

**Calendar No. 568**113<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION**S. 2141**

To amend the Federal Food, Drug, and Cosmetic Act to provide an alternative process for review of safety and effectiveness of nonprescription sunscreen active ingredients and for other purposes.

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**IN THE SENATE OF THE UNITED STATES**

MARCH 13, 2014

Mr. REED (for himself, Mr. ISAKSON, Mr. COONS, Mr. BROWN, Mr. CARPER, Mr. PORTMAN, Ms. AYOTTE, Mr. ROBERTS, Mr. KIRK, Ms. WARREN, Mr. MCCONNELL, Ms. LANDRIEU, Mr. PAUL, Mr. SCOTT, Mr. SCHUMER, Mrs. HAGAN, Mr. HARKIN, Mr. ALEXANDER, Mr. BURR, and Mr. BOOKER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

SEPTEMBER 17 (legislative day, SEPTEMBER 16), 2014

Reported by Mr. HARKIN, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to provide an alternative process for review of 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Sunscreen Innovation  
3 Act”.

4 **SEC. 2. REGULATION OF NONPRESCRIPTION SUNSCREEN**  
5 **ACTIVE INGREDIENTS.**

6 Subchapter A of chapter V (21 U.S.C. 351 et seq.)  
7 is amended by adding at the end the following:

8 **“SEC. 524B. PROCEDURES FOR CLASSIFYING SUNSCREEN**  
9 **ACTIVE INGREDIENTS.**

10 “(a) IN GENERAL.—The Secretary shall review and  
11 determine whether nonprescription sunscreen conditions  
12 are generally recognized as safe and effective and shall  
13 ensure that any such conditions that are marketed in the  
14 United States are appropriately labeled.

15 “(b) DEFINITIONS.—

16 “(1) ACTIVE INGREDIENT.—The term ‘active  
17 ingredient’ means any component that is intended to  
18 furnish pharmacological activity or other direct ef-  
19 fect in the diagnosis, cure, mitigation, treatment, or  
20 prevention of disease, or to affect the structure or  
21 function of the body of humans or animals. The  
22 term includes components that may undergo chem-  
23 ical change in the manufacture of a drug and may  
24 be present in a drug in a modified form intended to  
25 furnish the specified activity or effect.

1           “(2) SUNSCREEN ACTIVE INGREDIENT.—The  
 2 term ‘sunscreen active ingredient’ means an active  
 3 ingredient that absorbs, reflects, or scatters radi-  
 4 ation in the ultraviolet range at wavelengths from  
 5 290 to 400 nanometers.

6           “(3) SUNSCREEN CONDITION.—The term ‘sun-  
 7 screen condition’ means a sunscreen active ingre-  
 8 dient (or a combination of sunscreen active ingre-  
 9 dents), dosage form, dosage strength, or route of ad-  
 10 ministration, marketed for a specific nonprescription  
 11 use.

12          “(e) CRITERIA FOR ELIGIBILITY.—To be eligible for  
 13 review under this section, a sunscreen condition shall—

14           “(1) not be included in the stayed sunscreen  
 15 monograph; and

16           “(2) have been marketed as a nonprescription  
 17 sunscreen condition in the United States or at least  
 18 1 other country; or marketed as a cosmetic or die-  
 19 tary supplement in 1 or more countries other than  
 20 the United States—

21           “(A) for a minimum of 5 continuous years;  
 22 and

23           “(B) in sufficient quantity, as determined  
 24 by the Secretary based upon the information  
 25 submitted under subparagraphs (D) and (E) of

1 subsection (d)(1) and, if applicable, subsection  
2 (d)(2)(A)(ii).

3 “(d) APPLICATION FOR ELIGIBILITY.—

4 “(1) IN GENERAL.—A sponsor of a nonprescrip-  
5 tion sunscreen condition described in subsection (e)  
6 desiring to market such condition in the United  
7 States may submit an application to the Secretary,  
8 in such manner and containing such information as  
9 required by the Secretary, including the following:

10 “(A) Basic information about the sun-  
11 screen condition (including a description of each  
12 active ingredient, pharmacologic class, intended  
13 nonprescription use, nonprescription strength  
14 and dosage form, route of administration, and  
15 directions for use).

16 “(B) A detailed chemical description of the  
17 sunscreen active ingredient that includes a full  
18 description of the drug substance, including its  
19 physical and chemical characteristics, the meth-  
20 od of synthesis (or isolation) and purification of  
21 the drug substance, and any specifications and  
22 analytical methods necessary to ensure the  
23 identity, strength, quality, and purity of the  
24 drug substance, including reference to the cur-  
25 rent edition of the official National Formulary,

1 the United States Pharmacopeia, or foreign  
2 compendiums, where applicable.

3 “(C) A list of each country in which the  
4 sunscreen condition has been marketed.

5 “(D) The cumulative total number of dos-  
6 age units sold for each dosage form of the sun-  
7 screen condition, including total weight of the  
8 active ingredient, package size for each dosage  
9 form in which the condition is marketed as non-  
10 prescription, and an estimate of the minimum  
11 number of potential consumer exposures to the  
12 condition.

13 “(E) The use pattern (according to the  
14 label) for each country in which the sunscreen  
15 condition is marketed and any changes in use  
16 pattern that have occurred over time.

17 “(F) A list of all countries in which the  
18 sunscreen condition has been withdrawn from  
19 marketing or in which an application for non-  
20 prescription marketing approval has been de-  
21 nied and an explanation for such withdrawal or  
22 application denial.

23 “(2) SUNSCREEN CONDITIONS THAT HAVE NOT  
24 BEEN MARKETED IN THE UNITED STATES FOR 5  
25 CONTINUOUS YEARS.—

1           “(A) IN GENERAL.—In the case of an ap-  
2           plication with respect to a nonprescription sun-  
3           screen condition that has not been marketed in  
4           the United States for 5 continuous years, in ad-  
5           dition to the information required under para-  
6           graph (1), the sponsor shall submit the fol-  
7           lowing information for each country in which  
8           the sunscreen condition has been marketed:

9                   “(i) The manner in which the sun-  
10                  screen condition has been marketed to con-  
11                  sumers. If the sunscreen condition is mar-  
12                  keted to consumers as a nonprescription  
13                  pharmacy only condition, the Secretary  
14                  may require supplemental information.

15                  “(ii) A description of the population  
16                  demographics and the source from which  
17                  this information has been compiled, to en-  
18                  sure that the sunscreen condition’s use can  
19                  be reasonably extrapolated to the popu-  
20                  lation of the United States.

21                  “(iii) A description of the country’s  
22                  system for identifying adverse drug experi-  
23                  ences, especially those found in non-  
24                  prescription marketing experience, includ-  
25                  ing method of collection if applicable.

1           “(iv) A statement of how long the  
2           sunscreen condition has been marketed in  
3           each country and how long the current  
4           product labeling has been in use, accom-  
5           panied by a copy of the current product la-  
6           beling, including a translation into English  
7           of any labeling that is not in English, and  
8           a statement of whether the current product  
9           labeling has been authorized, accepted, or  
10          approved by a regulatory body in each  
11          country where the condition is marketed.

12          “(v) A list of all countries where the  
13          sunscreen condition is marketed as a pre-  
14          scription drug only and an explanation for  
15          such restriction.

16          “(B) SUNSCREEN CONDITIONS THAT HAVE  
17          BEEN MARKETED IN MORE THAN 5 COUN-  
18          TRIES.—

19          “(i) IN GENERAL.—In the case of a  
20          sunscreen condition that has been mar-  
21          keted as a nonprescription sunscreen in  
22          more than 5 countries, with a minimum of  
23          5 continuous years of marketing in at least  
24          one such country, the sponsor—

1           “(I) may submit information in  
2 accordance with clauses (i) through  
3 (iv) of subparagraph (A) with respect  
4 to only 5 such countries, including—

5           “(aa) the country with a  
6 minimum of 5 continuous years  
7 of nonprescription marketing;

8           “(bb) the country with the  
9 longest duration of marketing;  
10 and

11           “(cc) the country with the  
12 most support for marketing, such  
13 as a large volume of sales with  
14 cultural diversity among users of  
15 the product; and

16           “(II) shall explain the basis for  
17 the countries selected under subclause  
18 (I); and

19           “(III) shall provide information  
20 from more than 5 countries if such in-  
21 formation is needed to support the ap-  
22 plication.

23           “(ii) REQUIREMENT.—If the sun-  
24 screen condition meets the criteria under  
25 items (aa) through (cc) of clause (i)(I) in



1           1 or more countries listed in section  
2           802(b)(1)(A), at least 1 such country shall  
3           be included among the 5 countries selected  
4           under such clause (i)(I).

5           “(3) PENDING APPLICATIONS.—The require-  
6           ments of this subsection shall not apply to a sun-  
7           screen condition deemed eligible for review of safety  
8           and effectiveness by publication of a notice of eligi-  
9           bility in the Federal Register prior to the date of en-  
10          actment of the Sunscreen Innovation Act. Applica-  
11          tions for such sunscreen conditions shall be consid-  
12          ered in accordance with subsection (g).

13          “(e) PUBLIC AVAILABILITY.—If a condition is found  
14          eligible under subsection (d), the Secretary shall make the  
15          application publicly available, with redactions for confiden-  
16          tial commercial information or trade secret information,  
17          and any other information exempt from disclosure pursu-  
18          ant to section 1905 of title 18, United States Code, section  
19          552(b) of title 5, United States Code, or section 301(j)  
20          of this Act. Applications shall remain confidential during  
21          the Secretary’s consideration of eligibility.

22          “(f) NEW SUNSCREEN CONDITION APPLICATION.—

23                  “(1) ELIGIBILITY DETERMINATION.—Not later  
24                  than 60 days after the submission of an eligibility  
25                  application under subsection (d), the Secretary shall

1 determine if the sunscreen condition is eligible for  
2 further review for safety and effectiveness. In the  
3 case of a sunscreen condition determined to be eligi-  
4 ble, the Secretary shall publish a notice of eligibility  
5 in the Federal Register, and provide interested per-  
6 sons an opportunity to submit published and unpub-  
7 lished data related to the safety and effectiveness of  
8 the sunscreen condition for its intended nonprescrip-  
9 tion uses, in accordance with paragraph (2). In the  
10 case of a sunscreen condition determined not eligi-  
11 ble, the Secretary shall issue a letter to the sponsor,  
12 which shall be made publicly available.

13 ~~“(2) SAFETY AND EFFECTIVENESS DATA SUB-~~  
14 ~~MISSIONS.—~~

15 ~~“(A) IN GENERAL.—~~Within 60 days of the  
16 publication in the Federal Register of an appli-  
17 cation deemed eligible, as described in para-  
18 graph (1), the sponsor and other interested par-  
19 ties shall submit safety and effectiveness data  
20 to the Secretary for further review, as described  
21 in subparagraph (B).

22 ~~“(B) REQUIRED SUBMISSIONS REGARDING~~  
23 ~~DATA.—~~Submissions under this paragraph shall  
24 include the following:

25 ~~“(i) HUMAN SAFETY DATA.—~~

1           “(I) INDIVIDUAL ACTIVE COMPO-  
2           NENTS.—With respect to individual  
3           active components, controlled studies,  
4           partially controlled or uncontrolled  
5           studies, documented case reports, per-  
6           tinent marketing experiences that may  
7           influence a determination as to the  
8           safety of each individual active compo-  
9           nent, and pertinent medical and sci-  
10          entific literature.

11           “(II) COMBINATIONS OF INDI-  
12          VIDUAL ACTIVE COMPONENTS.—With  
13          respect to combinations of the indi-  
14          vidual active components, controlled  
15          studies, partially controlled or uncon-  
16          trolled studies, documented case re-  
17          ports, pertinent marketing experiences  
18          that may influence a determination as  
19          to the safety of combinations of the  
20          individual active component, and per-  
21          tinent medical and scientific lit-  
22          erature.

23           “(ii) EFFICACY DATA.—

24           “(I) INDIVIDUAL ACTIVE COMPO-  
25          NENTS.—With respect to individual

1 active components, controlled studies,  
2 partially controlled or uncontrolled  
3 studies, documented case reports, per-  
4 tinent marketing experiences that may  
5 influence a determination on the effi-  
6 cacy of each individual active compo-  
7 nent, pertinent medical and scientific  
8 literature.

9 “(II) COMBINATIONS OF INDI-  
10 VIDUAL ACTIVE COMPONENTS.—With  
11 respect to combinations of the indi-  
12 vidual active components, controlled  
13 studies, partially controlled or uncon-  
14 trolled studies, documented case re-  
15 ports, pertinent marketing experiences  
16 that may influence a determination on  
17 the efficacy of combinations of the in-  
18 dividual active components, and perti-  
19 nent medical and scientific literature.

20 “(iii) DATA SETTING FORTH MEDICAL  
21 RATIONALE AND PURPOSE.—A summary of  
22 the data and views setting forth the med-  
23 ical rationale and purpose (or lack thereof)  
24 for the sunscreen condition and the sci-  
25 entific basis (or lack thereof) for the con-

1           clusion that the condition has been proven  
2           safe and effective for the intended use. If  
3           there is an absence of controlled studies in  
4           the material submitted, an explanation as  
5           to why such studies are not considered  
6           necessary must be included.

7           “(iv) OFFICIAL DRUG MONOGRAPH.—

8           An applicable United States Pharma-  
9           copoeia or National Formulary for the sun-  
10          screen active ingredient or a proposed  
11          standard for inclusion in an article to be  
12          recognized in an official drug monograph  
13          for the active ingredient, including infor-  
14          mation showing that the official or pro-  
15          posed compendial monograph for the active  
16          ingredient is consistent with the active in-  
17          gredient used in the studies establishing  
18          safety and effectiveness and with the active  
19          ingredient marketed in the nonprescription  
20          product to a material extent and for a ma-  
21          terial time. If differences exist between the  
22          official or proposed compendial monograph  
23          for the active ingredient and the active in-  
24          gredient that is the subject of the applica-  
25          tion, sponsor shall explain such differences.

1           “(v) ADVERSE DRUG EXPERIENCES.—

2           A list of all serious adverse drug experi-  
3           ences, as defined by the Secretary, from  
4           each country where the condition has been  
5           or is currently marketed as a prescription  
6           drug or as a nonprescription drug or prod-  
7           uct.

8           “(C) OPTIONAL ANIMAL SAFETY DATA.—

9           In addition to the information required under  
10          subparagraph (B), the sponsor may submit in-  
11          formation with respect to animal safety data,  
12          including controlled studies and partially con-  
13          trolled or uncontrolled studies, in the case of an  
14          application for individual active components,  
15          and controlled studies and partially controlled  
16          or uncontrolled studies in the case of an appli-  
17          cation for combinations of individual active  
18          components.

19          “(D) CONFIDENTIALITY OF SUBMIS-

20          SIONS.—The Secretary shall make data and in-  
21          formation submitted by the sponsor, or pursu-  
22          ant to a notice requesting safety and effective-  
23          ness data published in the Federal Register,  
24          publicly available, with redactions for confiden-  
25          tial commercial information or trade secret in-

1           formation, and any other information exempt  
2           from disclosure pursuant to section 1905 of  
3           title 18, United States Code, section 552(b) of  
4           title 5, United States Code, or section 301(j) of  
5           this Act.

6           “(3) NEW SUNSCREEN CONDITION APPLICATION  
7           SUBMISSION TO THE ADVISORY COMMITTEE.—Not  
8           later than 30 days after the end of the public com-  
9           ment period described in paragraph (2), the Sec-  
10          retary shall submit the application and the safety  
11          and effectiveness data submitted under paragraph  
12          (2) to the Nonprescription Drugs Advisory Com-  
13          mittee (referred to in this section as the ‘advisory  
14          committee’) for review.

15          “(g) PENDING SUNSCREEN CONDITION APPLICA-  
16          TIONS.—Not later than 30 days after the date of enact-  
17          ment of the Sunscreen Innovation Act, the Secretary shall  
18          submit to the advisory committee all safety and effective-  
19          ness data submitted with respect to each application for  
20          review of sunscreen conditions that the Secretary had de-  
21          termined, prior to the date of enactment of the Sunscreen  
22          Innovation Act, to be eligible for review of safety and ef-  
23          fectiveness and for which the information required under  
24          subsection (f)(2) has been submitted to the Secretary prior  
25          to such date of enactment.

1       “(h) REVIEW AND RECOMMENDATION FOR NON-  
2 PRESCRIPTION SUNSCREEN CONDITION.—

3               “(1) IN GENERAL.—The Secretary shall require  
4 the advisory committee to evaluate the safety and ef-  
5 fectiveness data submitted in accordance with sub-  
6 section (f)(2) or (g).

7               “(2) STANDARDS.—In evaluating a non-  
8 prescription sunscreen condition under paragraph  
9 (1), the advisory committee shall use the regulations  
10 in effect at the time of the application, including  
11 regulations with respect to—

12                       “(A) the safety of the nonprescription sun-  
13 screen condition;

14                       “(B) the effectiveness of the nonprescrip-  
15 tion sunscreen condition;

16                       “(C) the benefit-to-risk ratio of the non-  
17 prescription sunscreen condition; and

18                       “(D) the labeling of the nonprescription  
19 sunscreen condition.

20               “(3) COMMUNICATIONS BETWEEN ADVISORY  
21 COMMITTEE AND OTHER INDIVIDUALS WHO SUBMIT  
22 DATA.—The advisory committee shall have the au-  
23 thority to communicate with the sponsor and other  
24 individuals who submit data during the advisory



1 committee's review, including requesting clarification  
2 or additional information.

3 ~~“(4) RECOMMENDATIONS.—~~

4 ~~“(A) IN GENERAL.—For each such sub-~~  
5 ~~mission under subsection (f)(3) or (g), the advi-~~  
6 ~~sory committee shall make one of the following~~  
7 ~~recommendations to the Secretary:~~

8 ~~“(i) The sunscreen condition is gen-~~  
9 ~~erally recognized as safe and effective (in-~~  
10 ~~cluding any or all indications); including~~  
11 ~~nonprescription sunscreen conditions for~~  
12 ~~which a new drug application has been ap-~~  
13 ~~proved by the Secretary.~~

14 ~~“(ii) Insufficient information has been~~  
15 ~~provided to support a recommendation that~~  
16 ~~the sunscreen condition is generally recog-~~  
17 ~~nized as safe and effective (including any~~  
18 ~~or all indications).~~

19 ~~“(iii) The sunscreen condition is not~~  
20 ~~generally recognized as safe and effective~~  
21 ~~to be marketed or sold, unless an applica-~~  
22 ~~tion with respect to such condition is ap-~~  
23 ~~proved under section 505(b).~~

24 ~~“(B) TIMING.—The advisory committee~~  
25 ~~shall make a recommendation under subpara-~~

1 graph (A) not later than 180 days after the ad-  
2 visory committee receives the application and  
3 data submitted under subsection (f)(3) or sub-  
4 section (g).

5 “(C) RESUBMISSION OF DATA.—If the ad-  
6 visory committee recommends that insufficient  
7 information has been provided, in accordance  
8 with subparagraph (A)(ii), the advisory com-  
9 mittee shall make such recommendation not  
10 later than 180 days after the date on which  
11 such additional information is submitted.

12 “(i) DETERMINATION BY THE CENTER FOR DRUG  
13 EVALUATION AND RESEARCH.—

14 “(1) IN GENERAL.—The Center for Drug Eval-  
15 uation and Research shall respond to the rec-  
16 ommendations of the advisory committee under sub-  
17 section (h)(4) as follows:

18 “(A) In the case of a recommendation by  
19 the advisory committee described in clause (i)  
20 of subsection (h)(4), not later than 45 days  
21 after the advisory committee issues the rec-  
22 ommendation, the Center for Drug Evaluation  
23 and Research shall issue a determination af-  
24 firming or denying the recommendation of the  
25 advisory committee. If the Center for Drug

1 Evaluation and Research affirms the rec-  
2 ommendation of the advisory committee, or if  
3 the Center for Drug Evaluation and Research  
4 takes no action regarding the recommendation  
5 within 45 days of receiving such recommenda-  
6 tion, the nonprescription sunscreen condition  
7 shall be generally recognized as safe and effec-  
8 tive, not misbranded, and permitted to be mar-  
9 keted and sold in accordance with all applicable  
10 rules and regulations for over-the-counter  
11 drugs.

12 “(B) In the case of a recommendation de-  
13 scribed in clause (ii) of such subsection, the  
14 Center for Drug Evaluation and Research shall  
15 issue a determination affirming or denying the  
16 recommendation of the advisory committee, to  
17 be made publicly available, within 45 days of  
18 receiving the recommendation, and inform the  
19 sponsor that the sponsor must submit addi-  
20 tional information to the advisory committee in  
21 order to continue the review by the advisory  
22 committee.

23 “(C) In the case of a recommendation de-  
24 scribed in clause (iii) of such subsection, the  
25 Center for Drug Evaluation and Research shall

1 issue a determination affirming or denying the  
2 recommendation of the advisory committee, to  
3 be made publicly available, within 45 days of  
4 receiving such recommendation, and indicate  
5 whether such sunscreen condition determined to  
6 be not generally recognized as safe and effective  
7 to be marketed and sold, unless an application  
8 with respect to such condition is approved  
9 under section 505(b), or whether additional  
10 data must be submitted to the advisory com-  
11 mittee.

12 “(2) SUPERVISORY REVIEW OF DETERMINA-  
13 TION.—

14 “(A) IN GENERAL.—Any person may re-  
15 quest a supervisory review of a determination of  
16 the Center for Drug Evaluation and Research  
17 to not accept a recommendation of an advisory  
18 committee. Such review may be conducted at  
19 the next supervisory or higher level above the  
20 individual who made the determination.

21 “(B) REQUEST FOR SUPERVISORY RE-  
22 VIEW.—A request described in subparagraph  
23 (A) shall be made to the Secretary not later  
24 than 30 days after such decision and shall indi-  
25 cate in the request whether such person seeks

1 an in-person meeting or a teleconference. The  
2 Secretary shall schedule an in-person or tele-  
3 conference review, if so requested, not later  
4 than 30 days after such request is made. The  
5 Secretary shall issue a decision to the person  
6 requesting a review under this paragraph not  
7 later than 45 days after the meeting.

8 “(C) STANDARD OF SUPERVISORY RE-  
9 VIEW.—The Secretary shall be authorized to  
10 overturn a determination of the Center for  
11 Drug Evaluation and Research not to accept a  
12 recommendation of the advisory committee if  
13 the supervisory review results in a decision by  
14 the reviewer that the individual who made the  
15 determination did not provide reasonable and  
16 sufficient substantive support for the decision  
17 to disregard the advisory committee’s rec-  
18 ommendation.

19 “(D) SUPERVISORY REVIEW DECISION.—If  
20 the Secretary overturns a determination by the  
21 Center for Drug Evaluation and Research not  
22 to accept a favorable recommendation of an ad-  
23 visory committee, the nonprescription sunscreen  
24 condition shall be generally recognized as safe  
25 and effective, not misbranded, and permitted to

1 be marketed and sold in accordance with all ap-  
2 plicable rules and regulations for over-the-  
3 counter drugs.

4 “(E) FINAL AGENCY ACTION.—A decision  
5 made through supervisory review shall con-  
6 stitute final agency action subject to judicial re-  
7 view.

8 “(j) REPORTS.—

9 “(1) IN GENERAL.—Not later than 1 year after  
10 the date of enactment of the Sunscreen Innovation  
11 Act, on March 1, 2015, and every 2 years thereafter,  
12 the Secretary shall issue a report to Congress de-  
13 scribing actions taken under this section.

14 “(2) CONTENTS.—The reports under paragraph  
15 (1) shall include—

16 “(A) a review of the progress made in  
17 issuing in a timely manner decisions on the  
18 safety and effectiveness for sunscreen condi-  
19 tions for applications pending as of the date of  
20 enactment of the Sunscreen Innovation Act, in-  
21 cluding the number of pending applications—

22 “(i) reviewed and the decision times  
23 for each application, measured from the  
24 date of original eligibility application sub-  
25 mission by the sponsor;

1           “(ii) resulting in a determination of  
2           generally recognized as safe and effective  
3           and not misbranded;

4           “(iii) resulting in a determination of  
5           not generally recognized as safe and effec-  
6           tive and not misbranded and the reasons  
7           for such determinations; and

8           “(iv) for which a determination has  
9           not been made, an explanation for the  
10          delay, a description of the current status of  
11          each such application, and the length of  
12          time such applications have been pending,  
13          measured from the date of original eligi-  
14          bility application submission by the spon-  
15          sor;

16          “(B) a review of the progress made in  
17          issuing in a timely manner a decision on safety  
18          and effectiveness for sunscreen condition appli-  
19          cations submitted after the date of enactment  
20          of the Sunscreen Innovation Act, including the  
21          number of such applications—

22                 “(i) reviewed and the decision times  
23                 for each application;

1           “(ii) resulting in a determination of  
2           generally recognized as safe and effective  
3           and not misbranded; and

4           “(iii) resulting in a determination of  
5           not generally recognized as safe and effec-  
6           tive and not misbranded and the reasons  
7           for such determinations;

8           “(C) a description of the staffing and re-  
9           sources relating to the costs associated with the  
10          review and decisionmaking pertaining to appli-  
11          cations;

12          “(D) a review of the progress in meeting  
13          the deadlines with respect to processing applica-  
14          tions under this section;

15          “(E) to the extent the Secretary deter-  
16          mines appropriate, recommendations for process  
17          improvements in the handling of pending and  
18          new applications; and

19          “(F) recommendations for expanding the  
20          applicability of this section to nonprescription  
21          active ingredients or conditions that are not re-  
22          lated to the sunscreen category of over-the-  
23          counter drugs.

24          “(3) METHOD.—The Secretary shall publish the  
25          reports required under this subsection in the manner



1 the Secretary determines to be the most effective for  
 2 efficiently disseminating the report, including publi-  
 3 cation of the report on the Internet website of the  
 4 Food and Drug Administration.

5 “(k) RULES OF CONSTRUCTION.—

6 “(1) AUTHORITY TO WITHDRAW OR SUS-  
 7 PEND.—Nothing in this section shall be construed to  
 8 alter the Secretary’s authority to withdraw or sus-  
 9 pend from the market a drug that the Secretary de-  
 10 termines to be unsafe or ineffective.

11 “(2) OTHER CONDITIONS.—Nothing in the sec-  
 12 tion shall affect the Secretary’s authority to review  
 13 nonprescription conditions other than sunscreen con-  
 14 ditions.”.

15 **SEC. 3. SUNSCREEN TESTING AND LABELING.**

16 Not later than 180 days after the date of enactment  
 17 of this Act, the Secretary shall issue determinations with  
 18 respect to—

19 (1) the appropriate testing and labeling require-  
 20 ments for sunscreens sold as an aerosol; and

21 (2) whether sunscreen may contain a label indi-  
 22 cating a sun protection factor greater than 50.

23 **SECTION 1. SHORT TITLE.**

24 *This Act may be cited as the “Sunscreen Innovation*  
 25 *Act”.*

1 **SEC. 2. REGULATION OF NONPRESCRIPTION SUNSCREEN**

2 **ACTIVE INGREDIENTS.**

3 (a) *IN GENERAL.*—Chapter V of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended  
5 by adding at the end the following:

6 **“Subchapter I—Nonprescription Sunscreen**  
7 **and Other Active Ingredients**

8 **“SEC. 586. DEFINITIONS.**

9 “In this subchapter—

10 “(1) the term ‘Advisory Committee’ means the  
11 Nonprescription Drug Advisory Committee of the  
12 Food and Drug Administration or any successor to  
13 such Committee;

14 “(2) the term ‘final sunscreen order’ means an  
15 order published by the Secretary in the Federal Reg-  
16 ister containing information stating that a non-  
17 prescription sunscreen active ingredient or combina-  
18 tion of nonprescription sunscreen active ingredients—

19 “(A) is GRASE and is not misbranded if  
20 marketed in accordance with such order; or

21 “(B) is not GRASE and is misbranded;

22 “(3) the term ‘GRASE’ means generally recog-  
23 nized, among experts qualified by scientific training  
24 and experience to evaluate the safety and effectiveness  
25 of drugs, as safe and effective for use under the condi-

1        *tions prescribed, recommended, or suggested in the la-*  
2        *beling of a drug as described in section 201(p);*

3            *“(4) the term ‘GRASE determination’ means,*  
4        *with respect to a nonprescription active ingredient or*  
5        *a combination of nonprescription active ingredients,*  
6        *a determination of whether such ingredient or com-*  
7        *bination of ingredients is GRASE;*

8            *“(5) the term ‘nonprescription’ means not subject*  
9        *to section 503(b)(1);*

10           *“(6) the term ‘pending request’ means each re-*  
11        *quest with respect to a nonprescription sunscreen ac-*  
12        *tive ingredient submitted under section 330.14 of title*  
13        *21, Code of Federal Regulations (as in effect on the*  
14        *date of enactment of the Sunscreen Innovation Act)*  
15        *for consideration for inclusion in the over-the-counter*  
16        *drug monograph system—*

17            *“(A) that was determined to be eligible for*  
18        *such review by publication of a notice of eligi-*  
19        *bility in the Federal Register prior to the date*  
20        *of enactment of such Act; and*

21            *“(B) for which safety and effectiveness data*  
22        *have been submitted to the Secretary prior to*  
23        *such date of enactment;*

24            *“(7) the term ‘proposed sunscreen order’ means*  
25        *an order containing a tentative determination pub-*

1 *lished by the Secretary in the Federal Register con-*  
2 *taining information proposing that a nonprescription*  
3 *sunscreen active ingredient or combination of non-*  
4 *prescription sunscreen active ingredients—*

5 *“(A) is GRASE and is not misbranded if*  
6 *marketed in accordance with such order;*

7 *“(B) is not GRASE and is misbranded; or*

8 *“(C) is not GRASE and is misbranded be-*  
9 *cause the data are insufficient to classify such*  
10 *ingredient or combination of ingredients as*  
11 *GRASE and not misbranded and additional in-*  
12 *formation is necessary to allow the Secretary to*  
13 *determine otherwise;*

14 *“(8) the term ‘sponsor’ means the person that*  
15 *submitted—*

16 *“(A) a request under section 586A;*

17 *“(B) a pending request; or*

18 *“(C) any other application subject to this*  
19 *subchapter;*

20 *“(9) the term ‘sunscreen’ means a drug con-*  
21 *taining one or more sunscreen active ingredients; and*

22 *“(10) the term ‘sunscreen active ingredient’*  
23 *means an active ingredient that is intended for appli-*  
24 *cation to the skin of humans for purposes of absorb-*  
25 *ing, reflecting, or scattering ultraviolet radiation.*

1 **“SEC. 586A. SUBMISSION OF REQUESTS.**

2       *“Any person may submit a request to the Secretary*  
3 *for a determination of whether a nonprescription sunscreen*  
4 *active ingredient or a combination of nonprescription sun-*  
5 *screen active ingredients, for use under specified conditions,*  
6 *to be prescribed, recommended, or suggested in the labeling*  
7 *thereof (including dosage form, dosage strength, and route*  
8 *of administration) is GRASE and should be included in*  
9 *part 352 of title 21, Code of Federal Regulations (or any*  
10 *successor regulations) concerning nonprescription sun-*  
11 *screen.*

12 **“SEC. 586B. ELIGIBILITY DETERMINATIONS; DATA SUBMIS-**  
13 **SION; FILING.**

14       *“(a) ELIGIBILITY DETERMINATIONS.—*

15               *“(1) IN GENERAL.—Not later than 60 calendar*  
16 *days after the date of receipt of a request under sec-*  
17 *tion 586A, the Secretary shall—*

18                       *“(A) determine, in accordance with para-*  
19 *graph (2), whether the request is eligible for fur-*  
20 *ther review under subsection (b) and section*  
21 *586C;*

22                       *“(B) notify the sponsor of the determination*  
23 *of the Secretary; and*

24                       *“(C) make such determination publicly*  
25 *available in accordance with paragraph (3) and*  
26 *subsection (b)(1).*

1           “(2) *CRITERIA FOR ELIGIBILITY.*—

2                   “(A) *IN GENERAL.*—*To be eligible for review*  
3                   *under subsection (b) and section 586C, a request*  
4                   *shall be for a nonprescription sunscreen active*  
5                   *ingredient or combination of nonprescription*  
6                   *sunscreen active ingredients, for use under speci-*  
7                   *fied conditions, to be prescribed, recommended,*  
8                   *or suggested in the labeling thereof, that—*

9                           “(i) *is not included in part 352 of title*  
10                           *21, Code of Federal Regulations (or any*  
11                           *successor regulations) concerning non-*  
12                           *prescription sunscreen; and*

13                           “(ii) *has been used to a material extent*  
14                           *and for a material time under such condi-*  
15                           *tions, as described in section 201(p)(2).*

16                   “(B) *ESTABLISHMENT OF TIME AND EX-*  
17                   *TENT.*—*A sponsor shall include in a request*  
18                   *under section 586A the information required*  
19                   *under section 330.14 of title 21, Code of Federal*  
20                   *Regulations (or any successor regulations) to*  
21                   *meet the standard described in subparagraph*  
22                   *(A)(ii).*

23           “(3) *PUBLIC AVAILABILITY.*—

24                   “(A) *REDACTIONS FOR CONFIDENTIAL IN-*  
25                   *FORMATION.*—*If a nonprescription sunscreen ac-*

1           *tive ingredient or combination of nonprescrip-*  
2           *tion sunscreen active ingredients is determined*  
3           *under paragraph (1)(A) to be eligible for further*  
4           *review, the Secretary shall make the request pub-*  
5           *licly available, with redactions for information*  
6           *that is treated as confidential under section*  
7           *552(b) of title 5, United States Code, section*  
8           *1905 of title 18, United States Code, or section*  
9           *301(j) of this Act.*

10           “(B) *IDENTIFICATION OF CONFIDENTIAL IN-*  
11           *FORMATION BY SPONSOR.—At the time that a re-*  
12           *quest is made under section 586A, the sponsor of*  
13           *such request shall identify any information that*  
14           *such sponsor considers to be confidential infor-*  
15           *mation described in subparagraph (A).*

16           “(C) *CONFIDENTIALITY DURING ELIGIBILITY*  
17           *REVIEW.—The information contained in a re-*  
18           *quest under section 586A shall remain confiden-*  
19           *tial during the Secretary’s consideration under*  
20           *this section of whether the request is eligible for*  
21           *further review consistent with section 330.14 of*  
22           *title 21, Code of Federal Regulations (or any*  
23           *successor regulations).*

24           “(b) *DATA SUBMISSION AND FILING OF REQUESTS.—*

1           “(1) *IN GENERAL.*—*In the case of a request*  
2 *under section 586A that is determined to be eligible*  
3 *under subsection (a) for further review under this sec-*  
4 *tion and section 586C, the Secretary shall, in noti-*  
5 *fying the public under subsection (a)(1)(C) of such*  
6 *eligibility determination, post the eligibility deter-*  
7 *mination on the Internet website of the Food and*  
8 *Drug Administration, invite the sponsor of such re-*  
9 *quest and any other interested party to submit com-*  
10 *ments, and provide a period of not less than 45 cal-*  
11 *endar days for comments in support of or otherwise*  
12 *relating to a GRASE determination, including pub-*  
13 *lished and unpublished data and other information*  
14 *related to the safety and efficacy of such request.*

15           “(2) *FILING DETERMINATION.*—*Not later than 60*  
16 *calendar days after the submission of data and other*  
17 *information described in paragraph (1) by the spon-*  
18 *sor, the Secretary shall determine whether the data*  
19 *and other information submitted by the sponsor under*  
20 *this section are sufficiently complete, including being*  
21 *formatted in a manner that enables the Secretary to*  
22 *determine the completeness of such data and informa-*  
23 *tion, to enable the Secretary to conduct a substantive*  
24 *review under section 586C with respect to such re-*  
25 *quest. Not later than 60 calendar days after the sub-*



1 mission of data and other information described in  
 2 paragraph (1) by the sponsor, if the Secretary deter-  
 3 mines—

4 “(A) that such data and other information  
 5 are sufficiently complete, the Secretary shall—

6 “(i) issue a written notification to the  
 7 sponsor of the determination to file such re-  
 8 quest, and make such notification publicly  
 9 available; and

10 “(ii) file such request made under sec-  
 11 tion 586A; or

12 “(B) that such data and other information  
 13 are not sufficiently complete, the Secretary shall  
 14 issue a written notification to the sponsor of the  
 15 determination to refuse to file the request, which  
 16 shall include the reasons for the refusal, includ-  
 17 ing why such data and other information are  
 18 not sufficiently complete, and make such notifi-  
 19 cation publicly available.

20 “(3) REFUSAL TO FILE A REQUEST.—

21 “(A) REQUEST FOR MEETINGS; SUBMISSION  
 22 OF ADDITIONAL DATA OR OTHER INFORMA-  
 23 TION.—If the Secretary refuses to file a request  
 24 made under section 586A, the sponsor may—

1           “(i) *within 30 calendar days of receipt*  
2 *of written notification of such refusal, re-*  
3 *quest, in writing, a meeting with the Sec-*  
4 *retary regarding the filing determination;*  
5 *and*

6           “(ii) *submit additional data or other*  
7 *information.*

8           “(B) *MEETINGS.—*

9           “(i) *IN GENERAL.—If a sponsor seeks a*  
10 *meeting under subparagraph (A)(i), the*  
11 *Secretary shall convene the meeting within*  
12 *30 calendar days of the request for such*  
13 *meeting.*

14           “(ii) *ACTIONS AFTER MEETING.—Fol-*  
15 *lowing any meeting held under clause (i)—*

16           “(I) *the Secretary may file the re-*  
17 *quest within 60 calendar days;*

18           “(II) *the sponsor may submit ad-*  
19 *ditional data or other information; or*

20           “(III) *if the sponsor elects, within*  
21 *120 calendar days, to have the Sec-*  
22 *retary file the request (with or without*  
23 *amendments to correct any purported*  
24 *deficiencies to the request)—*

1                   “(aa) the Secretary shall file  
2                   the request over protest, not later  
3                   than 30 calendar days after the  
4                   sponsor makes such election;

5                   “(bb) at the time of filing,  
6                   the Secretary shall provide writ-  
7                   ten notification of such filing to  
8                   the sponsor; and

9                   “(cc) the Secretary shall  
10                  make such notification publicly  
11                  available.

12                  “(iii) *REQUESTS FILED OVER PRO-*  
13                  *TEST.—The Secretary shall not require the*  
14                  *sponsor to resubmit a copy of the request for*  
15                  *purposes of filing a request filed over pro-*  
16                  *test, as described in clause (i)(III).*

17                  “(C) *SUBMISSIONS OF ADDITIONAL DATA OR*  
18                  *OTHER INFORMATION.—Within 60 calendar days*  
19                  *of any submission of additional data or other in-*  
20                  *formation under subparagraph (A)(i) or*  
21                  *(B)(i)(II), the Secretary shall reconsider the*  
22                  *previous determination made under paragraph*  
23                  *(2) with respect to the applicable request and*  
24                  *make a new determination in accordance with*  
25                  *paragraph (2).*

1           “(4) *PUBLIC AVAILABILITY.*—

2                   “(A) *REDACTIONS FOR CONFIDENTIAL IN-*  
 3 *FORMATION.*—*After the period of confidentiality*  
 4 *described in subsection (a)(3)(C), the Secretary*  
 5 *shall make data and other information submitted*  
 6 *in connection with a request under section 586A*  
 7 *publicly available, with redactions for informa-*  
 8 *tion that is treated as confidential under section*  
 9 *552(b) of title 5, United States Code, section*  
 10 *1905 of title 18, United States Code, or section*  
 11 *301(j) of this Act.*

12                   “(B) *IDENTIFICATION OF CONFIDENTIAL IN-*  
 13 *FORMATION BY SPONSOR.*—*A person submitting*  
 14 *information under this section shall identify at*  
 15 *the time of such submission the portions of such*  
 16 *information that the person considers to be con-*  
 17 *fidential information described in subparagraph*  
 18 *(A).*

19   **“SEC. 586C. *GRASE DETERMINATION.***

20           “(a) *REVIEW OF NEW REQUEST.*—

21                   “(1) *PROPOSED SUNSCREEN ORDER.*—*In the*  
 22 *case of a request under section 586A, not later than*  
 23 *300 calendar days after the date on which such re-*  
 24 *quest is filed under subsection (b)(2)(A) or*  
 25 *(b)(3)(B)(ii)(III) of section 586B, the Secretary—*

1           “(A) may convene a meeting of the Advisory  
2           Committee to review such request; and

3           “(B) shall complete the review of such re-  
4           quest and issue a proposed sunscreen order with  
5           respect to such request.

6           “(2) *PROPOSED SUNSCREEN ORDER BY COMMIS-*  
7           *SIONER.—If the Secretary does not issue a proposed*  
8           *sunscreen order under paragraph (1)(B) within such*  
9           *300-day period, the sponsor of such request may no-*  
10          *tify the Office of the Commissioner of such request*  
11          *and request review by the Office of the Commissioner.*  
12          *If such sponsor so notifies the Office of the Commis-*  
13          *sioner, the Commissioner shall, not later than 60 cal-*  
14          *endar days after the date of notification under this*  
15          *paragraph, issue a proposed sunscreen order with re-*  
16          *spect to such request.*

17          “(3) *PUBLIC COMMENT PERIOD.—A proposed*  
18          *sunscreen order issued under paragraph (1)(B) or (2)*  
19          *with respect to a request shall provide for a period of*  
20          *45 calendar days for public comment.*

21          “(4) *MEETING.—A sponsor may request, in writ-*  
22          *ing, a meeting with respect to a proposed sunscreen*  
23          *order issued under this subsection and described in*  
24          *subparagraph (B) or (C) of section 586(7), not later*  
25          *than 30 calendar days after the Secretary issues such*

1       *order. The Secretary shall convene a meeting with*  
2       *such sponsor not later than 45 calendar days after*  
3       *such request for a meeting.*

4               “(5) *FINAL SUNSCREEN ORDER.*—*With respect to*  
5       *a proposed sunscreen order under paragraph (1)(B)*  
6       *or (2)—*

7                       “(A) *the Secretary shall issue a final sun-*  
8       *screen order—*

9                               “(i) *in the case of a proposed sunscreen*  
10                              *order described in subparagraph (A) or (B)*  
11                              *of section 586(7), not later than 90 calendar*  
12                              *days after the end of the public comment*  
13                              *period under paragraph (3); or*

14                              “(ii) *in the case of a proposed sun-*  
15                              *screen order described in subparagraph (C)*  
16                              *of section 586(7), not later than 210 cal-*  
17                              *endar days after the date on which the*  
18                              *sponsor submits the additional information*  
19                              *requested pursuant to such proposed sun-*  
20                              *screen order; or*

21                              “(B) *if the Secretary does not issue such*  
22       *final sunscreen order within such 90- or 210-cal-*  
23       *endar-day period, as applicable, the sponsor of*  
24       *such request may notify the Office of the Com-*

1           *missioner of such request and request review by*  
2           *the Office of the Commissioner.*

3           “(6) *FINAL SUNSCREEN ORDER BY COMMIS-*  
4           *SIONER.—The Commissioner shall issue a final sun-*  
5           *screen order with respect to a proposed sunscreen*  
6           *order subject to paragraph (5)(B) not later than 60*  
7           *calendar days after the date of notification under*  
8           *such paragraph.*

9           “(b) *REVIEW OF PENDING REQUESTS.—*

10           “(1) *IN GENERAL.—The review of a pending re-*  
11           *quest shall be carried out by the Secretary in accord-*  
12           *ance with this subsection.*

13           “(2) *INAPPLICABILITY OF SECTIONS 586A AND*  
14           *586B.—Sections 586A and 586B shall not apply with*  
15           *respect to any pending request.*

16           “(3) *FEEDBACK LETTERS AS PROPOSED SUN-*  
17           *SCREEN ORDER.—Notwithstanding the requirements*  
18           *of section 586(7), a letter issued pursuant to section*  
19           *330.14(g) of title 21, Code of Federal Regulations be-*  
20           *fore the date of enactment of the Sunscreen Innova-*  
21           *tion Act, with respect to a pending request, shall be*  
22           *deemed to be a proposed sunscreen order and dis-*  
23           *played on the Internet website of the Food and Drug*  
24           *Administration. Notification of the availability of*  
25           *such letter shall be published in the Federal Register*

1     *not later than 45 calendar days after the date of en-*  
2     *actment of such Act.*

3             “(4) *PROPOSED SUNSCREEN ORDER.*—*In the*  
4     *case of a pending request for which the Secretary has*  
5     *not issued a letter pursuant to section 330.14(g) of*  
6     *title 21, Code of Federal Regulations before the date*  
7     *of enactment of the Sunscreen Innovation Act, the*  
8     *Secretary shall complete review of such request and,*  
9     *not later than 90 calendar days after the date of en-*  
10    *actment of such Act, issue a proposed sunscreen order*  
11    *with respect to such request.*

12            “(5) *PROPOSED SUNSCREEN ORDER BY COMMIS-*  
13    *SIONER.*—*If the Secretary does not issue a proposed*  
14    *sunscreen order under paragraph (4), or the Secretary*  
15    *does not publish a notification of the availability of*  
16    *a letter under paragraph (3), as applicable, the spon-*  
17    *sor of such request may notify the Office of the Com-*  
18    *missioner of such request and request review by the*  
19    *Office of the Commissioner. The Commissioner shall,*  
20    *not later than 60 calendar days after the date of noti-*  
21    *fication under this paragraph, issue a proposed order*  
22    *with respect to such request.*

23            “(6) *PUBLIC COMMENT PERIOD.*—*A proposed*  
24    *sunscreen order issued under paragraph (4) or (5), or*  
25    *a notification of the availability of a letter under*



1        *paragraph (3), with respect to a pending request shall*  
2        *provide for a period of 45 calendar days for public*  
3        *comment.*

4                *“(7) MEETING.—A sponsor may request, in writ-*  
5        *ing, a meeting with respect to a proposed sunscreen*  
6        *order issued under this subsection, including a letter*  
7        *deemed to be a proposed sunscreen order under para-*  
8        *graph (3), not later than 30 calendar days after the*  
9        *Secretary issues such order or the date upon which*  
10       *such feedback letter is deemed to be a proposed sun-*  
11       *screen order, as applicable. The Secretary shall con-*  
12       *vene a meeting with such sponsor not later than 45*  
13       *calendar days after the date of such request for a*  
14       *meeting.*

15                *“(8) ADVISORY COMMITTEE.—In the case of a*  
16        *proposed sunscreen order under paragraph (3), (4), or*  
17        *(5), an Advisory Committee meeting may be convened*  
18        *for the purpose of reviewing and providing rec-*  
19        *ommendations regarding the pending request.*

20                *“(9) FINAL SUNSCREEN ORDER.—In the case of*  
21        *a proposed sunscreen order under paragraph (3), (4),*  
22        *or (5)—*

23                        *“(A) the Secretary shall issue a final sun-*  
24        *screen order with respect to the request—*

1           “(i) in the case of a proposed sunscreen  
2 order described in subparagraph (A) or (B)  
3 of section 586(7), not later than 90 calendar  
4 days after the end of the public comment  
5 period under paragraph (6); or

6           “(ii) in the case of a proposed sun-  
7 screen order described in subparagraph (C)  
8 of section 586(7)—

9           “(I) if the Advisory Committee is  
10 not convened under paragraph (8), not  
11 later than 210 calendar days after the  
12 date on which the sponsor submits the  
13 additional information requested pur-  
14 suant to such proposed sunscreen order,  
15 which shall include a rationale for not  
16 convening such Advisory Committee; or

17           “(II) if the Advisory Committee is  
18 convened under paragraph (8), not  
19 later than 270 calendar days after the  
20 date on which the sponsor submits such  
21 additional information; or

22           “(B) if the Secretary does not issue such  
23 final sunscreen order within such 90-, 210-, or  
24 270-calendar-day period, as applicable, the spon-  
25 sor of such request may notify the Office of the

1           *Commissioner about such request and request re-*  
 2           *view by the Office of the Commissioner.*

3           “(10) *FINAL SUNSCREEN ORDER BY COMMIS-*  
 4           *SIONER.—The Commissioner shall issue a final sun-*  
 5           *screen order with respect to a proposed sunscreen*  
 6           *order subject to paragraph (9)(B) not later than 60*  
 7           *calendar days after the date of notification under*  
 8           *such paragraph.*

9           “(c) *ADVISORY COMMITTEE.—The Secretary shall not*  
 10          *be required to—*

11           “(1) *convene the Advisory Committee—*

12           “(A) *more than once with respect to any re-*  
 13           *quest under section 586A or any pending re-*  
 14           *quest; or*

15           “(B) *more than twice in any calendar year*  
 16           *with respect to the review under this section; or*

17           “(2) *submit more than a total of 3 requests*  
 18           *under section 586A or pending requests to the Advi-*  
 19           *sory Committee per meeting.*

20           “(d) *NO DELEGATION.—Any responsibility vested in*  
 21           *the Commissioner by subsection (a)(2), (a)(6), (b)(5), or*  
 22           *(b)(10) shall not be delegated.*

23           “(e) *EFFECT OF FINAL SUNSCREEN ORDER.—*

24           “(1) *IN GENERAL.—*

1           “(A) *SUNSCREEN ACTIVE INGREDIENTS DE-*  
2           *TERMINED TO BE GRASE.*—Upon issuance of a  
3           *final sunscreen order determining that a non-*  
4           *prescription sunscreen active ingredient or com-*  
5           *bination of nonprescription sunscreen active in-*  
6           *gredients is GRASE and is not misbranded, a*  
7           *sunscreen containing such ingredient or com-*  
8           *bination of ingredients shall be permitted to be*  
9           *introduced or delivered into interstate commerce*  
10           *for use under the conditions described in such*  
11           *final sunscreen order, in accordance with all re-*  
12           *quirements applicable to drugs not subject to sec-*  
13           *tion 503(b)(1), for so long as such final sun-*  
14           *screen order remains in effect.*

15           “(B) *SUNSCREEN ACTIVE INGREDIENTS DE-*  
16           *TERMINED NOT TO BE GRASE.*—Upon issuance of  
17           *a final sunscreen order determining that a non-*  
18           *prescription sunscreen active ingredient or com-*  
19           *bination of nonprescription sunscreen active in-*  
20           *gredients is not GRASE and is misbranded, a*  
21           *sunscreen containing such ingredient or com-*  
22           *bination of ingredients shall not be introduced or*  
23           *delivered into interstate commerce, for use under*  
24           *the conditions described in such final sunscreen*  
25           *order, unless an application is approved pursu-*

1           *ant to section 505 with respect to a sunscreen*  
2           *containing such ingredient or combination of in-*  
3           *redients, or unless conditions are later estab-*  
4           *lished under which such ingredient or combina-*  
5           *tion of ingredients is later determined to be*  
6           *GRASE and not misbranded under the over-the-*  
7           *counter drug monograph system.*

8           “(2) *AMENDMENTS TO FINAL SUNSCREEN OR-*  
9           *DEES.—*

10           “(A) *AMENDMENTS AT INITIATIVE OF SEC-*  
11           *RETARY.—In the event that information relevant*  
12           *to a nonprescription sunscreen active ingredient*  
13           *or combination of nonprescription sunscreen ac-*  
14           *tive ingredients becomes available to the Sec-*  
15           *retary after issuance of a final sunscreen order,*  
16           *the Secretary may amend such final sunscreen*  
17           *order by issuing a new proposed sunscreen order*  
18           *under subsection (a)(1) and following the proce-*  
19           *dures set forth in this section.*

20           “(B) *PETITION TO AMEND FINAL ORDER.—*  
21           *Any interested person may petition the Secretary*  
22           *to amend a final sunscreen order under section*  
23           *10.30, title 21 Code of Federal Regulations (or*  
24           *any successor regulations). If the Secretary*  
25           *grants any petition under such section, the Sec-*

1            *retary shall initiate the process for amending a*  
2            *final sunscreen order by issuing a new proposed*  
3            *sunscreen order under subsection (a)(1) and fol-*  
4            *lowing the procedures set forth in this section.*

5            “(C) *APPLICABILITY OF FINAL ORDERS.—*

6            *Once the Secretary issues a new proposed sun-*  
7            *screen order to amend a final sunscreen order*  
8            *under subparagraph (A) or (B), such final sun-*  
9            *screen order shall remain in effect and para-*  
10           *graph (3) shall not apply to such final sunscreen*  
11           *order until the Secretary has issued a new final*  
12           *sunscreen order or has determined not to amend*  
13           *the final sunscreen order.*

14           “(3) *INCLUSION OF INGREDIENTS THAT ARE*  
15           *SUBJECTS OF FINAL ORDERS IN THE SUNSCREEN*  
16           *MONOGRAPH.—*

17           “(A) *AMENDING REGULATIONS.—*

18           “(i) *REQUIREMENT.—At any time that*  
19           *the Secretary proposes to amend part 352 of*  
20           *title 21, Code of Federal Regulations (or*  
21           *any successor regulations) concerning non-*  
22           *prescription sunscreen, including pursuant*  
23           *to section 586E, except as provided in*  
24           *clause (iv), the Secretary shall include in*  
25           *such part 352 (or any successor regulations)*

1           any nonprescription sunscreen active ingre-  
2           dient or combination of nonprescription  
3           sunscreen active ingredients that is the sub-  
4           ject of an effective final sunscreen order of  
5           the type described in section 586(2)(A) and  
6           issued since the time that the Secretary last  
7           amended such regulations. Such regulation  
8           shall set forth conditions of use under which  
9           each such ingredient or combination of in-  
10          gredients is GRASE and not misbranded. If  
11          these conditions differ from, or are in addi-  
12          tion to, those previously set forth in the ap-  
13          plicable final sunscreen order, the Secretary  
14          shall provide notice and opportunity for  
15          comment on such conditions in the rule-  
16          making, and the applicable final sunscreen  
17          order shall continue in effect until the effec-  
18          tive date of a final regulation, as set forth  
19          in clause (iii).

20               “(ii) INCLUSION OF ORDERS.—In pro-  
21               posing to amend the regulations as de-  
22               scribed in clause (i), the Secretary shall in-  
23               clude in the proposed regulations a list of  
24               final sunscreen orders that shall cease to be  
25               effective on the effective date of a resulting

1           *final regulation. Such list shall include all*  
2           *final sunscreen orders of the type described*  
3           *in section 586(2)(A) that are in effect on the*  
4           *date that such regulations are proposed,*  
5           *with the exception that such list shall not*  
6           *include any final sunscreen orders that, on*  
7           *the date that the regulations are proposed,*  
8           *the Secretary is in the process of amending*  
9           *under paragraph (2).*

10           “(iii) *ORDERS NO LONGER EFFEC-*  
11           *TIVE.—Any final sunscreen order included*  
12           *by the Secretary in a list described in*  
13           *clause (ii) and in a list included in result-*  
14           *ing final regulations shall cease to be effec-*  
15           *tive on the date that such final regulations*  
16           *including such order in such list become ef-*  
17           *fective.*

18           “(iv) *INGREDIENTS NOT GRASE.—If,*  
19           *notwithstanding a final sunscreen order*  
20           *stating that a nonprescription sunscreen ac-*  
21           *tive ingredient or combination of non-*  
22           *prescription sunscreen active ingredients is*  
23           *GRASE and is not misbranded if marketed*  
24           *in accordance with such order, while*  
25           *amending the regulations as described in*



1           *clause (i), the Secretary concludes that such*  
2           *ingredient or combination of ingredients is*  
3           *no longer GRASE for use in nonprescrip-*  
4           *tion sunscreen, the Secretary shall, at the*  
5           *discretion of the Secretary, either initiate*  
6           *the process for amending the final sunscreen*  
7           *order set forth in paragraph (2) of this sub-*  
8           *section or include in a proposed regulation*  
9           *an explanation and information supporting*  
10          *the determination of the Secretary that such*  
11          *ingredient or combination of ingredients is*  
12          *no longer GRASE for use in nonprescrip-*  
13          *tion sunscreen.*

14           “(B) *PROCEDURE FOR UPDATING REGULA-*  
15          *TIONS.—After the Secretary amends and final-*  
16          *izes the regulations under part 352 of title 21,*  
17          *Code of Federal Regulations under section 586E*  
18          *and such regulations become effective, the Sec-*  
19          *retary may use direct final rulemaking to in-*  
20          *clude in such regulations any nonprescription*  
21          *sunscreen active ingredients that are the subject*  
22          *of effective final sunscreen orders.*

23          **“SEC. 586D. GUIDANCE; OTHER PROVISIONS.**

24           “(a) *GUIDANCE.—*

25           “(1) *IN GENERAL.—*

1           “(A) *DRAFT GUIDANCE.*—Not later than 1  
2           year after the date of enactment of the Sunscreen  
3           *Innovation Act*, the Secretary shall issue draft  
4           guidance on the implementation of, and compli-  
5           ance with, the requirements with respect to sun-  
6           screen under this subchapter, including guidance  
7           on—

8                   “(i) *the format and content of informa-*  
9                   *tion submitted by a sponsor in support of*  
10                  *a request under section 586A or a pending*  
11                  *request;*

12                  “(ii) *the data required to meet the safe-*  
13                  *ty and efficacy standard for determining*  
14                  *whether a nonprescription sunscreen active*  
15                  *ingredient or combination of nonprescrip-*  
16                  *tion sunscreen active ingredients is GRASE*  
17                  *and is not misbranded;*

18                  “(iii) *the process by which a request*  
19                  *under section 586A or a pending request is*  
20                  *withdrawn; and*

21                  “(iv) *the process by which the Sec-*  
22                  *retary will carry out section 586C(c), in-*  
23                  *cluding with respect to how the Secretary*  
24                  *will address the total number of requests re-*

1           *ceived under section 586A and pending re-*  
2           *quests.*

3           “(B) *FINAL GUIDANCE.*—*The Secretary*  
4           *shall finalize the guidance described in subpara-*  
5           *graph (A) not later than 2 years after the date*  
6           *of enactment of the Sunscreen Innovation Act.*

7           “(C) *INAPPLICABILITY OF PAPERWORK RE-*  
8           *DUCTION ACT.*—*Chapter 35 of title 44, United*  
9           *States Code shall not apply to collections of in-*  
10          *formation made for purposes of guidance under*  
11          *this subsection.*

12          “(2) *SUBMISSIONS PENDING ISSUANCE OF FINAL*  
13          *GUIDANCE.*—*Irrespective of whether final guidance*  
14          *under paragraph (1) has been issued—*

15                 “(A) *persons may, beginning on the date of*  
16                 *enactment of the Sunscreen Innovation Act,*  
17                 *make submissions under this subchapter; and*

18                 “(B) *the Secretary shall review and act*  
19                 *upon such submissions in accordance with this*  
20                 *subchapter.*

21          “(b) *RULES OF CONSTRUCTION.*—

22                 “(1) *CURRENTLY MARKETED SUNSCREENS.*—  
23                 *Nothing in this subchapter shall be construed to affect*  
24                 *the marketing of sunscreens that are marketed in*  
25                 *interstate commerce on or before the date of enactment*

1       of this subchapter, except as otherwise provided in  
2       this subchapter.

3               “(2) *ENSURING SAFETY AND EFFECTIVENESS.*—  
4       Nothing in this subchapter shall be construed to alter  
5       the authority of the Secretary with respect to prohib-  
6       iting the marketing of a sunscreen that is not safe  
7       and effective or is misbranded, or with respect to im-  
8       posing restrictions on the marketing of a sunscreen to  
9       ensure safety and effectiveness, except as otherwise  
10       provided in this subchapter, including section  
11       586C(e).

12               “(3) *OTHER DRUGS.*—Except as otherwise pro-  
13       vided in section 586F, nothing in this subchapter  
14       shall be construed to affect the authority of the Sec-  
15       retary under this Act or the Public Health Service  
16       Act (42 U.S.C. 201 et seq.) with respect to a drug  
17       other than a nonprescription sunscreen.

18               “(4) *EFFECT ON DRUGS OTHERWISE AP-*  
19       *PROVED.*—Nothing in this subchapter shall affect the  
20       marketing of a drug approved under section 505 of  
21       this Act or section 351 of the Public Health Service  
22       Act.

23               “(c) *TIMELINES.*—The timelines for the processes and  
24       procedures under paragraphs (1), (2), (5), and (6) of section  
25       586C(a) shall not apply to any requests submitted to the

1 *Secretary under section 586A after the date that is 6 years*  
2 *after the date of enactment of the Sunscreen Innovation Act.*

3 **“SEC. 586E. SUNSCREEN MONOGRAPH.**

4       “(a) *IN GENERAL.*—Not later than 5 years after the  
5 *date of enactment of the Sunscreen Innovation Act, the Sec-*  
6 *retary shall amend and finalize regulations under part 352*  
7 *of title 21, Code of Federal Regulations concerning non-*  
8 *prescription sunscreen that are effective not later than 5*  
9 *years after such date of enactment. The Secretary shall pub-*  
10 *lish such regulations not less than 30 calendar days before*  
11 *the effective date of such regulations.*

12       “(b) *REPORTS.*—If the regulations promulgated under  
13 *subsection (a) do not include provisions related to the effec-*  
14 *tiveness of various sun protection factor levels, and do not*  
15 *address all dosage forms known to the Secretary to be used*  
16 *in sunscreens marketed in the United States without a new*  
17 *drug approval under section 505, the Secretary shall submit*  
18 *a report to the Committee on Health, Education, Labor,*  
19 *and Pensions of the Senate and the Committee on Energy*  
20 *and Commerce of the House of Representatives on the ra-*  
21 *tionale for such provisions not being included in such regu-*  
22 *lations, and a plan and timeline to compile any informa-*  
23 *tion necessary to address such provisions through final reg-*  
24 *ulations.”.*

1       (b) *RULES OF CONSTRUCTION.*—*Nothing in the*  
 2 *amendment made by this section shall be construed to—*

3           (1) *limit the right of a sponsor (as defined in*  
 4 *section 586(8) of the Federal Food, Drug, and Cos-*  
 5 *metic Act, as added by subsection (a)) to request that*  
 6 *the Secretary of Health and Human Services convene*  
 7 *an advisory committee; or*

8           (2) *limit the authority of the Secretary of Health*  
 9 *and Human Services to meet with a sponsor (as de-*  
 10 *fined in section 586(8) of the Federal Food, Drug,*  
 11 *and Cosmetic Act, as added by subsection (a)).*

12 **SEC. 3. NON-SUNSCREEN TIME AND EXTENT APPLICA-**  
 13 **TIONS.**

14       *Subchapter I of chapter V of the Federal Food, Drug,*  
 15 *and Cosmetic Act, as added by section 2, is amended by*  
 16 *adding at the end the following:*

17 **“SEC. 586F. NON-SUNSCREEN TIME AND EXTENT APPLICA-**  
 18 **TIONS.**

19       “(a) *PENDING TIME AND EXTENT APPLICATIONS.*—

20           “(1) *IN GENERAL.*—

21               “(A) *REQUEST FOR FRAMEWORK FOR RE-*  
 22 *VIEW.*—*If, prior to the date of enactment of the*  
 23 *Sunscreen Innovation Act, an application was*  
 24 *submitted pursuant to section 330.14 of title 21,*  
 25 *Code of Federal Regulations for a GRASE deter-*

1            *mination for a drug other than a nonprescrip-*  
2            *tion sunscreen active ingredient or combination*  
3            *of nonprescription sunscreen active ingredients*  
4            *and such drug was found to be eligible to be con-*  
5            *sidered for inclusion in the over-the-counter drug*  
6            *monograph system pursuant to section 330.14 of*  
7            *title 21, Code of Federal Regulations, the sponsor*  
8            *of such application may request that the Sec-*  
9            *retary provide a framework under paragraph (2)*  
10           *for the review of such application.*

11            *“(B) REQUEST REQUIREMENTS.—A request*  
12            *for a framework for review of an application*  
13            *made under subparagraph (A) shall be made*  
14            *within 180 calendar days of the date of enact-*  
15            *ment of the Sunscreen Innovation Act and shall*  
16            *include the preference of such sponsor as to*  
17            *whether such application is reviewed by the Sec-*  
18            *retary in accordance with—*

19            *“(i) the processes and procedures set*  
20            *forth for pending requests under section*  
21            *586C(b), except that specific timelines shall*  
22            *be determined in accordance with other ap-*  
23            *plicable requirements under this section;*

24            *“(ii) the processes and procedures set*  
25            *forth under part 330 of title 21, Code of*

1           *Federal Regulations (or any successor regu-*  
2           *lations);*

3           “(iii) *an initial filing determination*  
4           *under the processes and procedures de-*  
5           *scribed in section 586B(b) and the processes*  
6           *and procedures set forth for pending re-*  
7           *quests under section 586C(b), except that*  
8           *specific timelines shall be determined in ac-*  
9           *cordance with other applicable requirements*  
10          *under this section; or*

11          “(iv) *an initial filing determination*  
12          *under the processes and procedures de-*  
13          *scribed in section 586B(b) and the processes*  
14          *and procedures set forth under part 330 of*  
15          *title 21, Code of Federal Regulations (or*  
16          *any successor regulations).*

17          “(C) *NO REQUEST.—If a sponsor described*  
18          *in subparagraph (A) does not make such request*  
19          *within 180 calendar days of the date of enact-*  
20          *ment of the Sunscreen Innovation Act, such ap-*  
21          *plication shall be reviewed by the Secretary in*  
22          *accordance with the timelines of the applicable*  
23          *regulations when such regulations are finalized*  
24          *under subsection (b).*



1           “(2) *FRAMEWORK.*—Not later than 1 year after  
2           the date of enactment of the Sunscreen Innovation  
3           Act, the Secretary shall provide, in writing, a frame-  
4           work to each sponsor that submitted a request under  
5           paragraph (1). Such framework shall set forth the  
6           various timelines, in calendar days, with respect to  
7           the processes and procedures for review under clauses  
8           (i), (ii), (iii), and (iv) of paragraph (1)(B) and—

9                   “(A) such timelines shall account for the  
10                  considerations under paragraph (5); and

11                  “(B) the timelines for the various processes  
12                  and procedures shall not be shorter than the  
13                  timelines set forth for pending requests under  
14                  sections 586B(b) and 586C(b), as applicable.

15           “(3) *GOVERNING PROCESSES AND PROCEDURES*  
16           *FOR REVIEW.*—

17                   “(A) *ELECTION.*—Not later than 60 cal-  
18                  endar days after the Secretary provides a frame-  
19                  work to a sponsor under paragraph (2), such  
20                  sponsor may provide an election to the Secretary  
21                  regarding the processes and procedures for review  
22                  under clause (i), (ii), (iii), or (iv) of paragraph  
23                  (1)(B). If such sponsor makes such election, the  
24                  Secretary shall review the application that is the  
25                  subject of such election pursuant to the processes

1           *and procedures elected by such sponsor and the*  
2           *applicable timelines in calendar days set forth*  
3           *under such framework, which the Secretary shall*  
4           *confirm in writing to the sponsor not later than*  
5           *the date upon which the Secretary provides a re-*  
6           *port under paragraph (4). If such sponsor does*  
7           *not make such election, such application shall be*  
8           *reviewed by the Secretary in accordance with the*  
9           *timelines of the applicable regulations when such*  
10          *regulations are finalized under subsection (b).*

11           “(B) *DIFFERENT PROCESSES AND PROCE-*  
12          *DURES.—At any time during review of an appli-*  
13          *cation, the Secretary may review such applica-*  
14          *tion under different processes and procedures*  
15          *under clause (i), (ii), (iii), or (iv) of paragraph*  
16          *(1)(B) than the processes and procedures the*  
17          *sponsor elected in accordance with subparagraph*  
18          *(A), so long as the Secretary proposes, in writ-*  
19          *ing, the change and the sponsor agrees, in writ-*  
20          *ing, to such change.*

21           “(C) *INCLUSION OF INGREDIENTS IN MONO-*  
22          *GRAPHS.—If the sponsor elects to use the proc-*  
23          *esses and procedures for review in accordance*  
24          *with clause (i) or (iii) of paragraph (1)(B), the*  
25          *Secretary may incorporate any resulting final*

1           *order into a regulation addressing the conditions*  
2           *under which other drugs in the same therapeutic*  
3           *category are GRASE and not misbranded, in-*  
4           *cluding through direct final rulemaking, and the*  
5           *final order so incorporated shall cease to be effec-*  
6           *tive on the effective date of the final regulation*  
7           *that addresses such drug.*

8           “(4) *LETTER REGARDING PENDING APPLICA-*  
9           *TIONS.—Not later than 18 months after the date of*  
10          *enactment of the Sunscreen Innovation Act, the Sec-*  
11          *retary shall report to the Committee on Health, Edu-*  
12          *cation, Labor, and Pensions of the Senate and the*  
13          *Committee on Energy and Commerce of the House of*  
14          *Representatives, in writing, regarding all pending*  
15          *applications subject to paragraph (1). In such letter,*  
16          *the Secretary shall provide a report on the review of*  
17          *such applications, including the timelines, in cal-*  
18          *endar days, for the review and GRASE determination*  
19          *for each application. Such timelines shall account for*  
20          *the considerations under paragraph (5).*

21          “(5) *TIMELINES.—The timelines in calendar*  
22          *days established by the Secretary pursuant to this*  
23          *subsection—*

1           “(A) may vary based on the content, com-  
2           plexity, and format of the application submitted  
3           to the Secretary; and

4           “(B) shall—

5           “(i) reflect the public health priorities  
6           of the Food and Drug Administration, in-  
7           cluding the potential public health benefits  
8           posed by the inclusion of additional drugs  
9           in the over-the-counter drug monograph sys-  
10          tem;

11          “(ii) take into consideration the re-  
12          sources available to the Secretary for car-  
13          rying out such priorities and the processes  
14          and procedures described in paragraphs  
15          (1)(B) and (2); and

16          “(iii) be reasonable, taking into consid-  
17          eration the requirements described in  
18          clauses (i) and (ii).

19          “(b) *NEW TIME AND EXTENT APPLICATIONS.*—

20          “(1) *IN GENERAL.*—Not later than 18 months  
21          after the date of enactment of the Sunscreen Innova-  
22          tion Act, the Secretary shall issue proposed regula-  
23          tions establishing timelines for the review of applica-  
24          tions for *GRASE* determinations for drugs other than  
25          nonprescription sunscreen active ingredients or com-

1        *binations of nonprescription sunscreen active ingredi-*  
2        *ents that are submitted to the Secretary after the date*  
3        *of enactment of the Sunscreen Innovation Act, under*  
4        *section 330.14 of title 21, Code of Federal Regulations*  
5        *(or any successor regulations), and that are found to*  
6        *be eligible to be considered for inclusion in the over-*  
7        *the-counter drug monograph system pursuant to sec-*  
8        *tion 330.14 of title 21, Code of Federal Regulations*  
9        *(or any successor regulations), or that are subject to*  
10       *this subsection pursuant to paragraph (1) or (3) of*  
11       *subsection (a), as applicable, providing—*

12                *“(A) timely and efficient completion of eval-*  
13                *uations of applications under section 330.14 of*  
14                *title 21, Code of Federal Regulations (or any*  
15                *successor regulations) for drugs other than sun-*  
16                *screens; and*

17                *“(B) timely and efficient completion of the*  
18                *review of the safety and effectiveness submissions*  
19                *pursuant to such applications, including estab-*  
20                *lishing—*

21                        *“(i) reasonable timelines, in calendar*  
22                        *days, for the applicable proposed and final*  
23                        *regulations for applications of various con-*  
24                        *tent, complexity, and format, and timelines*

1           *for internal procedures related to such proc-*  
2           *esses; and*

3           “(ii) *measurable metrics for tracking*  
4           *the extent to which the timelines set forth in*  
5           *the regulations are met.*

6           “(2) *TIMELINES.—The timelines in calendar*  
7           *days established in the regulations under paragraph*  
8           *(1)—*

9           “(A) *may vary based on the content, com-*  
10          *plexity, and format of the application submitted*  
11          *to the Secretary; and*

12          “(B) *shall—*

13               “(i) *reflect the public health priorities*  
14               *of the Food and Drug Administration, in-*  
15               *cluding the potential public health benefits*  
16               *posed by the inclusion of additional drugs*  
17               *in the over-the-counter drug monograph sys-*  
18               *tem;*

19               “(ii) *take into consideration the re-*  
20               *sources available to the Secretary for car-*  
21               *rying out such priorities and the processes*  
22               *and procedures described in paragraph (1);*  
23               *and*

1                   “(iii) be reasonable, taking into consid-  
2                   eration the requirements described in  
3                   clauses (i) and (ii).

4                   “(3) *PROCEDURE*.—In promulgating regulations  
5                   under this subsection, the Secretary shall issue a no-  
6                   tice of proposed rulemaking that includes a copy of  
7                   the proposed regulation, provide a period of not less  
8                   than 60 calendar days for comments on the proposed  
9                   regulation, and publish the final regulation not less  
10                  than 30 calendar days before the effective date of the  
11                  regulation.

12                  “(4) *RESTRICTIONS*.—Notwithstanding any other  
13                  provision of law, the Secretary shall promulgate regu-  
14                  lations implementing this section only as described in  
15                  paragraphs (1), (2), and (3).

16                  “(5) *FINAL REGULATIONS*.—The Secretary shall  
17                  finalize the regulations under this section not later  
18                  than 27 months after the date of enactment of the  
19                  *Sunscreen Innovation Act*.”.

20 **SEC. 4. REPORTS.**

21                  “(a) *INITIAL GAO REPORT*.—Not later than 3 years  
22                  after the date of enactment of this Act, the Comptroller Gen-  
23                  eral of the United States shall submit to the Committee on  
24                  Health, Education, Labor, and Pensions of the Senate and  
25                  the Committee on Energy and Commerce of the House of

1 *Representatives a report reviewing the overall progress of*  
2 *the Secretary of Health and Human Services in carrying*  
3 *out subchapter I of chapter V of the Federal Food, Drug,*  
4 *and Cosmetic Act (as added by section 2 and amended by*  
5 *section 3 and subsection (c)), including findings on and rec-*  
6 *ommendations with respect to—*

7           (1) *the progress made in completing the review*  
8 *of requests under subchapter I of chapter V of the*  
9 *Federal Food, Drug, and Cosmetic Act, including*  
10 *pending requests, and the feasibility of the timelines*  
11 *associated with such subchapter;*

12           (2) *the role of the Office of the Commissioner of*  
13 *Food and Drugs in issuing determinations with re-*  
14 *spect to requests reviewed under such subchapter, in-*  
15 *cluding the number of requests transferred to the Of-*  
16 *fice of the Commissioner under section 586C of such*  
17 *Act;*

18           (3) *the extent to which advisory committees were*  
19 *convened by the Secretary regarding requests under*  
20 *subchapter I of chapter V of the Federal Food, Drug,*  
21 *and Cosmetic Act, including pending requests; and*

22           (4) *the types of metrics that have been, or should*  
23 *be, established for the review of time and extent appli-*  
24 *cations.*



1           (b) *SUBSEQUENT GAO REPORT.*—Not later than 5½  
2 years after the date of enactment of this Act, the Comp-  
3 troller General of the United States shall submit to the Com-  
4 mittee on Health, Education, Labor, and Pensions of the  
5 Senate and the Committee on Energy and Commerce of the  
6 House of Representatives a report reviewing the overall  
7 progress of the Secretary of Health and Human Services  
8 in carrying out subchapter I of chapter V of the Federal  
9 Food, Drug, and Cosmetic Act (as added by section 2 and  
10 amended by section 3 and subsection (c)) and the regulation  
11 of over-the-counter drug products, including findings on  
12 and recommendations with respect to—

13           (1) updates on the matters reported on by the  
14 Comptroller General under subsection (a);

15           (2) significant factors impacting the ability of  
16 the Food and Drug Administration to fulfill the mis-  
17 sion of the agency with regard to the regulation of  
18 over-the-counter drug products, including finalizing  
19 outstanding monographs and responding to emerging  
20 and novel safety issues;

21           (3) the performance of the Secretary in carrying  
22 out section 586E of the Federal Food, Drug, and Cos-  
23 metic Act;

1           (4) *the types of metrics that have been, or should*  
2 *be, established for the review and regulation of over-*  
3 *the-counter drug products; and*

4           (5) *timeliness, efficiency, and accountability in*  
5 *reviewing time and extent applications and safety*  
6 *and effectiveness reviews for over-the-counter drug*  
7 *products.*

8           (c) *FDA REPORT.*—*Subchapter I of chapter V of the*  
9 *Federal Food, Drug, and Cosmetic Act, as amended by sec-*  
10 *tion 3, is further amended by adding at the end the fol-*  
11 *lowing:*

12 **“SEC. 586G. REPORT.**

13           “(a) *IN GENERAL.*—

14           “(1) *IN GENERAL.*—*Not later than 18 months*  
15 *after the date of enactment of the Sunscreen Innova-*  
16 *tion Act, and on the dates that are 2 and 4 years*  
17 *thereafter, the Secretary shall issue a report to the*  
18 *Committee on Health, Education, Labor, and Pen-*  
19 *sions of the Senate and the Committee on Energy and*  
20 *Commerce of the House of Representatives describing*  
21 *actions taken under this subchapter.*

22           “(2) *CONTENTS.*—*The reports under this sub-*  
23 *section shall include—*

24           “(A) *a review of the progress made in*  
25 *issuing GRASE determinations for pending re-*

1            *quests, including the number of pending re-*  
2            *quests—*

3                    *“(i) reviewed and the decision times*  
4                    *for each request, measured from the date of*  
5                    *the original request for an eligibility deter-*  
6                    *mination submitted by the sponsor;*

7                    *“(ii) resulting in a determination that*  
8                    *the nonprescription sunscreen active ingre-*  
9                    *redient or combination of nonprescription*  
10                   *sunscreen active ingredients is GRASE and*  
11                   *is not misbranded;*

12                   *“(iii) resulting in a determination that*  
13                   *the nonprescription sunscreen active ingre-*  
14                   *redient or combination of nonprescription*  
15                   *sunscreen active ingredients is not GRASE*  
16                   *and is misbranded and the reasons for such*  
17                   *determinations; and*

18                   *“(iv) for which a determination has*  
19                   *not been made, and an explanation for the*  
20                   *delay, a description of the current status of*  
21                   *each such request, and the length of time*  
22                   *each such request has been pending, meas-*  
23                   *ured from the date of original request for an*  
24                   *eligibility determination by the sponsor;*

1           “(B) a review of the progress made in  
2           issuing GRASE determinations for requests not  
3           included in the reporting under subparagraph  
4           (A), including the number of such requests—

5                   “(i) reviewed and the decision times  
6                   for each request;

7                   “(ii) resulting in a determination that  
8                   the nonprescription sunscreen active ingre-  
9                   dient, combination of nonprescription sun-  
10                   screen active ingredients, or other ingredient  
11                   is GRASE and is not misbranded;

12                   “(iii) resulting in a determination that  
13                   the nonprescription sunscreen active ingre-  
14                   dient, combination of nonprescription sun-  
15                   screen active ingredients, or other ingredient  
16                   is not GRASE and is misbranded and the  
17                   reasons for such determinations; and

18                   “(iv) for which a determination has  
19                   not been made, and an explanation for the  
20                   delay, a description of the current status of  
21                   each such request, and the length of time  
22                   each such request has been pending, meas-  
23                   ured from the date of original request for an  
24                   eligibility determination by the sponsor;

1           “(C) *an annual accounting (including in-*  
2 *formation from years prior to the date of enact-*  
3 *ment of the Sunscreen Innovation Act where*  
4 *such information is available) of the total num-*  
5 *ber of requests submitted, pending, or completed*  
6 *under this subchapter, including whether such*  
7 *requests were the subject of an advisory com-*  
8 *mittee convened by the Secretary;*

9           “(D) *a description of the staffing and re-*  
10 *sources relating to the costs associated with the*  
11 *review and decisionmaking pertaining to re-*  
12 *quests under this subchapter;*

13           “(E) *a review of the progress made in meet-*  
14 *ing the deadlines with respect to processing re-*  
15 *quests under this subchapter; and*

16           “(F) *to the extent the Secretary determines*  
17 *appropriate, recommendations for process im-*  
18 *provements in the handling of requests under*  
19 *this subchapter, including the advisory com-*  
20 *mittee review process.*

21           “(b) *METHOD.—The Secretary shall publish the re-*  
22 *ports under subsection (a) in the manner the Secretary de-*  
23 *termines to be the most effective for efficiently disseminating*  
24 *the report, including publication of the report on the Inter-*  
25 *net website of the Food and Drug Administration.”.*

Calendar No. 568

113<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION  
**S. 2141**

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## **A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to provide an alternative process for review of safety and effectiveness of nonprescription sunscreen active ingredients and for other purposes.

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SEPTEMBER 17 (legislative day, SEPTEMBER 16), 2014  
Reported with an amendment