II

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113TH CONGRESS
2D 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.

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]

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.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Sunscreen Innovation Act''.

SEC. 2. REGULATION OF NONPRESCRIPTION SUNSCREEN ACTIVE INGREDIENTS.

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

''SEC. 524B. PROCEDURES FOR CLASSIFYING SUNSCREEN ACTIVE INGREDIENTS.

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

''(b) DEFINITIONS.—

''(1) ACTIVE INGREDIENT.—The term 'active ingredient' means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body of humans or animals. The term includes components that may undergo chemical change in the manufacture of a drug and may be present in a drug in a modified form intended to furnish the specified activity or effect.

''(2) SUNSCREEN ACTIVE INGREDIENT.—The term 'sunscreen active ingredient' means an active ingredient that absorbs, reflects, or scatters radiation in the ultraviolet range at wavelengths from 290 to 400 nanometers.

''(3) SUNSCREEN CONDITION.—The term 'sunscreen condition' means a sunscreen active ingredient (or a combination of sunscreen active ingredients), dosage form, dosage strength, or route of administration, marketed for a specific nonprescription use.

''(c) CRITERIA FOR ELIGIBILITY.—To be eligible for review under this section, a sunscreen condition shall—

''(1) not be included in the stayed sunscreen monograph; and

''(2) have been marketed as a nonprescription sunscreen condition in the United States or at least 1 other country, or marketed as a cosmetic or dietary supplement in 1 or more counties other than the United States—

''(A) for a minimum of 5 continuous years; and

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

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

''(d) APPLICATION FOR ELIGIBILITY.—

''(1) IN GENERAL.—A sponsor of a nonprescription sunscreen condition described in subsection (c) desiring to market such condition in the United States may submit an application to the Secretary, in such manner and containing such information as required by the Secretary, including the following:

''(A) Basic information about the sunscreen condition (including a description of each active ingredient, pharmacologic class, intended nonprescription use, nonprescription strength and dosage form, route of administration, and directions for use).

''(B) A detailed chemical description of the sunscreen active ingredient that includes a full description of the drug substance, including its physical and chemical characteristics, the method of synthesis (or isolation) and purification of the drug substance, and any specifications and analytical methods necessary to ensure the identity, strength, quality, and purity of the drug substance, including reference to the current edition of the official National Formulary,

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

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

"(D) The cumulative total number of dosage units sold for each dosage form of the sunscreen condition, including total weight of the active ingredient, package size for each dosage form in which the condition is marketed as nonprescription, and an estimate of the minimum number of potential consumer exposures to the condition.

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

"(F) A list of all countries in which the sunscreen condition has been withdrawn from marketing or in which an application for nonprescription marketing approval has been denied and an explanation for such withdrawal or application denial.

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

‘‘(A) IN GENERAL.—In the case of an application with respect to a nonprescription sunscreen condition that has not been marketed in the United States for 5 continuous years, in addition to the information required under paragraph (1), the sponsor shall submit the following information for each country in which the sunscreen condition has been marketed:

‘‘(i) The manner in which the sunscreen condition has been marketed to consumers. If the sunscreen condition is marketed to consumers as a nonprescription pharmacy only condition, the Secretary may require supplemental information.

‘‘(ii) A description of the population demographics and the source from which this information has been compiled, to ensure that the sunscreen condition's use can be reasonably extrapolated to the population of the United States.

‘‘(iii) A description of the country's system for identifying adverse drug experiences, especially those found in nonprescription marketing experience, including method of collection if applicable.

"(iv) A statement of how long the sunscreen condition has been marketed in each country and how long the current product labeling has been in use, accompanied by a copy of the current product labeling, including a translation into English of any labeling that is not in English, and a statement of whether the current product labeling has been authorized, accepted, or approved by a regulatory body in each country where the condition is marketed.

"(v) A list of all countries where the sunscreen condition is marketed as a prescription drug only and an explanation for such restriction.

"(B) SUNSCREEN CONDITIONS THAT HAVE BEEN MARKETED IN MORE THAN 5 COUNTRIES.—

"(i) IN GENERAL.—In the case of a sunscreen condition that has been marketed as a nonprescription sunscreen in more than 5 countries, with a minimum of 5 continuous years of marketing in at least one such country, the sponsor—

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

‘‘(aa) the country with a minimum of 5 continuous years of nonprescription marketing;

‘‘(bb) the country with the longest duration of marketing; and

‘‘(cc) the country with the most support for marketing, such as a large volume of sales with cultural diversity among users of the product; and

‘‘(II) shall explain the basis for the countries selected under subclause (I); and

‘‘(III) shall provide information from more than 5 countries if such information is needed to support the application.

‘‘(ii) REQUIREMENT.—If the sunscreen condition meets the criteria under 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~~

determine if the sunscreen condition is eligible for further review for safety and effectiveness. In the case of a sunscreen condition determined to be eligible, the Secretary shall publish a notice of eligibility in the Federal Register, and provide interested persons an opportunity to submit published and unpublished data related to the safety and effectiveness of the sunscreen condition for its intended nonprescription uses, in accordance with paragraph (2). In the case of a sunscreen condition determined not eligible, the Secretary shall issue a letter to the sponsor, which shall be made publicly available.

"(2) SAFETY AND EFFECTIVENESS DATA SUBMISSIONS.—

"(A) IN GENERAL.—Within 60 days of the publication in the Federal Register of an application deemed eligible, as described in paragraph (1), the sponsor and other interested parties shall submit safety and effectiveness data to the Secretary for further review, as described in subparagraph (B).

"(B) REQUIRED SUBMISSIONS REGARDING DATA.—Submissions under this paragraph shall include the following:

"(i) HUMAN SAFETY DATA.—

"(I) INDIVIDUAL ACTIVE COMPONENTS.—With respect to individual active components, controlled studies, partially controlled or uncontrolled studies, documented case reports, pertinent marketing experiences that may influence a determination as to the safety of each individual active component, and pertinent medical and scientific literature.

"(II) COMBINATIONS OF INDIVIDUAL ACTIVE COMPONENTS.—With respect to combinations of the individual active components, controlled studies, partially controlled or uncontrolled studies, documented case reports, pertinent marketing experiences that may influence a determination as to the safety of combinations of the individual active component, and pertinent medical and scientific literature.

"(ii) EFFICACY DATA.—

"(I) INDIVIDUAL ACTIVE COMPONENTS.—With respect to individual

active components, controlled studies, partially controlled or uncontrolled studies, documented case reports, pertinent marketing experiences that may influence a determination on the efficacy of each individual active component, pertinent medical and scientific literature.

''(II) COMBINATIONS OF INDIVIDUAL ACTIVE COMPONENTS.—With respect to combinations of the individual active components, controlled studies, partially controlled or uncontrolled studies, documented case reports, pertinent marketing experiences that may influence a determination on the efficacy of combinations of the individual active components, and pertinent medical and scientific literature.

''(iii) DATA SETTING FORTH MEDICAL RATIONALE AND PURPOSE.—A summary of the data and views setting forth the medical rationale and purpose (or lack thereof) for the sunscreen condition and the scientific basis (or lack thereof) for the con-

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

''(iv) OFFICIAL DRUG MONOGRAPH.—An applicable United States Pharmacopoeia or National Formulary for the sunscreen active ingredient or a proposed standard for inclusion in an article to be recognized in an official drug monograph for the active ingredient, including information showing that the official or proposed compendial monograph for the active ingredient is consistent with the active ingredient used in the studies establishing safety and effectiveness and with the active ingredient marketed in the nonprescription product to a material extent and for a material time. If differences exist between the official or proposed compendial monograph for the active ingredient and the active ingredient that is the subject of the application, sponsor shall explain such differences.

"(v) ADVERSE DRUG EXPERIENCES.—A list of all serious adverse drug experiences, as defined by the Secretary, from each country where the condition has been or is currently marketed as a prescription drug or as a nonprescription drug or product.

"(C) OPTIONAL ANIMAL SAFETY DATA.—In addition to the information required under subparagraph (B), the sponsor may submit information with respect to animal safety data, including controlled studies and partially controlled or uncontrolled studies, in the case of an application for individual active components, and controlled studies and partially controlled or uncontrolled studies in the case of an application for combinations of individual active components.

"(D) CONFIDENTIALITY OF SUBMISSIONS.—The Secretary shall make data and information submitted by the sponsor, or pursuant to a notice requesting safety and effectiveness data published in the Federal Register, publicly available, with redactions for confidential commercial information or trade secret in-

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

''(3) NEW SUNSCREEN CONDITION APPLICATION SUBMISSION TO THE ADVISORY COMMITTEE.—Not later than 30 days after the end of the public comment period described in paragraph (2), the Secretary shall submit the application and the safety and effectiveness data submitted under paragraph (2) to the Nonprescription Drugs Advisory Committee (referred to in this section as the 'advisory committee') for review.

''(g) PENDING SUNSCREEN CONDITION APPLICATIONS.—Not later than 30 days after the date of enactment of the Sunscreen Innovation Act, the Secretary shall submit to the advisory committee all safety and effectiveness data submitted with respect to each application for review of sunscreen conditions that the Secretary had determined, prior to the date of enactment of the Sunscreen Innovation Act, to be eligible for review of safety and effectiveness and for which the information required under subsection (f)(2) has been submitted to the Secretary prior to such date of enactment.

~~"(h) REVIEW AND RECOMMENDATION FOR NONPRESCRIPTION SUNSCREEN CONDITION.—~~

~~"(1) IN GENERAL.—The Secretary shall require the advisory committee to evaluate the safety and effectiveness data submitted in accordance with subsection (f)(2) or (g).~~

~~"(2) STANDARDS.—In evaluating a nonprescription sunscreen condition under paragraph (1), the advisory committee shall use the regulations in effect at the time of the application, including regulations with respect to—~~

~~"(A) the safety of the nonprescription sunscreen condition;~~

~~"(B) the effectiveness of the nonprescription sunscreen condition;~~

~~"(C) the benefit-to-risk ratio of the nonprescription sunscreen condition; and~~

~~"(D) the labeling of the nonprescription sunscreen condition.~~

~~"(3) COMMUNICATIONS BETWEEN ADVISORY COMMITTEE AND OTHER INDIVIDUALS WHO SUBMIT DATA.—The advisory committee shall have the authority to communicate with the sponsor and other individuals who submit data during the advisory~~

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

''(4) RECOMMENDATIONS.—

''(A) IN GENERAL.—For each such submission under subsection (f)(3) or (g), the advisory committee shall make one of the following recommendations to the Secretary:

''(i) The sunscreen condition is generally recognized as safe and effective (including any or all indications), including nonprescription sunscreen conditions for which a new drug application has been approved by the Secretary.

''(ii) Insufficient information has been provided to support a recommendation that the sunscreen condition is generally recognized as safe and effective (including any or all indications).

''(iii) The sunscreen condition is not generally recognized as safe and effective to be marketed or sold, unless an application with respect to such condition is approved under section 505(b).

''(B) TIMING.—The advisory committee shall make a recommendation under subpara-

graph (A) not later than 180 days after the advisory committee receives the application and data submitted under subsection (f)(3) or subsection (g).

"(C) RESUBMISSION OF DATA.—If the advisory committee recommends that insufficient information has been provided, in accordance with subparagraph (A)(ii), the advisory committee shall make such recommendation not later than 180 days after the date on which such additional information is submitted.

"(i) DETERMINATION BY THE CENTER FOR DRUG EVALUATION AND RESEARCH.—

"(1) IN GENERAL.—The Center for Drug Evaluation and Research shall respond to the recommendations of the advisory committee under subsection (h)(4) as follows:

"(A) In the case of a recommendation by the advisory committee described in clause (i) of subsection (h)(4), not later than 45 days after the advisory committee issues the recommendation, the Center for Drug Evaluation and Research shall issue a determination affirming or denying the recommendation of the advisory committee. If the Center for Drug

Evaluation and Research affirms the recommendation of the advisory committee, or if the Center for Drug Evaluation and Research takes no action regarding the recommendation within 45 days of receiving such recommendation, the nonprescription sunscreen condition shall be generally recognized as safe and effective, not misbranded, and permitted to be marketed and sold in accordance with all applicable rules and regulations for over-the-counter drugs.

''(B) In the case of a recommendation described in clause (ii) of such subsection, the Center for Drug Evaluation and Research shall issue a determination affirming or denying the recommendation of the advisory committee, to be made publicly available, within 45 days of receiving the recommendation, and inform the sponsor that the sponsor must submit additional information to the advisory committee in order to continue the review by the advisory committee.

''(C) In the case of a recommendation described in clause (iii) of such subsection, the Center for Drug Evaluation and Research shall

issue a determination affirming or denying the recommendation of the advisory committee, to be made publicly available, within 45 days of receiving such recommendation, and indicate whether such sunscreen condition determined to be not generally recognized as safe and effective to be marketed and sold, unless an application with respect to such condition is approved under section 505(b), or whether additional data must be submitted to the advisory committee.

"(2) SUPERVISORY REVIEW OF DETERMINATION.—

"(A) IN GENERAL.—Any person may request a supervisory review of a determination of the Center for Drug Evaluation and Research to not accept a recommendation of an advisory committee. Such review may be conducted at the next supervisory or higher level above the individual who made the determination.

"(B) REQUEST FOR SUPERVISORY REVIEW.—A request described in subparagraph (A) shall be made to the Secretary not later than 30 days after such decision and shall indicate in the request whether such person seeks

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

"(C) STANDARD OF SUPERVISORY REVIEW.—The Secretary shall be authorized to overturn a determination of the Center for Drug Evaluation and Research not to accept a recommendation of the advisory committee if the supervisory review results in a decision by the reviewer that the individual who made the determination did not provide reasonable and sufficient substantive support for the decision to disregard the advisory committee's recommendation.

"(D) SUPERVISORY REVIEW DECISION.—If the Secretary overturns a determination by the Center for Drug Evaluation and Research not to accept a favorable recommendation of an advisory committee, the nonprescription sunscreen condition shall be generally recognized as safe and effective, not misbranded, and permitted to

be marketed and sold in accordance with all applicable rules and regulations for over-the-counter drugs.

''(E) FINAL AGENCY ACTION.—A decision made through supervisory review shall constitute final agency action subject to judicial review.

''(j) REPORTS.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Sunscreen Innovation Act, on March 1, 2015, and every 2 years thereafter, the Secretary shall issue a report to Congress describing actions taken under this section.

''(2) CONTENTS.—The reports under paragraph (1) shall include—

''(A) a review of the progress made in issuing in a timely manner decisions on the safety and effectiveness for sunscreen conditions for applications pending as of the date of enactment of the Sunscreen Innovation Act, including the number of pending applications—

''(i) reviewed and the decision times for each application, measured from the date of original eligibility application submission by the sponsor;

"(ii) resulting in a determination of generally recognized as safe and effective and not misbranded;

"(iii) resulting in a determination of not generally recognized as safe and effective and not misbranded and the reasons for such determinations; and

"(iv) for which a determination has not been made, an explanation for the delay, a description of the current status of each such application, and the length of time such applications have been pending, measured from the date of original eligibility application submission by the sponsor;

"(B) a review of the progress made in issuing in a timely manner a decision on safety and effectiveness for sunscreen condition applications submitted after the date of enactment of the Sunscreen Innovation Act, including the number of such applications—

"(i) reviewed and the decision times for each application;

~~"(ii) resulting in a determination of generally recognized as safe and effective and not misbranded; and~~

~~"(iii) resulting in a determination of not generally recognized as safe and effective and not misbranded and the reasons for such determinations;~~

~~"(C) a description of the staffing and resources relating to the costs associated with the review and decisionmaking pertaining to applications;~~

~~"(D) a review of the progress in meeting the deadlines with respect to processing applications under this section;~~

~~"(E) to the extent the Secretary determines appropriate, recommendations for process improvements in the handling of pending and new applications; and~~

~~"(F) recommendations for expanding the applicability of this section to nonprescription active ingredients or conditions that are not related to the sunscreen category of over-the-counter drugs.~~

~~"(3) METHOD.—The Secretary shall publish the reports required under this subsection in the manner~~

the Secretary determines to be the most effective for efficiently disseminating the report, including publication of the report on the Internet website of the Food and Drug Administration.

''(k) RULES OF CONSTRUCTION.—

''(1) AUTHORITY TO WITHDRAW OR SUSPEND.—Nothing in this section shall be construed to alter the Secretary's authority to withdraw or suspend from the market a drug that the Secretary determines to be unsafe or ineffective.

''(2) OTHER CONDITIONS.—Nothing in the section shall affect the Secretary's authority to review nonprescription conditions other than sunscreen conditions.''.

SEC. 3. SUNSCREEN TESTING AND LABELING.

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

(1) the appropriate testing and labeling requirements for sunscreens sold as an aerosol; and

(2) whether sunscreen may contain a label indicating a sun protection factor greater than 50.

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Sunscreen Innovation Act''.

SEC. 2. REGULATION OF NONPRESCRIPTION SUNSCREEN ACTIVE INGREDIENTS.

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

"Subchapter I—Nonprescription Sunscreen and Other Active Ingredients

"SEC. 586. DEFINITIONS.

"In this subchapter—

"(1) the term 'Advisory Committee' means the Nonprescription Drug Advisory Committee of the Food and Drug Administration or any successor to such Committee;

"(2) the term 'final sunscreen order' means an order published by the Secretary in the Federal Register containing information stating that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients—

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

"(B) is not GRASE and is misbranded;

"(3) the term 'GRASE' means generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condi-

tions prescribed, recommended, or suggested in the labeling of a drug as described in section 201(p);

"(4) the term 'GRASE determination' means, with respect to a nonprescription active ingredient or a combination of nonprescription active ingredients, a determination of whether such ingredient or combination of ingredients is GRASE;

"(5) the term 'nonprescription' means not subject to section 503(b)(1);

"(6) the term 'pending request' means each request with respect to a nonprescription sunscreen active ingredient submitted under section 330.14 of title 21, Code of Federal Regulations (as in effect on the date of enactment of the Sunscreen Innovation Act) for consideration for inclusion in the over-the-counter drug monograph system—

"(A) that was determined to be eligible for such review by publication of a notice of eligibility in the Federal Register prior to the date of enactment of such Act; and

"(B) for which safety and effectiveness data have been submitted to the Secretary prior to such date of enactment;

"(7) the term 'proposed sunscreen order' means an order containing a tentative determination pub-

lished by the Secretary in the Federal Register containing information proposing that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients—

"(A) is GRASE and is not misbranded if marketed in accordance with such order;

"(B) is not GRASE and is misbranded; or

"(C) is not GRASE and is misbranded because the data are insufficient to classify such ingredient or combination of ingredients as GRASE and not misbranded and additional information is necessary to allow the Secretary to determine otherwise;

"(8) the term 'sponsor' means the person that submitted—

"(A) a request under section 586A;

"(B) a pending request; or

"(C) any other application subject to this subchapter;

"(9) the term 'sunscreen' means a drug containing one or more sunscreen active ingredients; and

"(10) the term 'sunscreen active ingredient' means an active ingredient that is intended for application to the skin of humans for purposes of absorbing, reflecting, or scattering ultraviolet radiation.

"SEC. 586A. SUBMISSION OF REQUESTS.

"Any person may submit a request to the Secretary for a determination of whether a nonprescription sunscreen active ingredient or a combination of nonprescription sunscreen active ingredients, for use under specified conditions, to be prescribed, recommended, or suggested in the labeling thereof (including dosage form, dosage strength, and route of administration) is GRASE and should be included in part 352 of title 21, Code of Federal Regulations (or any successor regulations) concerning nonprescription sunscreen.

"SEC. 586B. ELIGIBILITY DETERMINATIONS; DATA SUBMISSION; FILING.

"(a) ELIGIBILITY DETERMINATIONS.—

"(1) IN GENERAL.—Not later than 60 calendar days after the date of receipt of a request under section 586A, the Secretary shall—

"(A) determine, in accordance with paragraph (2), whether the request is eligible for further review under subsection (b) and section 586C;

"(B) notify the sponsor of the determination of the Secretary; and

"(C) make such determination publicly available in accordance with paragraph (3) and subsection (b)(1).

"(2) CRITERIA FOR ELIGIBILITY.—

"(A) IN GENERAL.—To be eligible for review under subsection (b) and section 586C, a request shall be for a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients, for use under specified conditions, to be prescribed, recommended, or suggested in the labeling thereof, that—

"(i) is not included in part 352 of title 21, Code of Federal Regulations (or any successor regulations) concerning nonprescription sunscreen; and

"(ii) has been used to a material extent and for a material time under such conditions, as described in section 201(p)(2).

"(B) ESTABLISHMENT OF TIME AND EXTENT.—A sponsor shall include in a request under section 586A the information required under section 330.14 of title 21, Code of Federal Regulations (or any successor regulations) to meet the standard described in subparagraph (A)(ii).

"(3) PUBLIC AVAILABILITY.—

"(A) REDACTIONS FOR CONFIDENTIAL INFORMATION.—If a nonprescription sunscreen ac-

tive ingredient or combination of nonprescription sunscreen active ingredients is determined under paragraph (1)(A) to be eligible for further review, the Secretary shall make the request publicly available, with redactions for information that is treated as confidential under section 552(b) of title 5, United States Code, section 1905 of title 18, United States Code, or section 301(j) of this Act.

"(B) IDENTIFICATION OF CONFIDENTIAL INFORMATION BY SPONSOR.—At the time that a request is made under section 586A, the sponsor of such request shall identify any information that such sponsor considers to be confidential information described in subparagraph (A).

"(C) CONFIDENTIALITY DURING ELIGIBILITY REVIEW.—The information contained in a request under section 586A shall remain confidential during the Secretary's consideration under this section of whether the request is eligible for further review consistent with section 330.14 of title 21, Code of Federal Regulations (or any successor regulations).

"(b) DATA SUBMISSION AND FILING OF REQUESTS.—

"(1) IN GENERAL.—In the case of a request under section 586A that is determined to be eligible under subsection (a) for further review under this section and section 586C, the Secretary shall, in notifying the public under subsection (a)(1)(C) of such eligibility determination, post the eligibility determination on the Internet website of the Food and Drug Administration, invite the sponsor of such request and any other interested party to submit comments, and provide a period of not less than 45 calendar days for comments in support of or otherwise relating to a GRASE determination, including published and unpublished data and other information related to the safety and efficacy of such request.

"(2) FILING DETERMINATION.—Not later than 60 calendar days after the submission of data and other information described in paragraph (1) by the sponsor, the Secretary shall determine whether the data and other information submitted by the sponsor under this section are sufficiently complete, including being formatted in a manner that enables the Secretary to determine the completeness of such data and information, to enable the Secretary to conduct a substantive review under section 586C with respect to such request. Not later than 60 calendar days after the sub-

mission of data and other information described in paragraph (1) by the sponsor, if the Secretary determines—

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

"(i) issue a written notification to the sponsor of the determination to file such request, and make such notification publicly available; and

"(ii) file such request made under section 586A; or

"(B) that such data and other information are not sufficiently complete, the Secretary shall issue a written notification to the sponsor of the determination to refuse to file the request, which shall include the reasons for the refusal, including why such data and other information are not sufficiently complete, and make such notification publicly available.

"(3) REFUSAL TO FILE A REQUEST.—

"(A) REQUEST FOR MEETINGS; SUBMISSION OF ADDITIONAL DATA OR OTHER INFORMATION.—If the Secretary refuses to file a request made under section 586A, the sponsor may—

"(i) within 30 calendar days of receipt of written notification of such refusal, request, in writing, a meeting with the Secretary regarding the filing determination; and

"(ii) submit additional data or other information.

"(B) MEETINGS.—

"(i) IN GENERAL.—If a sponsor seeks a meeting under subparagraph (A)(i), the Secretary shall convene the meeting within 30 calendar days of the request for such meeting.

"(ii) ACTIONS AFTER MEETING.—Following any meeting held under clause (i)—

"(I) the Secretary may file the request within 60 calendar days;

"(II) the sponsor may submit additional data or other information; or

"(III) if the sponsor elects, within 120 calendar days, to have the Secretary file the request (with or without amendments to correct any purported deficiencies to the request)—

"(aa) the Secretary shall file the request over protest, not later than 30 calendar days after the sponsor makes such election;

"(bb) at the time of filing, the Secretary shall provide written notification of such filing to the sponsor; and

"(cc) the Secretary shall make such notification publicly available.

"(iii) REQUESTS FILED OVER PROTEST.—The Secretary shall not require the sponsor to resubmit a copy of the request for purposes of filing a request filed over protest, as described in clause (ii)(III).

"(C) SUBMISSIONS OF ADDITIONAL DATA OR OTHER INFORMATION.—Within 60 calendar days of any submission of additional data or other information under subparagraph (A)(ii) or (B)(ii)(II), the Secretary shall reconsider the previous determination made under paragraph (2) with respect to the applicable request and make a new determination in accordance with paragraph (2).

"(4) PUBLIC AVAILABILITY.—

"(A) REDACTIONS FOR CONFIDENTIAL INFORMATION.—After the period of confidentiality described in subsection (a)(3)(C), the Secretary shall make data and other information submitted in connection with a request under section 586A publicly available, with redactions for information that is treated as confidential under section 552(b) of title 5, United States Code, section 1905 of title 18, United States Code, or section 301(j) of this Act.

"(B) IDENTIFICATION OF CONFIDENTIAL INFORMATION BY SPONSOR.—A person submitting information under this section shall identify at the time of such submission the portions of such information that the person considers to be confidential information described in subparagraph (A).

"SEC. 586C. GRASE DETERMINATION.

"(a) REVIEW OF NEW REQUEST.—

"(1) PROPOSED SUNSCREEN ORDER.—In the case of a request under section 586A, not later than 300 calendar days after the date on which such request is filed under subsection (b)(2)(A) or (b)(3)(B)(ii)(III) of section 586B, the Secretary—

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

"(B) shall complete the review of such request and issue a proposed sunscreen order with respect to such request.

"(2) PROPOSED SUNSCREEN ORDER BY COMMISSIONER.—If the Secretary does not issue a proposed sunscreen order under paragraph (1)(B) within such 300-day period, the sponsor of such request may notify the Office of the Commissioner of such request and request review by the Office of the Commissioner. If such sponsor so notifies the Office of the Commissioner, the Commissioner shall, not later than 60 calendar days after the date of notification under this paragraph, issue a proposed sunscreen order with respect to such request.

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

"(4) MEETING.—A sponsor may request, in writing, a meeting with respect to a proposed sunscreen order issued under this subsection and described in subparagraph (B) or (C) of section 586(7), not later than 30 calendar days after the Secretary issues such

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

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

"(A) the Secretary shall issue a final sunscreen order—

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

"(ii) in the case of a proposed sunscreen order described in subparagraph (C) of section 586(7), not later than 210 calendar days after the date on which the sponsor submits the additional information requested pursuant to such proposed sunscreen order; or

"(B) if the Secretary does not issue such final sunscreen order within such 90- or 210-calendar-day period, as applicable, the sponsor of such request may notify the Office of the Com-

missioner of such request and request review by the Office of the Commissioner.

"(6) FINAL SUNSCREEN ORDER BY COMMISSIONER.—The Commissioner shall issue a final sunscreen order with respect to a proposed sunscreen order subject to paragraph (5)(B) not later than 60 calendar days after the date of notification under such paragraph.

"(b) REVIEW OF PENDING REQUESTS.—

"(1) IN GENERAL.—The review of a pending request shall be carried out by the Secretary in accordance with this subsection.

"(2) INAPPLICABILITY OF SECTIONS 586A AND 586B.—Sections 586A and 586B shall not apply with respect to any pending request.

"(3) FEEDBACK LETTERS AS PROPOSED SUNSCREEN ORDER.—Notwithstanding the requirements of section 586(7), a letter issued pursuant to section 330.14(g) of title 21, Code of Federal Regulations before the date of enactment of the Sunscreen Innovation Act, with respect to a pending request, shall be deemed to be a proposed sunscreen order and displayed on the Internet website of the Food and Drug Administration. Notification of the availability of such letter shall be published in the Federal Register

not later than 45 calendar days after the date of enactment of such Act.

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

"(5) PROPOSED SUNSCREEN ORDER BY COMMISSIONER.—If the Secretary does not issue a proposed sunscreen order under paragraph (4), or the Secretary does not publish a notification of the availability of a letter under paragraph (3), as applicable, the sponsor of such request may notify the Office of the Commissioner of such request and request review by the Office of the Commissioner. The Commissioner shall, not later than 60 calendar days after the date of notification under this paragraph, issue a proposed order with respect to such request.

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

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

"(7) MEETING.—A sponsor may request, in writing, a meeting with respect to a proposed sunscreen order issued under this subsection, including a letter deemed to be a proposed sunscreen order under paragraph (3), not later than 30 calendar days after the Secretary issues such order or the date upon which such feedback letter is deemed to be a proposed sunscreen order, as applicable. The Secretary shall convene a meeting with such sponsor not later than 45 calendar days after the date of such request for a meeting.

"(8) ADVISORY COMMITTEE.—In the case of a proposed sunscreen order under paragraph (3), (4), or (5), an Advisory Committee meeting may be convened for the purpose of reviewing and providing recommendations regarding the pending request.

"(9) FINAL SUNSCREEN ORDER.—In the case of a proposed sunscreen order under paragraph (3), (4), or (5)—

"(A) the Secretary shall issue a final sunscreen order with respect to the request—

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

"(ii) in the case of a proposed sunscreen order described in subparagraph (C) of section 586(7)—

"(I) if the Advisory Committee is not convened under paragraph (8), not later than 210 calendar days after the date on which the sponsor submits the additional information requested pursuant to such proposed sunscreen order, which shall include a rationale for not convening such Advisory Committee; or

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

"(B) if the Secretary does not issue such final sunscreen order within such 90-, 210-, or 270-calendar-day period, as applicable, the sponsor of such request may notify the Office of the

Commissioner about such request and request review by the Office of the Commissioner.

"(10) FINAL SUNSCREEN ORDER BY COMMISSIONER.—The Commissioner shall issue a final sunscreen order with respect to a proposed sunscreen order subject to paragraph (9)(B) not later than 60 calendar days after the date of notification under such paragraph.

"(c) ADVISORY COMMITTEE.—The Secretary shall not be required to—

"(1) convene the Advisory Committee—

"(A) more than once with respect to any request under section 586A or any pending request; or

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

"(2) submit more than a total of 3 requests under section 586A or pending requests to the Advisory Committee per meeting.

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

"(e) EFFECT OF FINAL SUNSCREEN ORDER.—

"(1) IN GENERAL.—

"(A) SUNSCREEN ACTIVE INGREDIENTS DETERMINED TO BE GRASE.—Upon issuance of a final sunscreen order determining that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded, a sunscreen containing such ingredient or combination of ingredients shall be permitted to be introduced or delivered into interstate commerce for use under the conditions described in such final sunscreen order, in accordance with all requirements applicable to drugs not subject to section 503(b)(1), for so long as such final sunscreen order remains in effect.

"(B) SUNSCREEN ACTIVE INGREDIENTS DETERMINED NOT TO BE GRASE.—Upon issuance of a final sunscreen order determining that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is not GRASE and is misbranded, a sunscreen containing such ingredient or combination of ingredients shall not be introduced or delivered into interstate commerce, for use under the conditions described in such final sunscreen order, unless an application is approved pursu-

ant to section 505 with respect to a sunscreen containing such ingredient or combination of ingredients, or unless conditions are later established under which such ingredient or combination of ingredients is later determined to be GRASE and not misbranded under the over-the-counter drug monograph system.

"(2) AMENDMENTS TO FINAL SUNSCREEN ORDERS.—

"(A) AMENDMENTS AT INITIATIVE OF SECRETARY.—In the event that information relevant to a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients becomes available to the Secretary after issuance of a final sunscreen order, the Secretary may amend such final sunscreen order by issuing a new proposed sunscreen order under subsection (a)(1) and following the procedures set forth in this section.

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

retary shall initiate the process for amending a final sunscreen order by issuing a new proposed sunscreen order under subsection (a)(1) and following the procedures set forth in this section.

"(C) APPLICABILITY OF FINAL ORDERS.—Once the Secretary issues a new proposed sunscreen order to amend a final sunscreen order under subparagraph (A) or (B), such final sunscreen order shall remain in effect and paragraph (3) shall not apply to such final sunscreen order until the Secretary has issued a new final sunscreen order or has determined not to amend the final sunscreen order.

"(3) INCLUSION OF INGREDIENTS THAT ARE SUBJECTS OF FINAL ORDERS IN THE SUNSCREEN MONOGRAPH.—

"(A) AMENDING REGULATIONS.—

"(i) REQUIREMENT.—At any time that the Secretary proposes to amend part 352 of title 21, Code of Federal Regulations (or any successor regulations) concerning nonprescription sunscreen, including pursuant to section 586E, except as provided in clause (iv), the Secretary shall include in such part 352 (or any successor regulations)

any nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of an effective final sunscreen order of the type described in section 586(2)(A) and issued since the time that the Secretary last amended such regulations. Such regulation shall set forth conditions of use under which each such ingredient or combination of ingredients is GRASE and not misbranded. If these conditions differ from, or are in addition to, those previously set forth in the applicable final sunscreen order, the Secretary shall provide notice and opportunity for comment on such conditions in the rulemaking, and the applicable final sunscreen order shall continue in effect until the effective date of a final regulation, as set forth in clause (iii).

"(ii) INCLUSION OF ORDERS.—In proposing to amend the regulations as described in clause (i), the Secretary shall include in the proposed regulations a list of final sunscreen orders that shall cease to be effective on the effective date of a resulting

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

"(iii) ORDERS NO LONGER EFFECTIVE.—Any final sunscreen order included by the Secretary in a list described in clause (ii) and in a list included in resulting final regulations shall cease to be effective on the date that such final regulations including such order in such list become effective.

"(iv) INGREDIENTS NOT GRASE.—If, notwithstanding a final sunscreen order stating that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded if marketed in accordance with such order, while amending the regulations as described in

clause (i), the Secretary concludes that such ingredient or combination of ingredients is no longer GRASE for use in nonprescription sunscreen, the Secretary shall, at the discretion of the Secretary, either initiate the process for amending the final sunscreen order set forth in paragraph (2) of this subsection or include in a proposed regulation an explanation and information supporting the determination of the Secretary that such ingredient or combination of ingredients is no longer GRASE for use in nonprescription sunscreen.

"(B) PROCEDURE FOR UPDATING REGULATIONS.—After the Secretary amends and finalizes the regulations under part 352 of title 21, Code of Federal Regulations under section 586E and such regulations become effective, the Secretary may use direct final rulemaking to include in such regulations any nonprescription sunscreen active ingredients that are the subject of effective final sunscreen orders.

"SEC. 586D. GUIDANCE; OTHER PROVISIONS.

"(a) GUIDANCE.—

"(1) IN GENERAL.—

"(A) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of the Sunscreen Innovation Act, the Secretary shall issue draft guidance on the implementation of, and compliance with, the requirements with respect to sunscreen under this subchapter, including guidance on—

"(i) the format and content of information submitted by a sponsor in support of a request under section 586A or a pending request;

"(ii) the data required to meet the safety and efficacy standard for determining whether a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded;

"(iii) the process by which a request under section 586A or a pending request is withdrawn; and

"(iv) the process by which the Secretary will carry out section 586C(c), including with respect to how the Secretary will address the total number of requests re-

ceived under section 586A and pending requests.

"(B) FINAL GUIDANCE.—The Secretary shall finalize the guidance described in subparagraph (A) not later than 2 years after the date of enactment of the Sunscreen Innovation Act.

"(C) INAPPLICABILITY OF PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code shall not apply to collections of information made for purposes of guidance under this subsection.

"(2) SUBMISSIONS PENDING ISSUANCE OF FINAL GUIDANCE.—Irrespective of whether final guidance under paragraph (1) has been issued—

"(A) persons may, beginning on the date of enactment of the Sunscreen Innovation Act, make submissions under this subchapter; and

"(B) the Secretary shall review and act upon such submissions in accordance with this subchapter.

"(b) RULES OF CONSTRUCTION.—

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

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

"(2) ENSURING SAFETY AND EFFECTIVENESS.—Nothing in this subchapter shall be construed to alter the authority of the Secretary with respect to prohibiting the marketing of a sunscreen that is not safe and effective or is misbranded, or with respect to imposing restrictions on the marketing of a sunscreen to ensure safety and effectiveness, except as otherwise provided in this subchapter, including section 586C(e).

"(3) OTHER DRUGS.—Except as otherwise provided in section 586F, nothing in this subchapter shall be construed to affect the authority of the Secretary under this Act or the Public Health Service Act (42 U.S.C. 201 et seq.) with respect to a drug other than a nonprescription sunscreen.

"(4) EFFECT ON DRUGS OTHERWISE APPROVED.—Nothing in this subchapter shall affect the marketing of a drug approved under section 505 of this Act or section 351 of the Public Health Service Act.

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

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

"SEC. 586E. SUNSCREEN MONOGRAPH.

"(a) IN GENERAL.—Not later than 5 years after the date of enactment of the Sunscreen Innovation Act, the Secretary shall amend and finalize regulations under part 352 of title 21, Code of Federal Regulations concerning nonprescription sunscreen that are effective not later than 5 years after such date of enactment. The Secretary shall publish such regulations not less than 30 calendar days before the effective date of such regulations.

"(b) REPORTS.—If the regulations promulgated under subsection (a) do not include provisions related to the effectiveness of various sun protection factor levels, and do not address all dosage forms known to the Secretary to be used in sunscreens marketed in the United States without a new drug approval under section 505, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the rationale for such provisions not being included in such regulations, and a plan and timeline to compile any information necessary to address such provisions through final regulations.".

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

(1) limit the right of a sponsor (as defined in section 586(8) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)) to request that the Secretary of Health and Human Services convene an advisory committee; or

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

SEC. 3. NON-SUNSCREEN TIME AND EXTENT APPLICATIONS.

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

"SEC. 586F. NON-SUNSCREEN TIME AND EXTENT APPLICATIONS.

"(a) PENDING TIME AND EXTENT APPLICATIONS.—

"(1) IN GENERAL.—

"(A) REQUEST FOR FRAMEWORK FOR REVIEW.—If, prior to the date of enactment of the Sunscreen Innovation Act, an application was submitted pursuant to section 330.14 of title 21, Code of Federal Regulations for a GRASE deter-

mination for a drug other than a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients and such drug was found to be eligible to be considered for inclusion in the over-the-counter drug monograph system pursuant to section 330.14 of title 21, Code of Federal Regulations, the sponsor of such application may request that the Secretary provide a framework under paragraph (2) for the review of such application.

"(B) REQUEST REQUIREMENTS.—A request for a framework for review of an application made under subparagraph (A) shall be made within 180 calendar days of the date of enactment of the Sunscreen Innovation Act and shall include the preference of such sponsor as to whether such application is reviewed by the Secretary in accordance with—

"(i) the processes and procedures set forth for pending requests under section 586C(b), except that specific timelines shall be determined in accordance with other applicable requirements under this section;

"(ii) the processes and procedures set forth under part 330 of title 21, Code of

Federal Regulations (or any successor regulations);

"(iii) an initial filing determination under the processes and procedures described in section 586B(b) and the processes and procedures set forth for pending requests under section 586C(b), except that specific timelines shall be determined in accordance with other applicable requirements under this section; or

"(iv) an initial filing determination under the processes and procedures described in section 586B(b) and the processes and procedures set forth under part 330 of title 21, Code of Federal Regulations (or any successor regulations).

"(C) NO REQUEST.—If a sponsor described in subparagraph (A) does not make such request within 180 calendar days of the date of enactment of the Sunscreen Innovation Act, such application shall be reviewed by the Secretary in accordance with the timelines of the applicable regulations when such regulations are finalized under subsection (b).

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

"(A) such timelines shall account for the considerations under paragraph (5); and

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

"(3) GOVERNING PROCESSES AND PROCEDURES FOR REVIEW.—

"(A) ELECTION.—Not later than 60 calendar days after the Secretary provides a framework to a sponsor under paragraph (2), such sponsor may provide an election to the Secretary regarding the processes and procedures for review under clause (i), (ii), (iii), or (iv) of paragraph (1)(B). If such sponsor makes such election, the Secretary shall review the application that is the subject of such election pursuant to the processes

and procedures elected by such sponsor and the applicable timelines in calendar days set forth under such framework, which the Secretary shall confirm in writing to the sponsor not later than the date upon which the Secretary provides a report under paragraph (4). If such sponsor does not make such election, such application shall be reviewed by the Secretary in accordance with the timelines of the applicable regulations when such regulations are finalized under subsection (b).

"(B) DIFFERENT PROCESSES AND PROCEDURES.—At any time during review of an application, the Secretary may review such application under different processes and procedures under clause (i), (ii), (iii), or (iv) of paragraph (1)(B) than the processes and procedures the sponsor elected in accordance with subparagraph (A), so long as the Secretary proposes, in writing, the change and the sponsor agrees, in writing, to such change.

"(C) INCLUSION OF INGREDIENTS IN MONOGRAPHS.—If the sponsor elects to use the processes and procedures for review in accordance with clause (i) or (iii) of paragraph (1)(B), the Secretary may incorporate any resulting final

order into a regulation addressing the conditions under which other drugs in the same therapeutic category are GRASE and not misbranded, including through direct final rulemaking, and the final order so incorporated shall cease to be effective on the effective date of the final regulation that addresses such drug.

"(4) LETTER REGARDING PENDING APPLICATIONS.—Not later than 18 months after the date of enactment of the Sunscreen Innovation Act, the Secretary shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, in writing, regarding all pending applications subject to paragraph (1). In such letter, the Secretary shall provide a report on the review of such applications, including the timelines, in calendar days, for the review and GRASE determination for each application. Such timelines shall account for the considerations under paragraph (5).

"(5) TIMELINES.—The timelines in calendar days established by the Secretary pursuant to this subsection—

"(A) may vary based on the content, complexity, and format of the application submitted to the Secretary; and

"(B) shall—

"(i) reflect the public health priorities of the Food and Drug Administration, including the potential public health benefits posed by the inclusion of additional drugs in the over-the-counter drug monograph system;

"(ii) take into consideration the resources available to the Secretary for carrying out such priorities and the processes and procedures described in paragraphs (1)(B) and (2); and

"(iii) be reasonable, taking into consideration the requirements described in clauses (i) and (ii).

"(b) NEW TIME AND EXTENT APPLICATIONS.—

"(1) IN GENERAL.—Not later than 18 months after the date of enactment of the Sunscreen Innovation Act, the Secretary shall issue proposed regulations establishing timelines for the review of applications for GRASE determinations for drugs other than nonprescription sunscreen active ingredients or com-

binations of nonprescription sunscreen active ingredients that are submitted to the Secretary after the date of enactment of the Sunscreen Innovation Act, under section 330.14 of title 21, Code of Federal Regulations (or any successor regulations), and that are found to be eligible to be considered for inclusion in the over-the-counter drug monograph system pursuant to section 330.14 of title 21, Code of Federal Regulations (or any successor regulations), or that are subject to this subsection pursuant to paragraph (1) or (3) of subsection (a), as applicable, providing—

"(A) timely and efficient completion of evaluations of applications under section 330.14 of title 21, Code of Federal Regulations (or any successor regulations) for drugs other than sunscreens; and

"(B) timely and efficient completion of the review of the safety and effectiveness submissions pursuant to such applications, including establishing—

"(i) reasonable timelines, in calendar days, for the applicable proposed and final regulations for applications of various content, complexity, and format, and timelines

for internal procedures related to such processes; and

"(ii) measurable metrics for tracking the extent to which the timelines set forth in the regulations are met.

"(2) TIMELINES.—The timelines in calendar days established in the regulations under paragraph (1)—

"(A) may vary based on the content, complexity, and format of the application submitted to the Secretary; and

"(B) shall—

"(i) reflect the public health priorities of the Food and Drug Administration, including the potential public health benefits posed by the inclusion of additional drugs in the over-the-counter drug monograph system;

"(ii) take into consideration the resources available to the Secretary for carrying out such priorities and the processes and procedures described in paragraph (1); and

"(iii) be reasonable, taking into consideration the requirements described in clauses (i) and (ii).

"(3) PROCEDURE.—In promulgating regulations under this subsection, the Secretary shall issue a notice of proposed rulemaking that includes a copy of the proposed regulation, provide a period of not less than 60 calendar days for comments on the proposed regulation, and publish the final regulation not less than 30 calendar days before the effective date of the regulation.

"(4) RESTRICTIONS.—Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraphs (1), (2), and (3).

"(5) FINAL REGULATIONS.—The Secretary shall finalize the regulations under this section not later than 27 months after the date of enactment of the Sunscreen Innovation Act.".

SEC. 4. REPORTS.

(a) INITIAL GAO REPORT.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of

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

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

(2) the role of the Office of the Commissioner of Food and Drugs in issuing determinations with respect to requests reviewed under such subchapter, including the number of requests transferred to the Office of the Commissioner under section 586C of such Act;

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

(4) the types of metrics that have been, or should be, established for the review of time and extent applications.

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

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

(2) significant factors impacting the ability of the Food and Drug Administration to fulfill the mission of the agency with regard to the regulation of over-the-counter drug products, including finalizing outstanding monographs and responding to emerging and novel safety issues;

(3) the performance of the Secretary in carrying out section 586E of the Federal Food, Drug, and Cosmetic Act;

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

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

(c) FDA REPORT.—Subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 3, is further amended by adding at the end the following:

"SEC. 586G. REPORT.

"(a) IN GENERAL.—

"(1) IN GENERAL.—Not later than 18 months after the date of enactment of the Sunscreen Innovation Act, and on the dates that are 2 and 4 years thereafter, the Secretary shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives describing actions taken under this subchapter.

"(2) CONTENTS.—The reports under this subsection shall include—

"(A) a review of the progress made in issuing GRASE determinations for pending re-

quests, including the number of pending requests—

"(i) reviewed and the decision times for each request, measured from the date of the original request for an eligibility determination submitted by the sponsor;

"(ii) resulting in a determination that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded;

"(iii) resulting in a determination that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is not GRASE and is misbranded and the reasons for such determinations; and

"(iv) for which a determination has not been made, and an explanation for the delay, a description of the current status of each such request, and the length of time each such request has been pending, measured from the date of original request for an eligibility determination by the sponsor;

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

"(i) reviewed and the decision times for each request;

"(ii) resulting in a determination that the nonprescription sunscreen active ingredient, combination of nonprescription sunscreen active ingredients, or other ingredient is GRASE and is not misbranded;

"(iii) resulting in a determination that the nonprescription sunscreen active ingredient, combination of nonprescription sunscreen active ingredients, or other ingredient is not GRASE and is misbranded and the reasons for such determinations; and

"(iv) for which a determination has not been made, and an explanation for the delay, a description of the current status of each such request, and the length of time each such request has been pending, measured from the date of original request for an eligibility determination by the sponsor;

"(C) an annual accounting (including information from years prior to the date of enactment of the Sunscreen Innovation Act where such information is available) of the total number of requests submitted, pending, or completed under this subchapter, including whether such requests were the subject of an advisory committee convened by the Secretary;

"(D) a description of the staffing and resources relating to the costs associated with the review and decisionmaking pertaining to requests under this subchapter;

"(E) a review of the progress made in meeting the deadlines with respect to processing requests under this subchapter; and

"(F) to the extent the Secretary determines appropriate, recommendations for process improvements in the handling of requests under this subchapter, including the advisory committee review process.

"(b) METHOD.—The Secretary shall publish the reports under subsection (a) in the manner the Secretary determines to be the most effective for efficiently disseminating the report, including publication of the report on the Internet website of the Food and Drug Administration.".

Calendar No. 568

113TH CONGRESS
2D SESSION

S. 2141

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.

SEPTEMBER 17 (legislative day, SEPTEMBER 16), 2014

Reported with an amendment