

119TH CONGRESS
1ST SESSION

H. R. 6868

To amend the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services to apply the least burdensome appropriate means for supporting certain administrative order requests with respect to over-the-counter monograph drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 18, 2025

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 direct the Secretary of Health and Human Services to apply the least burdensome appropriate means for supporting certain administrative order requests with respect to 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 “Advancing Consumer
5 Choice, Equity, Safety, and Self-Care Through OTC Inno-

1 vation Act” or the “ACCESS Through OTC Innovation
2 Act”.

3 **SEC. 2. LEAST BURDENSOME MEANS FOR SUPPORTING**
4 **CERTAIN ADMINISTRATIVE ORDER RE-**
5 **QUESTS WITH RESPECT TO OVER-THE-**
6 **COUNTER MONOGRAPH DRUGS.**

7 Section 505G of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 355h) is amended—

9 (1) by redesignating subsection (q) as sub-
10 section (r); and

11 (2) by inserting after subsection (p) the fol-
12 lowing:

13 “(q) LEAST BURDENSOME MEANS FOR SUPPORTING
14 REQUESTS FOR CERTAIN ADMINISTRATIVE ORDERS.—

15 “(1) IN GENERAL.—For purposes of deter-
16 mining whether a drug is generally recognized as
17 safe and effective under section 201(p)(1) when
18 evaluating a request submitted under subsection
19 (b)(5), the Secretary shall apply the least burden-
20 some appropriate means for supporting such a re-
21 quest and satisfying the requirements of this section.

22 “(2) MEETING REQUESTS.—

23 “(A) IN GENERAL.—In the case of an
24 order requested under subsection (b)(5), and if
25 published reports are insufficient to support the

1 requested findings, the Secretary shall meet
2 with the requestor, if the requestor makes a
3 reasonable written request for the meeting, for
4 the purpose of providing recommendations on
5 the types of evidence necessary, including, if ap-
6 propriate, the potential design and size of any
7 studies to support a demonstration that the
8 drug is generally recognized as safe and effec-
9 tive.

10 “(B) PREPARATION AND AVAILABILITY OF
11 MEETING MINUTES.—The Secretary shall pre-
12 pare, and make available to the requestor, the
13 minutes of any such meeting.

14 “(C) ADMINISTRATIVE RECORD.—In the
15 case of any such meeting, the Secretary shall
16 reduce to writing and make a part of the ad-
17 ministrative record—

18 “(i) any recommendations regarding
19 the parameters of studies under this para-
20 graph that the Secretary provides to the
21 requestor; and

22 “(ii) a summary of the meeting dis-
23 cussion.

1 “(3) RULE OF CONSTRUCTION.—Nothing in
2 this subsection shall be construed to alter, super-
3 sede, or limit the criteria—

4 “(A) for determining under subsection
5 (b)(5)(A) whether a request is sufficiently com-
6 plete and formatted to permit a substantive re-
7 view; or

8 “(B) for determining whether a drug is
9 generally recognized as safe and effective under
10 section 201(p)(1).”.

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