

119<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 2491

To amend the Federal Food, Drug, and Cosmetic Act to improve the regulatory review process to determine the safety and effectiveness of non-prescription drugs intended for topical administration, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

JULY 29, 2025

Ms. HASSAN (for herself and Mr. MARSHALL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to improve the regulatory review process to determine the safety and effectiveness of nonprescription drugs intended for topical administration, 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 “Supporting Accessible,  
5 Flexible, and Effective Sunscreen Standards” or the  
6 “SAFE Sunscreen Standards Act”.

1 **SEC. 2. TREATMENT OF ACTIVE INGREDIENTS FOR TOP-**  
2 **ICAL ADMINISTRATION.**

3 Section 505G of the Federal Food, Drug, and Cos-  
4 metic Act (21 U.S.C. 355h) is amended by adding at the  
5 end the following:

6 “(r) EVIDENCE AND TESTING STANDARDS FOR AC-  
7 TIVE INGREDIENTS FOR TOPICAL ADMINISTRATION.—

8 “(1) EVIDENCE AND TESTING STANDARDS FOR  
9 ACTIVE INGREDIENTS FOR TOPICAL ADMINISTRA-  
10 TION.—The Secretary shall—

11 “(A) in evaluating the generally recognized  
12 as safe and effective status of active ingredients  
13 used in nonprescription drugs intended for top-  
14 ical administration for purposes of subsection  
15 (a), utilize standards that allow for the use of  
16 real world evidence (as defined in section  
17 505F(b)), as appropriate, as part of a com-  
18 prehensive evaluation of scientific evidence to  
19 demonstrate the safety and effectiveness of such  
20 active ingredients, to supplement evidence from  
21 traditional clinical trials, provided that such  
22 standards allow the Secretary to evaluate  
23 whether the benefits of such active ingredients  
24 outweigh the risks; and

1           “(B) apply subsection (b)(6)(C) to the reg-  
2           ulation of active ingredients used in drugs in-  
3           tended for topical administration.

4           “(2) NON-ANIMAL TESTING METHODS FOR TOP-  
5           ICAL ACTIVE INGREDIENTS.—

6           “(A) IN GENERAL.—The Secretary shall  
7           consider the types of nonclinical tests described  
8           in paragraphs (1) through (4) of the first sub-  
9           section (z) of section 505 (as inserted by sec-  
10          tion 3209(a)(2) of the Health Extenders, Im-  
11          proving Access to Medicare, Medicaid, and  
12          CHIP, and Strengthening Public Health Act of  
13          2022 (division FF of Public Law 117–328)), or  
14          any other alternative to animal testing that the  
15          Secretary determines appropriate, in the consid-  
16          eration of drugs intended for topical adminis-  
17          tration under this section.

18          “(B) GUIDANCE.—Not later than 1 year  
19          after the date of enactment of this subsection,  
20          the Secretary shall issue new draft guidance on  
21          how sponsors can use nonclinical testing alter-  
22          natives to animal testing, as appropriate, to  
23          meet safety and efficacy standards under this  
24          section for drugs intended for topical adminis-  
25          tration.

1           “(3) CLARIFICATION.—Nothing in this sub-  
2           section shall be construed to alter, supersede, or  
3           limit the standards for making determinations of  
4           whether a drug is generally recognized as safe and  
5           effective under section 201(p) or the standards set  
6           forth under section 505 for determining the safety  
7           and effectiveness of drugs.”.

8   **SEC. 3. SUNSCREEN FINAL ADMINISTRATIVE ORDER.**

9           A final administrative order on nonprescription sun-  
10          screen active ingredients issued under section 3854 of the  
11          Coronavirus Aid, Relief, and Economic Security Act (Pub-  
12          lic Law 116–136; 21 U.S.C. 360fff–3 note) shall—

13                 (1) account for historical data regarding the  
14                 safety of sunscreen active ingredients that have pre-  
15                 viously been accepted for marketing in the United  
16                 States;

17                 (2) account for the role of broad spectrum sun-  
18                 screens with a Sun Protection Factor of 15 or high-  
19                 er in effective skin cancer prevention; and

20                 (3) incorporate the evidence and testing stand-  
21                 ards for sunscreen active ingredients detailed in sec-  
22                 tion 505G(r) of the Federal Food, Drug, and Cos-  
23                 metic Act (21 U.S.C. 355h) (as added by section 2).

1 **SEC. 4. REPORTING AND TRANSPARENCY.**

2 (a) IN GENERAL.—The Secretary of Health and  
3 Human Services (in this section referred to as the “Sec-  
4 retary”) shall, not later than 18 months after the date  
5 of enactment of this Act and annually for 5 years there-  
6 after, submit to the Committee on Energy and Commerce  
7 of the House of Representatives and the Committee on  
8 Health, Education, Labor, and Pensions of the Senate a  
9 report describing, in compliance with section 505G(d) of  
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
11 355h(d))—

12 (1) the status of implementation of evidence  
13 and testing standards for nonprescription drugs in-  
14 tended for topical administration, including—

15 (A) the application of evidence or testing  
16 standards made under section 505G(r) of the  
17 Federal Food, Drug, and Cosmetic Act (21  
18 U.S.C. 355h) (as added by section 2); and

19 (B) the number of sunscreen active ingre-  
20 dient requests reviewed using the standards  
21 under such section 505G(b); and

22 (2) the progress of the Food and Drug Admin-  
23 istration in allowing nonclinical testing alternatives  
24 to animal testing for the consideration of sunscreen  
25 active ingredients.

1       (b) PUBLICATION.—Not later than 7 days after the  
2 date on which the Secretary submits a report under sub-  
3 section (a), the Secretary shall publish such report on the  
4 website of the Food and Drug Administration.

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