AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

119TH CONGRESS
1ST 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 nonprescription drugs intended for topical administration, and for other purposes.

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

---

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Supporting Accessible, Flexible, and Effective Sunscreen Standards'' or the ''SAFE Sunscreen Standards Act''.

SEC. 2. TREATMENT OF ACTIVE INGREDIENTS FOR TOPICAL ADMINISTRATION.

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

''(r) EVIDENCE AND TESTING STANDARDS FOR ACTIVE INGREDIENTS FOR TOPICAL ADMINISTRATION.—

''(1) EVIDENCE AND TESTING STANDARDS FOR ACTIVE INGREDIENTS FOR TOPICAL ADMINISTRATION.—The Secretary shall—

''(A) in evaluating the generally recognized as safe and effective status of active ingredients used in nonprescription drugs intended for topical administration for purposes of subsection (a), utilize standards that allow for the use of real world evidence (as defined in section 505F(b)), as appropriate, as part of a comprehensive evaluation of scientific evidence to demonstrate the safety and effectiveness of such active ingredients, to supplement evidence from traditional clinical trials, provided that such standards allow the Secretary to evaluate whether the benefits of such active ingredients outweigh the risks; and

''(B) apply subsection (b)(6)(C) to the regulation of active ingredients used in drugs intended for topical administration.

''(2) NON-ANIMAL TESTING METHODS FOR TOPICAL ACTIVE INGREDIENTS.—

''(A) IN GENERAL.—The Secretary shall consider the types of nonclinical tests described in paragraphs (1) through (4) of the first subsection (z) of section 505 (as inserted by section 3209(a)(2) of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022 (division FF of Public Law 117–328)), or any other alternative to animal testing that the Secretary determines appropriate, in the consideration of drugs intended for topical administration under this section.

''(B) GUIDANCE.—Not later than 1 year after the date of enactment of this subsection, the Secretary shall issue new draft guidance on how sponsors can use nonclinical testing alternatives to animal testing, as appropriate, to meet safety and efficacy standards under this section for drugs intended for topical administration.

''(3) CLARIFICATION.—Nothing in this subsection shall be construed to alter, supersede, or limit the standards for making determinations of whether a drug is generally recognized as safe and effective under section 201(p) or the standards set forth under section 505 for determining the safety and effectiveness of drugs.''.

SEC. 3. SUNSCREEN FINAL ADMINISTRATIVE ORDER.

A final administrative order on nonprescription sunscreen active ingredients issued under section 3854 of the Coronavirus Aid, Relief, and Economic Security Act (Public Law 116–136; 21 U.S.C. 360fff–3 note) shall—

(1) account for historical data regarding the safety of sunscreen active ingredients that have previously been accepted for marketing in the United States;

(2) account for the role of broad spectrum sunscreens with a Sun Protection Factor of 15 or higher in effective skin cancer prevention; and

(3) incorporate the evidence and testing standards for sunscreen active ingredients detailed in section 505G(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355h) (as added by section 2).

SEC. 4. REPORTING AND TRANSPARENCY.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall, not later than 18 months after the date of enactment of this Act and annually for 5 years thereafter, submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report describing, in compliance with section 505G(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355h(d))—

(1) the status of implementation of evidence and testing standards for nonprescription drugs intended for topical administration, including—

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

(B) the number of sunscreen active ingredient requests reviewed using the standards under such section 505G(b); and

(2) the progress of the Food and Drug Administration in allowing nonclinical testing alternatives to animal testing for the consideration of sunscreen active ingredients.

(b) PUBLICATION.—Not later than 7 days after the date on which the Secretary submits a report under subsection (a), the Secretary shall publish such report on the website of the Food and Drug Administration.

○