

119TH CONGRESS
1ST SESSION

H. R. 3686

To amend the Federal Food, Drug, and Cosmetic Act to improve the regulatory review process to determine the safety and effectiveness of non-prescription sunscreen active ingredients, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 3, 2025

Mr. JOYCE of Pennsylvania (for himself, Mrs. DINGELL, Mr. JOYCE of Ohio, and Ms. ROSS) 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 improve the regulatory review process to determine the safety and effectiveness of nonprescription sunscreen active ingredients, 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”.

7 **SEC. 2. FINDINGS.**

8 Congress finds the following:

1 (1) Skin cancer is the most common cancer in
2 the United States.

3 (2) More people are diagnosed with skin cancer
4 each year in the United States than all other cancers
5 combined.

6 (3) The United States Surgeon General issued
7 a Call to Action to Prevent Skin Cancer in 2014
8 based on finding that nearly 5,000,000 Americans
9 are treated for skin cancer each year at a cost that
10 exceeds \$8,100,000,000.

11 (4) It is estimated that the number of new
12 melanoma cases diagnosed in 2024 will increase by
13 7.3 percent, with an estimated 200,340 cases of
14 melanoma diagnosed.

15 (5) Skin cancer is a deadly disease, and it is ex-
16 pected that there will be 8,290 deaths from mela-
17 noma in 2024.

18 (6) Skin cancer affects individuals of all ages,
19 and melanoma is one of the most common cancers
20 in young adults.

21 (7) In the United States, more than 9,500 peo-
22 ple are diagnosed with skin cancer every day and
23 more than 2 people die of the disease every hour.

1 (8) According to the World Health Organiza-
2 tion (“WHO”), 4 out of 5 cases of skin cancer can
3 be prevented by adopting sun-safe practices.

4 (9) According to the Environmental Protection
5 Agency (“EPA”), the Ultraviolet (UV) Index in the
6 United States continues to rise, increasing the risk
7 of melanoma and other skin cancers for Americans.

8 (10) The EPA recommends Americans “Use a
9 broad spectrum sunscreen with a Sun Protection
10 Factor (“SPF”) of at least 30” to protect against the
11 risks of a rising UV Index.

12 (11) Congress unanimously passed the Sun-
13 screen Innovation Act in 2014 to streamline the ap-
14 proval process for sunscreen active ingredients to
15 improve access to new sunscreens, but no new sun-
16 screen active ingredients have been approved
17 through the Food and Drug Administration’s over-
18 the-counter approval process since 1999.

19 **SEC. 3. REGULATIONS ESTABLISHING REQUIREMENTS FOR**
20 **SUNSCREEN ACTIVE INGREDIENTS.**

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

24 “(r) REGULATIONS ESTABLISHING REQUIREMENTS
25 FOR SUNSCREEN ACTIVE INGREDIENTS.—

1 “(1) EVIDENCE AND TESTING STANDARDS FOR
2 SUNSCREEN ACTIVE INGREDIENTS.—The Secretary
3 shall establish, through guidance or regulation,
4 standards for evaluating the safety and efficacy of
5 sunscreen active ingredients, provided that such
6 standards—

7 “(A) ensure the safety of consumers based
8 on a comprehensive evaluation of scientific evi-
9 dence;

10 “(B) allow for the use of real-world evi-
11 dence (as defined in section 505F(b)), observa-
12 tional studies, and other scientifically valid ap-
13 proaches in place of, or to supplement, tradi-
14 tional clinical tests to demonstrate safety and
15 effectiveness; and

16 “(C) apply subsection (b)(6)(C) to the reg-
17 ulation of sunscreen active ingredients in dem-
18 onstrating a prima facie safe nonprescription
19 marketing and use.

20 “(2) NON-ANIMAL TESTING METHODS FOR SUN-
21 SCREEN ACTIVE INGREDIENTS.—

22 “(A) IN GENERAL.—The Secretary shall
23 consider the types of nonclinical tests described
24 in paragraphs (1) through (4) of the first sub-
25 section (z) of section 505 (as inserted by sec-

1 tion 3209(a)(2) of the Health Extenders, Im-
2 proving Access to Medicare, Medicaid, and
3 CHIP, and Strengthening Public Health Act of
4 2022 (division FF of Public Law 117–328)), or
5 any other alternative to animal testing that the
6 Secretary deems appropriate, in the consider-
7 ation of sunscreen active ingredients.

8 “(B) GUIDANCE.—Not later than 180 days
9 after the date of enactment of this subsection,
10 the Secretary shall issue new guidance on how
11 sponsors can use nonclinical testing alternatives
12 to animal testing to meet safety and efficacy
13 standards for sunscreen active ingredients.”.

14 **SEC. 4. SUNSCREEN FINAL ADMINISTRATIVE ORDER.**

15 The final administrative order on pending over-the-
16 counter sunscreen active ingredient submissions issued
17 under section 3854 of the Coronavirus Aid, Relief, and
18 Economic Security Act (Public Law 116–136; 21 U.S.C.
19 360fff–3 note) shall—

20 (1) account for historical data demonstrating
21 safe use of sunscreen active ingredients that have
22 previously been accepted for marketing in the United
23 States;

24 (2) emphasize that sunscreen is an effective
25 skin cancer prevention tool; and

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

5 **SEC. 5. REPORTING AND TRANSPARENCY.**

6 (a) TO CONGRESS.—The Secretary of Health and
7 Human Services (in this section referred to as the “Sec-
8 retary”) shall, beginning not later than 1 year after the
9 date of enactment of this Act, annually submit to the
10 Committee on Energy and Commerce of the House of
11 Representatives and the Committee on Health, Education,
12 Labor, and Pensions of the Senate a report describing—

13 (1) the status of implementation of evidence
14 and testing standards for sunscreen active ingredi-
15 ents, including—

16 (A) any adjustments to evidence or testing
17 standards made under section 505G(r) of the
18 Federal Food, Drug, and Cosmetic Act (21
19 U.S.C. 355h) (as added by section 3); and

20 (B) the number and types of sunscreen ac-
21 tive ingredient applications reviewed using the
22 standards under such section 505G(r); and

23 (2) the progress of the Food and Drug Admin-
24 istration in allowing nonclinical testing alternatives

1 to animal testing for the consideration of sunscreen
2 active ingredients.

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

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