTION DEFINED.—In this sec-
8 tion, the term ‘nonprescription’ means, with respect
9 to a drug, that such drug is not subject to section
10 503(b)(1).

11 “(b) REQUEST FOR DESIGNATION.—The sponsor of
12 a drug subject to a pending application under section
13 505(b) for nonprescription use may request that the Sec-
14 retary designate the drug as a priority nonprescription
15 drug.

16 “(c) DESIGNATION.—Not later than 60 calendar days
17 after the receipt of a request under subsection (b), the
18 Secretary shall determine whether a drug meets the cri-
19 teria for designation as a priority nonprescription drug
20 under this section, and if so, make such designation.

21 “(d) CRITERIA.—

22 “(1) ELIGIBILITY.—Except as provided in para-
23 graph (2), a drug described in subsection (a) is eligi-
24 ble for designation as a priority nonprescription
25 drug if—

1 “(A) the drug is intended for a novel non-
2 prescription indication that could provide a
3 meaningful public health benefit;

4 “(B) the drug is a new molecular entity; or

5 “(C) the drug contains an active ingredient
6 that has never been available in a nonprescrip-
7 tion drug.

8 “(2) EXCLUSION.—A drug is not eligible for
9 designation as a priority nonprescription drug if the
10 drug is subject to a risk evaluation and mitigation
11 strategy under section 505–1 or if the drug is a con-
12 trolled substance (as defined in section 102 of the
13 Controlled Substances Act).

14 “(e) ACTIONS.—If the Secretary designates a drug
15 as a priority nonprescription drug, the Secretary shall take
16 such actions as are appropriate to facilitate the develop-
17 ment of, and expedite the review of, an application or sup-
18 plement to an application for such drug, which may in-
19 clude—

20 “(1) holding meetings with the sponsor and the
21 review team throughout the development of the
22 drug;

23 “(2) providing timely advice to, and interactive
24 communication with, the sponsor regarding the de-
25 velopment of the drug to ensure that the develop-

1 ment program to gather the nonclinical and clinical
2 data necessary to demonstrate the inapplicability of
3 the criteria described in section 503(b)(1) is as effi-
4 cient as practicable;

5 “(3) involving senior managers and experienced
6 review staff, as appropriate, in a collaborative, cross-
7 disciplinary review;

8 “(4) assigning a cross-disciplinary project lead
9 for the Food and Drug Administration team to fa-
10 cilitate an efficient review of the development pro-
11 gram and to serve as a scientific liaison between the
12 review team and the sponsor; and

13 “(5) taking steps to ensure that the design of
14 any necessary nonclinical or clinical trials is as effi-
15 cient as practicable, when scientifically appropriate,
16 including reliance on real world evidence.

17 “(f) LIST OF CONDITIONS.—

18 “(1) ESTABLISHMENT.—Not later than 18
19 months after the date of enactment of this section,
20 the Secretary shall publish in the Federal Register
21 a list of conditions for which a nonprescription drug,
22 if developed for the condition, could provide mean-
23 ingful public health benefit.

1 “(2) PUBLIC COMMENT.—The Secretary shall
2 provide a period of not less than 30 days for public
3 comment on—

4 “(A) the list under paragraph (1); and

5 “(B) any updates to such list.”.

6 (b) RULE OF CONSTRUCTION.—The amendment
7 made by subsection (a) shall not be construed to alter the
8 evidentiary standards or the information required for ap-
9 proval of a nonprescription drug under section 505 of the
10 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

11 (c) REPORT TO CONGRESS.—Not later than 4 years
12 after the date of enactment of this Act, the Secretary of
13 Health and Human Services shall submit to Congress a
14 report containing—

15 (1) the number of nonprescription drugs for
16 which a sponsor requested that the Secretary des-
17 ignate such a drug as a priority nonprescription
18 drug under section 506M of the Federal Food,
19 Drug, and Cosmetic Act, as added by subsection (a);

20 (2) the number of nonprescription drugs for
21 which the Secretary approved such request;

22 (3) the number of priority nonprescription
23 drugs (as designated under such section) for which
24 the Secretary approved an application under section

1 505 of the Federal Food, Drug, and Cosmetic Act
2 (21 U.S.C. 355);

3 (4) an overview of the resources used to imple-
4 ment such section; and

5 (5) any recommendation on further improve-
6 ment on increasing over-the-counter drug approvals
7 using a framework similar to the designation frame-
8 work established in such section.

9 (d) SUNSET DATE.—The authority provided to the
10 Secretary of Health and Human Services under section
11 506M of the Federal Food, Drug, and Cosmetic Act, as
12 added by subsection (a), shall cease to be effective Sep-
13 tember 30, 2032.

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