

SUNSCREEN INNOVATION ACT

JULY 24, 2014.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 4250]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4250) 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, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

**SECTION 1. SHORT TITLE.**

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

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

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 Active Ingredients****“SEC. 586. DEFINITIONS.**

“In this subchapter:

“(1) The term ‘Advisory Committee’ means the Nonprescription Drug Advisory Committee or any successor to such Committee.

“(2) The terms ‘generally recognized as safe and effective’ and ‘GRASE’ mean 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 conditions prescribed, recommended, or suggested in the product’s labeling, as described in section 201(p).

“(3) The term ‘GRASE determination’ means, with respect to a nonprescription sunscreen active ingredient or a combination of nonprescription sunscreen active ingredients, a determination of whether such ingredients or combination of ingredients is generally recognized as safe and effective and not misbranded for use under the conditions prescribed, recommended, or suggested in the product’s labeling, as described in section 201(p).

“(4) The term ‘nonprescription’ means not subject to section 503(b)(1).

“(5) The term ‘pending request’ means each request submitted to the Secretary—

“(A) for consideration for inclusion in the over-the-counter drug monograph system;

“(B) that was deemed eligible for such review by publication of a notice of eligibility in the Federal Register prior to the date of enactment of the Sunscreen Innovation Act; and

“(C) for which safety and effectiveness data has been submitted to the Secretary prior to such date of enactment.

“(6) The term ‘sponsor’ means the person submitting the request under section 586A(a), including a time and extent application under section 586B, or the person that submitted the pending request.

“(7) 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 radiation.

“(8) The term ‘sunscreen’ means a product containing one or more sunscreen active ingredients.

**“SEC. 586A. GENERAL PROVISIONS.**

“(a) 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 generally recognized as safe and effective and not misbranded.

“(b) RULES OF CONSTRUCTION.—

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

“(2) ENSURING SAFETY AND EFFECTIVENESS.—Nothing in this subchapter shall be construed to alter the Secretary’s authority to prohibit the marketing of a sunscreen that is not safe and effective or to impose restrictions on the marketing of a sunscreen to ensure safety and effectiveness.

“(3) OTHER PRODUCTS.—Nothing in this subchapter shall be construed to affect the Secretary’s regulation of products other than sunscreens.

“(c) SUNSET.—This subchapter shall cease to be effective at the end of the 5-year period beginning on the date of enactment of this subchapter.

**“SEC. 586B. ELIGIBILITY DETERMINATION.**

“(a) IN GENERAL.—Upon receipt of a request under section 586A(a), not later than 60 days after the date of receipt of such request, the Secretary shall—

“(1) determine whether the request is eligible for further review under sections 586C and 586D, as described in subsection (b);

“(2) notify the sponsor of the Secretary’s determination; and

“(3) make such determination publicly available in accordance with subsection (c).

“(b) CRITERIA FOR ELIGIBILITY.—

“(1) IN GENERAL.—To be eligible for review under sections 586C and 586D, 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—

“(A) is not included in the stayed sunscreen monograph in part 352 of title 21, Code of Federal Regulations; and

“(B) has been used to a material extent and for a material time, as described in section 201(p)(2).

“(2) TIME AND EXTENT APPLICATION.—A sponsor shall include in a request under section 586A(a) a time and extent application including all the information required to meet the standard described in paragraph (1)(B).

“(c) PUBLIC AVAILABILITY.—

“(1) REDACTIONS FOR CONFIDENTIAL INFORMATION.—If a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is determined to be eligible for further review under subsection (a)(1), 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.

“(2) IDENTIFICATION OF CONFIDENTIAL INFORMATION BY SPONSOR.—Sponsors shall identify any information which the sponsor considers to be confidential information described in paragraph (1).

“(3) CONFIDENTIALITY DURING ELIGIBILITY REVIEW.—The information contained in a request under section 586A(a) shall remain confidential during the Secretary’s consideration under this section of whether the request is eligible for further review.

“SEC. 586C. DATA SUBMISSION; FILING DETERMINATION.

“(a) IN GENERAL.—In the case of a request under section 586A(a) that is determined to be eligible under section 586B for further review under this section and section 586D—

“(1) the Secretary shall, in notifying the public under section 586B(a)(3) of such eligibility determination, invite the sponsor of the request and any other interested party to submit, in support of or otherwise relating to a GRASE determination—

“(A) published and unpublished data and other information related to the safety and effectiveness of the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients for its intended nonprescription uses; or

“(B) any other comments; and

“(2) not later than 60 days after the submission of such data and other information by the sponsor, including any revised submission of such data and other information following a refusal to file under subparagraph (B), the Secretary shall—

“(A)(i) issue a written notification to the sponsor determining that the request under section 586A(a), together with such data and other information, is sufficiently complete to conduct a substantive review and make such notification publicly available; and

“(ii) file such request; or

“(B) issue a written notification to the sponsor refusing to file the request and stating the reasons for the refusal and why the data and other information submitted is not sufficiently complete to conduct a substantive review and make such notification publicly available;

“(3) the Secretary shall, in filing a request under paragraph (2)—

“(A) invite the public to submit further comments with respect to such filing; and

“(B) limit such public comment, and the comment period under paragraph (1), to the period ending on the date that is 60 days after such filing;

“(4) if the Secretary refuses to file the request—

“(A) the sponsor may, within 30 days of receipt of written notification of such refusal, seek a meeting with the Secretary regarding whether the Secretary should file the request; and

“(B) the Secretary shall convene the meeting; and

“(5) following any such meeting—

“(A) if the sponsor asks that the Secretary file the request (with or without amendments to correct any purported deficiencies to the request) the Secretary shall file the request over protest, issue a written notification of the filing to the sponsor, and make such notification publicly available; and

“(B) if the request is so filed over protest, the Secretary shall not require the sponsor to resubmit a copy of the request for purposes of such filing.

“(b) REASONS FOR REFUSAL TO FILE REQUEST.—The Secretary may refuse to file a request submitted under section 586A(a) if the Secretary determines the data or other information submitted by the sponsor under this section are not sufficiently complete to conduct a substantive review with respect to such request.

“(c) PUBLIC AVAILABILITY.—

“(1) REDACTIONS FOR CONFIDENTIAL INFORMATION.—The Secretary shall make data and other information submitted in connection with a request under section 586A(a) 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.

“(2) IDENTIFICATION OF CONFIDENTIAL INFORMATION BY SPONSOR.—Sponsors or any other individual submitting data or other information under this section shall identify any information which the sponsor or individual considers to be confidential information described in paragraph (1).

**“SEC. 586D. GRASE DETERMINATION.**

“(a) REVIEW OF NEW REQUEST.—

“(1) PROPOSED ORDER BY CDER.—In the case of a request under section 586A(a), the Director of the Center for Drug Evaluation and Research shall—

“(A) not later than 300 days after the date on which the request is filed under section 586C(a), complete the review of the request and issue a proposed order determining that—

“(i) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the request—

“(I) is GRASE; and

“(II) is not misbranded;

“(ii) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the request—

“(I) is not GRASE; or

“(II) is misbranded; or

“(iii) additional information is necessary to allow the Director of the Center for Drug Evaluation and Research to complete the review of such request;

“(B) within such 300-day period, convene a meeting of the Advisory Committee to review the request under section 586A(a); and

“(C) if the Director fails to issue such proposed order within the 300-day period referred to in subparagraph (A), transmit the request to the Commissioner of Food and Drugs for review.

“(2) PROPOSED ORDER BY COMMISSIONER.—With respect to a request transmitted to the Commissioner of Food and Drugs under paragraph (1)(C), the Commissioner shall, not later than 60 days after the date of such transmission, issue—

“(A) a proposed order described in paragraph (1)(A)(i);

“(B) a proposed order described in paragraph (1)(A)(ii); or

“(C) a proposed order described in paragraph (1)(A)(iii).

“(3) PUBLICATION IN FEDERAL REGISTER; PUBLIC COMMENT PERIOD.—A proposed order issued under paragraph (1) or (2) with respect to a request shall—

“(A) be published in the Federal Register; and

“(B) solicit public comments for a period of not more than 45 days.

“(4) FINAL ORDER BY CDER.—In the case of a proposed order under paragraph (1)(A) or (2) with respect to a request, the Director of the Center for Drug Evaluation and Research shall—

“(A) issue a final order with respect to the request—

“(i) in the case of a proposed order under clause (i) or (ii) of paragraph (1)(A) or subparagraph (A) or (B) of paragraph (2), not later than 90 days after the end of the public comment period under paragraph (3)(B); or

“(ii) in the case of a proposed order under paragraph (1)(A)(iii) or paragraph (2)(C), not later than 210 days after the date on which the sponsor submits the additional information requested pursuant to such proposed order; or

“(B) if the Director fails to issue such final order within such 90- or 210-day period, as applicable, transmit such proposed order to the Commissioner of Food and Drugs for review.

“(5) FINAL ORDER BY COMMISSIONER.—With respect to a proposed order transmitted to the Commissioner of Food and Drugs under paragraph (4)(B), the Commissioner shall issue a final order with respect to such proposed order not later than 60 days after the date of such transmission.

“(b) REVIEW OF PENDING REQUESTS.—

“(1) IN GENERAL.—The review of a pending request shall be carried out by the Director of the Center for Drug Evaluation and Research in accordance with paragraph (3).

“(2) INAPPLICABILITY OF CERTAIN PROVISIONS.—Sections 586B and 586C shall not apply with respect to any pending request.

“(3) PROPOSED ORDER BY CDER.—The Director of the Center for Drug Evaluation and Research shall—

“(A) within the timeframe applicable under paragraph (4), complete the review of the request and issue a proposed order determining that—

“(i) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the pending request—

“(I) is GRASE; and

“(II) is not misbranded;

“(ii) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the pending request—

“(I) is not GRASE; or

“(II) is misbranded; or

“(iii) additional information is necessary to allow the Director of the Center for Drug Evaluation and Research to complete the review of the pending request; and

“(B) if the Director fails to issue such proposed order within the timeframe applicable under paragraph (4), transmit the pending request to the Commissioner of Food and Drugs for review.

“(4) TIMEFRAME FOR ISSUANCE OF PROPOSED ORDER BY CDER.—The Director of the Center for Drug Evaluation and Research shall issue a proposed order, as required by paragraph (3)(A)—

“(A) in the case of a pending request for which the Food and Drug Administration has issued a feedback letter before the date of enactment of the Sunscreen Innovation Act, not later than 45 days after such date of enactment; and

“(B) in the case of a pending request for which the Food and Drug Administration has not issued a feedback letter before the date of enactment of the Sunscreen Innovation Act, not later than 90 days after such date of enactment.

“(5) PROPOSED ORDER BY COMMISSIONER.—With respect to a pending request transmitted to the Commissioner of Food and Drugs under paragraph (3)(B), the Commissioner shall, not later than 60 days after the date of such transmission, issue—

“(A) a proposed order described in paragraph (3)(A)(i);

“(B) a proposed order described in paragraph (3)(A)(ii); or

“(C) a proposed order described in paragraph (3)(A)(iii).

“(6) PUBLICATION IN FEDERAL REGISTER; PUBLIC COMMENT PERIOD.—A proposed order issued under paragraph (3) or (5) with respect to a pending request shall—

“(A) be published in the Federal Register; and

“(B) solicit public comments for a period of not more than 45 days.

“(7) ADVISORY COMMITTEE.—For a proposed order issued under paragraph (3)(A)(iii) or (5)(C) requesting additional information, an Advisory Committee meeting shall be convened if the sponsor requests, or the Director of the Center for Drug Evaluation and Research or the Commissioner of Food and Drugs decides, to convene such a meeting for the purpose of reviewing the pending request.

“(8) FINAL ORDER BY CDER.—In the case of a proposed order under paragraph (3)(A) or (5) with respect to a request, the Director of the Center for Drug Evaluation and Research shall—

“(A) issue a final order with respect to the request—

“(i) in the case of a proposed order under clause (i) or (ii) of paragraph (3)(A) or subparagraph (A) or (B) of paragraph (5), not later than

90 days after the end of the public comment period under paragraph (3)(B); or

“(ii) in the case of a proposed order under paragraph (3)(A)(iii) or paragraph (5)(C)—

“(I) if the Advisory Committee is not convened pursuant to paragraph (7), not later than 210 days after the date on which the sponsor submits the additional information requested pursuant to such proposed order; or

“(II) if the Advisory Committee is convened pursuant to paragraph (7), not later than 270 days after date on which the sponsor submits such additional information; or

“(B) if the Director fails to issue such final order within such 90-, 210-, and 270-day period, as applicable, transmit such proposed order to the Commissioner of Food and Drugs for review.

“(9) FINAL ORDER BY COMMISSIONER.—With respect to a proposed order transmitted to the Commissioner of Food and Drugs under paragraph (8)(B), the Commissioner shall issue a final order with respect to such proposed order not later than 60 days after the date of such transmission.

“(c) ADVISORY COMMITTEE.—

“(1) LIMITATIONS.—The Food and Drug Administration—

“(A) shall not be required to convene the Advisory Committee—

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

“(ii) more than twice in any twelve month period with respect to the review of submissions under this section; and

“(B) shall not be required to submit more than 3 submissions to the Advisory Committee per meeting.

“(2) MEMBERSHIP.—In appointing the members of the Advisory Committee, the Secretary may select to serve temporarily as voting members on the Advisory Committee—

“(A) members of other Federal advisory committees; or

“(B) consultants from outside of the Department of Health and Human Services who have substantive expertise regarding sunscreen active ingredients.

“(d) NO DELEGATION.—Any responsibility vested by this section in the Commissioner of Food and Drugs is not delegable.

“(e) EFFECT OF FINAL ORDER.—

“(1) CONTENT.—A final order under subsection (a)(4), (a)(5), (b)(8), or (b)(9) with respect to a request under section 586A(a) or a pending request shall determine that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the request—

“(A) is GRASE and is not misbranded; or

“(B) is not GRASE or is misbranded.

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

“(3) ACTIVE INGREDIENTS DETERMINED NOT TO BE GRASE.—Upon issuance of a final order determining that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is not GRASE or is misbranded, the active ingredient or combination of active ingredients shall not be introduced or delivered into interstate commerce, for use under the conditions subject to the final order, unless an application submitted pursuant to section 505(b) with respect to such active ingredient or combination of active ingredients is approved.

“SEC. 586E. REPORTS.

“(a) GAO REPORT.—Not later than 1 year after the date of enactment of the Sunscreen Innovation Act, the Comptroller General of the United States shall—

“(1) submit a report reviewing the overall progress of the Secretary in carrying out this subchapter to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives; and

“(2) include findings on—

“(A) the progress made in completing the review of pending requests; and

“(B) the role of the Office of the Commissioner of Food and Drugs in issuing determinations with respect to pending requests, including the number of requests transferred to the Office of the Commissioner under section 586D.

“(b) SECRETARY’S REPORT.—

“(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Sunscreen Innovation Act, and every 2 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 section. Each report under this subsection shall be posted on the Internet site of the Food and Drug Administration.

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

“(A) a review of the progress made in issuing GRASE determinations for pending requests, 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 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, 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 in a timely manner GRASE determinations for requests submitted under section 586A(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 or combination of nonprescription sunscreen active ingredients is GRASE and 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, 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) a description of the staffing and resources relating to the costs associated with the review and decisionmaking pertaining to requests under this subchapter;

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

“(E) to the extent the Secretary determines appropriate, recommendations for process improvements in the handling of pending and new requests, including the advisory committee review process; and

“(F) recommendations for expanding the applicability of this subchapter to nonprescription active ingredients that are not related to the sunscreen category of over-the-counter drugs.

“(c) METHOD.—The Secretary shall publish the reports required under subsection (b) 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.”

### SEC. 3. GUIDANCE.

(a) IN GENERAL.—

(1) ISSUANCE.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance, in accordance with good guidance practices, on the implementation of, and compliance with, subchapter I of

chapter V of the Federal Food, Drug, and Cosmetic Act, as added by section 2, including guidance on—

(A) the criteria for determining whether a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients has been used to a material extent and for a material time, as described in section 201(p)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)(2));

(B) the format and content of a safety and effectiveness data submission; and

(C) the safety and efficacy standards for determining whether a nonprescription sunscreen active ingredients or combination of nonprescription sunscreen active ingredients is generally recognized as safe and effective, as defined in section 586 of such subchapter I.

(2) 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.

(b) SUBMISSIONS PENDING ISSUANCE OF FINAL GUIDANCE.—Irrespective of whether final guidance under subsection (a) has been issued—

(1) persons may, beginning on the date of enactment of this Act, make submissions under subchapter I of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by section 2; and

(2) the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall review and act upon such submissions in accordance with such subchapter.

#### PURPOSE AND SUMMARY

H.R. 4250, the “Sunscreen Innovation Act,” would address the current backlog of applications for nonprescription sunscreen active ingredients pending at the Food and Drug Administration (FDA), as well as establish a predictable and transparent review process for new applications, incorporating meaningful input from experts and the public.

#### BACKGROUND AND NEED FOR LEGISLATION

Skin cancer is a public health crisis in the United States. Each year there are more new cases of skin cancer than the combined incidence of breast, prostate, lung, and colon cancer.<sup>1</sup> By 2015, it is estimated that one in fifty Americans will develop melanoma in their lifetime.<sup>2</sup>

The FDA has not approved a new nonprescription sunscreen ingredient through the monograph process in nearly two decades, despite the fact that several applications have been pending at the agency for years. The FDA has listed action on sunscreen ingredient applications as a priority since 2008 in the Unified Agenda; however, no new sunscreen ingredients have received a decision from FDA. The pre-existing time and extent application (TEA) process did not include deadlines for the timely review of such ingredients, which this bill would establish. Further, it would remove administrative hurdles identified by FDA to the sunscreen approval process and ensure sunscreens receive a transparent review within a predictable timeframe.

H.R. 4250 does not independently address FDA’s review of sunscreen products with sun protection factor (SPF) values higher than 50 and the labeling thereof. However, FDA recently published a proposed rule that would limit the maximum SPF value on non-

<sup>1</sup>Cancer Facts and Figures 2014, American Cancer Society <http://www.cancer.org/acs/groups/content/@research/documents/webcontent/acspc-042151.pdf>.

<sup>2</sup>Rigel DS, Russak J, Friedman R. The evolution of melanoma diagnosis: 25 years beyond the ABCDs. *CA Cancer J Clin.* 2010 Sep–Oct; 60(5): 301–16.



prescription product labeling to “50+,” unless FDA were to receive data demonstrating that products with SPF values higher than 50 provide additional clinical benefit. In the proposed rule, FDA recommended that anyone interested in conducting studies to develop such data should contact FDA before beginning the studies. The Committee understands that at least two organizations have responded to this recommendation by submitting a clinical protocol to FDA describing how, together, they would conduct a study to demonstrate the clinical benefit of SPF 50+ sunscreen products. The Committee also understands that, as of yet, FDA has not provided a response to the submitting organizations.

Such products could protect consumers from harmful exposure. To ensure that a final rule on this issue is informed by the most recent and best available scientific data, the Committee expects FDA to respond in a timely manner to any suggested clinical protocols FDA may have received in response to the offer the agency made in its 2011 proposed rule.

#### HEARINGS

The Subcommittee on Health, held a hearing on H.R. 4250 on April 7, 2014. The Subcommittee received testimony from:

- Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research;
- Mr. Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration;
- Dr. Nathan B. Fountain, Chair, Medical Advisory Board, Epilepsy Foundation;
- Mr. John M. Gray, President and CEO, Healthcare Distribution Management Association;
- Mr. Linden D. Barber, Partner and Director, DEA Compliance Operations, Quarles & Brady;
- Ms. Wendy K.D. Selig, President and CEO Melanoma Research Alliance; and,
- Mr. Scott Faber, Vice President, Government Affairs, Environmental Working Group.

#### COMMITTEE CONSIDERATION

On June 19, 2014, the Subcommittee on Health met in open markup session and forwarded H.R. 4250 to the full Committee consideration, as amended, by a voice vote.

#### COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no recorded votes taken in connection with ordering H.R. 4250 reported. A motion by Mr. Upton to order H.R. 4250 reported to the House, as amended, was agreed to by a voice vote.

## COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a hearing and made findings that are reflected in this report.

## STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

H.R. 4250 would establish a predictable and timely review process for pending and new sunscreen ingredient applications.

## NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 4250 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

## EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 4250 contains no earmarks, limited tax benefits, or limited tariff benefits.

## COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

## CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,  
CONGRESSIONAL BUDGET OFFICE,  
*Washington, DC, July 23, 2014.*

Hon. FRED UPTON,  
*Chairman, Committee on Energy and Commerce,  
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 4250, the Sunscreen Innovation Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Ellen Werble.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

*H.R. 4250—Sunscreen Innovation Act*

Summary: H.R. 4250 would modify the review process that allows the marketing of certain new ingredients in non-prescription sunscreen based on a determination by the Food and Drug Admin-

istration (FDA) that they are generally recognized as safe and effective. CBO estimates that implementing H.R. 4250 would cost \$28 million over the 2015–2019 period, assuming appropriation of the necessary amounts. H.R. 4250 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 4250 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA).

The bill would impose private-sector mandates, as defined in UMRA, because it would allow FDA to require that marketing applications for certain sunscreen products be submitted in a new standardized format. CBO estimates that the direct cost of complying with those requirements would not exceed the annual threshold established by UMRA for private-sector mandates (\$152 million in 2014, adjusted annually for inflation).

Estimated cost to the Federal Government: The estimated budgetary effect of H.R. 4250 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					2015–2019
	2015	2016	2017	2018	2019	
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
Estimated Authorization Level .....	4	5	7	7	9	32
Estimated Outlays .....	3	4	6	7	8	28

Basis of estimate: For this estimate, CBO assumes that H.R. 4250 will be enacted near the beginning of fiscal year 2015, that the necessary amounts will be appropriated for each year, and that outlays will follow historical spending patterns for similar activities.

Drugs marketed in the United States generally must be tested for safety and efficacy and approved by FDA through an application process. However, certain products currently are marketed under a determination by FDA that they are generally recognized as safe and effective and have been marketed for a specific time and extent under the conditions of their labeling. Under current law, non-prescription sunscreen products are marketed under such a determination and are subject to a multistep process that involves scientific review and notice-and-comment rulemaking by FDA.

H.R. 4250 would change the process for reviewing certain new drug ingredients in non-prescription sunscreen by FDA. In addition, the bill would require that the agency adhere to specific timelines and issue administrative orders. Based on information provided by FDA, CBO estimates that implementing the bill would cost \$28 million over the 2015–2019 period, assuming appropriation of the necessary amounts.

Pay-As-You-Go considerations: None.

Estimated impact on state, local, and tribal governments: H.R. 4250 contains no intergovernmental mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimated impact on the private sector: H.R. 4250 would impose a mandate on firms seeking to market certain new active ingredients for sunscreen by giving FDA the authority to modify the format of marketing applications. Under current law, FDA can refuse to allow marketing of a sunscreen product if the agency finds that

the sponsor does not provide sufficient data to demonstrate that the product is generally recognized as safe and effective. However, FDA currently cannot require that applicants submit their applications in a standardized format. Such lack of uniformity can slow down the review process. Under H.R. 4250, FDA would have the authority to impose and enforce a standard format on such applications. The number of applications for new sunscreen ingredients is low in any given year, and the additional cost to each sponsor of complying with the new requirements would be low as well. Therefore, CBO expects that the cost of complying with this new requirement would not exceed the threshold defined in UMRA (\$152 million in 2014, adjusted annually for inflation) in any of the first five years following enactment.

Estimate prepared by: Federal costs: Ellen Werble; Impact on state, local, and tribal governments: J'nell L. Blanco; Impact on the private sector: Kyle Redfield.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

#### FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

#### DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 4250 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

#### DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 4250 does not specifically direct any specific rule making within the meaning of 5 U.S.C. 551.

#### ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

#### APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

#### SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

##### *Section 1. Short title*

Section 1 provides a short title of “Sunscreen Innovation Act.”

*Section 2. Regulation of nonprescription sunscreen active ingredients*

Section 2 amends the Federal Food, Drug, and Cosmetic Act by adding a new subchapter: “Subchapter I. Nonprescription Sunscreen Active Ingredients.” An analysis of the new subchapter is provided below.

*Section 586. Definitions*

This section provides definitions for terms used in the legislation. Among other technical definitions that are consistent with existing statutory and regulatory definitions, this section defines “pending request” as requests that were submitted and deemed eligible for a safety and effectiveness review by the FDA and for which the sponsor has submitted safety and effectiveness data to FDA prior to the date of enactment.

This section designates the existing “Nonprescription Drug Advisory Committee” (NDAC) as the advisory committee that may be convened under this subchapter.

This section defines “GRASE determination” as a determination of whether the sunscreen active ingredient or combination of sunscreen active ingredients that is the subject of a request under this subchapter is generally recognized as safe and effective (GRASE) and not misbranded.

*Section 586A. General Provisions*

*(a) Requests*

This section provides an opportunity for sponsors to request from the Secretary a determination as to whether a nonprescription active ingredient or a combination of sunscreen active ingredients for use under specified conditions is GRASE and not misbranded.

*(b) Rules of construction*

Sunscreen products which are lawfully marketed in the U.S. on or before the date of enactment are not subject to the review process created by this legislation. The Secretary’s authority to prohibit marketing of a sunscreen that is not safe and effective or to impose restrictions on the marketing of a sunscreen to ensure safety and effectiveness is not affected by this legislation. This section specifies that the review process created by this legislation does not apply to the review of drug products other than sunscreen.

*(c) Sunset*

The provisions of the Sunscreen Innovation Act will sunset on a date five years from the date of enactment. The subsection makes clear that any request submitted before the date of sunset must continue to be reviewed under the Sunscreen Innovation Act (SIA) process.

*Section 586B. Eligibility determination*

This section sets out the process by which the Secretary determines that a sunscreen active ingredient or combination of sunscreen active ingredients has been marketed for a material time and to a material extent, and therefore, is eligible to be reviewed for a GRASE determination by the Secretary.

*(a) In general*

The Secretary shall act on a sunscreen request under Section 586A(a) no later than 60 days after the receipt of such a request, by determining whether the request is eligible for a safety and effectiveness review.

*(b) Criteria for eligibility*

To be eligible for a safety and effectiveness review, a sunscreen active ingredient or combination of sunscreen active ingredients must not be included on the stayed monograph and must have been marketed for a material time and to a material extent, as established by the information included in its request under Section 586A(a).

*(c) Public availability*

Requests under this Act will remain confidential during FDA's consideration of eligibility. The request will be published only if FDA determines that the condition is eligible for review of safety and effectiveness data. However, confidential or proprietary information will be redacted from the public record in accordance with existing law.

*Section 586C. Data submission; Filing determination**(a) In general*

In the case of a request that is determined by FDA to be eligible for safety and effectiveness review, FDA shall include in the public notice of eligibility a request for the submission of comments and of published and unpublished data related to the safety and effectiveness of the sunscreen active ingredient or combination of sunscreen active ingredients for its intended use.

Once a sponsor has submitted its safety and effectiveness data package, FDA has 60 days to issue a written filing determination regarding whether the data and other information submitted by the sponsor is sufficiently complete for FDA to conduct a substantive review and either file the request or refuse to file the request. If FDA refuses to file the request, it must provide the sponsor with a justification for refusing to file the request, including an explanation of why the data submitted is not sufficiently complete to conduct a substantive review.

If FDA files the request, FDA shall invite the public to submit further comments within 60 days of the filing date.

If FDA refuses to file the request, the sponsor may, within 30 days, seek a meeting with the Secretary regarding the refusal. The Secretary is authorized to file the request over protest at the request of the applicant.

The Committee expects that FDA and the applicant will work together so that appropriate safety and effectiveness data is submitted.

*(b) Reasons for refusal to file request*

This subsection defines the standard under which FDA may refuse to file. FDA may refuse to file if the data package submitted by the sponsor is not sufficiently complete for FDA to conduct a substantive review with respect to the request.

*(c) Public availability*

This subsection protects confidential or proprietary information contained within a data package submitted by a sponsor or any other person. Such confidential information will be redacted from the public record, in accordance with existing law.

*Section 586D. GRASE determination*

This section provides processes for FDA to conduct a safety and effectiveness review for both new and pending requests.

*(a) Review of new requests*

This subsection provides a description of the process by which FDA will review new requests submitted under section 586A after the date of enactment.

*(1) Proposed order by CDER*

FDA's Center for Drug Evaluation and Research (CDER) has 300 days from the date FDA files a request under Section 586C to make an initial GRASE determination or a determination that additional information is needed to make such GRASE determination. CDER must issue a proposed order articulating such initial determination.

Within the 300-day period, CDER is required to convene the NDAC to review the request and provide advice and recommendations, unless the sponsor and CDER agree that the advisory committee is not necessary.

*(2) Proposed order by Commissioner*

Should CDER fail to issue a proposed order within 300 days, the request must be submitted to the FDA Commissioner (Commissioner) for review, and within 60 days, the Commissioner must issue a proposed order. The Committee expects CDER to issue the proposed order within 300 days and that referral to the Commissioner will not be necessary. However, if such referral is made, the Commissioner must act within 60 days.

*(3) Publication in Federal Register; Public comment period*

The proposed order shall be published in the Federal Register, and include a public comment period of not more than 45 days.

*(4) Final order by CDER*

This paragraph provides timelines for the issuance of a final order containing a final GRASE determination after consideration of public comments and/or any required additional data.

In the case of a proposed order that contained an initial determination that the sunscreen active ingredient or combination of sunscreen active ingredients is GRASE and not misbranded, or an initial determination that the sunscreen active ingredient or combination of sunscreen active ingredients is not GRASE and is misbranded, this paragraph requires CDER to publish a final order not later than 90 days after the end of the 45-day comment period.

In the case of an initial determination that additional data and information is needed to determine whether the sunscreen active ingredient or combination of sunscreen active ingredients is

GRASE and not misbranded, this paragraph requires CDER to publish a final order not later than 210 days after the sponsor submits additional data and information to support its request.

*(5) Final order by Commissioner*

This paragraph provides that if CDER fails to issue a final order within the 90-day or 210-day periods described in subsection (4), the request must be submitted to the Commissioner and within 60 days the Commissioner must issue a final order. Again, the Committee expects CDER to issue the final order and that referral to the Commissioner will not be necessary. However, if such referral is made, the Commissioner must act within 60 days.

*(b) Review of pending requests*

This subsection provides a description of the process by which FDA will review “pending requests,” as defined in the legislation.

*(1) In general*

This paragraph requires FDA to carry out the review of a pending request in accordance with paragraph (3) below.

*(2) Inapplicability of certain provisions*

This paragraph makes clear that pending requests will not be subject to an eligibility determination (section 586B) or a filing determination (section 586C) because these requests already have been determined by FDA to be eligible prior to the date of enactment.

*(3) Proposed order by CDER*

CDER shall make an initial GRASE determination or a determination that additional information is needed to make such determination. CDER must issue a proposed order articulating such GRASE determination.

*(4) Timeframe for issuance of proposed order by CDER*

CDER shall issue a proposed order within 45 days of enactment of this legislation for pending requests for which FDA has issued a feedback letter before enactment. For pending requests for which FDA has not issued a feedback letter before enactment, CDER must issue a proposed order within 90 days of enactment.

*(5) Proposed order by Commissioner*

In the event that CDER does not issued a proposed order within the 45-day or 90-day required timeframes, this paragraph requires that the request be submitted to the Commissioner for review, and within 60 days, the Commissioner must issue a proposed order. The Committee expects CDER to issue the proposed order and that referral to the Commissioner will not be necessary. However, if such referral is made, the Commissioner must act within 60 days.

*(6) Publication in Federal Register; Public comment period*

This paragraph requires that the proposed order for pending requests be published in the Federal Register and include a public comment period of not more than 45 days.



(7) *Advisory committee*

In the case of a proposed order determining that additional information is needed to make a GRASE determination, this paragraph provides that the NDAC shall be convened if the sponsor, at the time of submission of additional information, requests it to be convened, or if CDER decides to convene it.

(8) *Final order by CDER*

This paragraph provides timelines for the issuance of a final order containing a final GRASE determination after consideration of public comments and/or any required additional data.

In the case of an active ingredient or combination of active ingredients subject to a proposed order that contains an initial determination that the sunscreen active ingredient or combination of sunscreen active ingredients is GRASE and not misbranded or an initial determination that the sunscreen active ingredient or combination of sunscreen active ingredients is not GRASE and is misbranded, CDER must publish a final order not later than 90 days after the end of the 45-day comment period.

In the case of an active ingredient or combination of active ingredients subject to a proposed order that contains a determination that additional data and information is needed to make a GRASE determination, CDER must publish a final order not later than 210 days after the sponsor submits additional data and information to support its request. However, in the case that an advisory committee is convened under paragraph (7) above, this paragraph provides CDER with 270 days from the submission of additional data to issue the final order.

(9) *Final order by Commissioner*

If CDER fails to issue a final order within the 210-day or 270-day periods described in subsection (8), the request must be submitted to the Commissioner and within 60 days the Commissioner must issue a final order. Again, the Committee expects CDER to issue the final order and that referral to the Commissioner will not be necessary. However, if such referral is made, the Commissioner must act within 60 days.

(c) *Advisory Committee*

(1) *Limitations*

This paragraph provides that FDA shall not be required to convene the NDAC (A) more than once with respect to any new or pending request, or (B) more than twice in any 12-month period with respect to review of submissions under this section, and (C) shall not be required to submit more than 3 submissions to the advisory committee per meeting. The Committee intends for FDA to strive to consider all applications in coordination with NDAC in a timely fashion and within statutory deadlines to ensure sunscreen ingredients receive a timely review to meet the pressing public health need for these new ingredients.

(2) *Membership*

FDA is permitted to augment the NDAC by appointing as temporary members relevant experts and consultants with substantive

expertise related to the evaluation of the safety and effectiveness of sunscreen active ingredients.

*(d) No delegation*

This subsection prohibits delegation of the responsibility invested in the Commissioner to issue proposed and final rules under this legislation.

*(e) Effect of final order*

*(1) Content*

A final order issued under this legislation must include a final GRASE determination.

*(2) Active ingredients determined to be GRASE*

Upon issuance of a final order determining that the sunscreen active ingredient or combination of sunscreen active ingredients is GRASE and not misbranded, the sunscreen active ingredient or combination of sunscreen active ingredients may be introduced or delivered into commerce, for use under conditions subject to the final order and in accordance with all applicable FDA requirements.

*(3) Active ingredients determined not to be GRASE*

If FDA issues a final order determining that the sunscreen active ingredient or combination of sunscreen active ingredients is not GRASE and is misbranded, the sunscreen active ingredient or combination of sunscreen active ingredients may not be introduced or delivered into commerce unless it has been approved under a new drug application.

*Section 586E. Reports*

To help ensure accountability for meeting the deadlines set forth in the legislation and to gather information about FDA's implementation of the review process, Congress included two reporting requirements in the Act.

*(a) GAO report*

The Comptroller General of the United States is required to 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 not later than 1 year after the date of enactment of the Act, demonstrating the overall progress of FDA in implementing the legislation, focusing on the progress made with respect to pending requests and the role played by the Commissioner in ensuring timely issuance of proposed and final orders.

*(b) Secretary's report*

This subsection requires FDA to 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 not later than 2 years after the date of enactment of the Act, and every 2 years thereafter, demonstrating actions taken under the Act. The report must include specific information detailed in Section 586E(b)(2). For example, FDA must describe its progress in meet-

ing the deadlines set out in the Act, an accounting of the number of requests reviewed under the Act and the decision times associated with such reviews, the number of requests that remain pending and the amount of time they have been pending (measured from the date of original submission), and a description of the staffing and resources relating to this process. The reports are to be made publically available.

*Section 3. Guidance*

*(a) In General*

FDA is required to issue guidance that includes (A) the criteria for determining whether a nonprescription sunscreen active ingredient or a combination of nonprescription sunscreen active ingredients has been marketed to a material extent and for a material time, (B) the format and content of a safety and effectiveness data submission, and (C) the safety and effectiveness standards for determining whether a nonprescription sunscreen active ingredient or a combination of nonprescription sunscreen active ingredients is generally recognized as safe and effective.

The Committee expects FDA to produce guidance that establishes the appropriate eligibility, data submission and safety and effectiveness testing requirements that are appropriate for such products that have been marketed to a material extent for a material time with a history of safe and effective use in a comparable jurisdiction. The Committee expects that the stakeholder community will have adequate opportunity to provide public comment during the creation of guidance.

*(b) Submissions pending issuance of final guidance*

Irrespective of whether guidance has been issued under subsection (a), FDA must review and act on pending requests in accordance with this legislation, and, as of the date of enactment, sponsors of new requests may submit such requests to FDA, and FDA must review and act upon the requests as set forth in this legislation.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

**FEDERAL FOOD, DRUG, AND COSMETIC ACT**

\* \* \* \* \*

CHAPTER V—DRUGS AND DEVICES

\* \* \* \* \*

## ***Subchapter I—Nonprescription Sunscreen Active Ingredients***

### **SEC. 586. DEFINITIONS.**

*In this subchapter:*

(1) The term “Advisory Committee” means the Nonprescription Drug Advisory Committee or any successor to such Committee.

(2) The terms “generally recognized as safe and effective” and “GRASE” mean 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 conditions prescribed, recommended, or suggested in the product’s labeling, as described in section 201(p).

(3) The term “GRASE determination” means, with respect to a nonprescription sunscreen active ingredient or a combination of nonprescription sunscreen active ingredients, a determination of whether such ingredients or combination of ingredients is generally recognized as safe and effective and not misbranded for use under the conditions prescribed, recommended, or suggested in the product’s labeling, as described in section 201(p).

(4) The term “nonprescription” means not subject to section 503(b)(1).

(5) The term “pending request” means each request submitted to the Secretary—

(A) for consideration for inclusion in the over-the-counter drug monograph system;

(B) that was deemed eligible for such review by publication of a notice of eligibility in the Federal Register prior to the date of enactment of the Sunscreen Innovation Act; and

(C) for which safety and effectiveness data has been submitted to the Secretary prior to such date of enactment.

(6) The term “sponsor” means the person submitting the request under section 586A(a), including a time and extent application under section 586B, or the person that submitted the pending request.

(7) 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 radiation.

(8) The term “sunscreen” means a product containing one or more sunscreen active ingredients.

### **SEC. 586A. GENERAL PROVISIONS.**

(a) **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 generally recognized as safe and effective and not misbranded.

(b) **RULES OF CONSTRUCTION.**—

(1) **CURRENTLY MARKETED SUNSCREENS.**—Nothing in this subchapter shall be construed to affect the marketing of sun-

screens that are lawfully marketed in the United States on or before the date of enactment of this subchapter.

(2) *ENSURING SAFETY AND EFFECTIVENESS.*—Nothing in this subchapter shall be construed to alter the Secretary's authority to prohibit the marketing of a sunscreen that is not safe and effective or to impose restrictions on the marketing of a sunscreen to ensure safety and effectiveness.

(3) *OTHER PRODUCTS.*—Nothing in this subchapter shall be construed to affect the Secretary's regulation of products other than sunscreens.

(c) *SUNSET.*—This subchapter shall cease to be effective at the end of the 5-year period beginning on the date of enactment of this subchapter.

**SEC. 586B. ELIGIBILITY DETERMINATION.**

(a) *IN GENERAL.*—Upon receipt of a request under section 586A(a), not later than 60 days after the date of receipt of such request, the Secretary shall—

(1) determine whether the request is eligible for further review under sections 586C and 586D, as described in subsection (b);

(2) notify the sponsor of the Secretary's determination; and

(3) make such determination publicly available in accordance with subsection (c).

(b) *CRITERIA FOR ELIGIBILITY.*—

(1) *IN GENERAL.*—To be eligible for review under sections 586C and 586D, 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—

(A) is not included in the stayed sunscreen monograph in part 352 of title 21, Code of Federal Regulations; and

(B) has been used to a material extent and for a material time, as described in section 201(p)(2).

(2) *TIME AND EXTENT APPLICATION.*—A sponsor shall include in a request under section 586A(a) a time and extent application including all the information required to meet the standard described in paragraph (1)(B).

(c) *PUBLIC AVAILABILITY.*—

(1) *REDACTIONS FOR CONFIDENTIAL INFORMATION.*—If a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is determined to be eligible for further review under subsection (a)(1), 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.

(2) *IDENTIFICATION OF CONFIDENTIAL INFORMATION BY SPONSOR.*—Sponsors shall identify any information which the sponsor considers to be confidential information described in paragraph (1).

(3) *CONFIDENTIALITY DURING ELIGIBILITY REVIEW.*—The information contained in a request under section 586A(a) shall remain confidential during the Secretary's consideration under this section of whether the request is eligible for further review.

**SEC. 586C. DATA SUBMISSION; FILING DETERMINATION.**

(a) *IN GENERAL.*—*In the case of a request under section 586A(a) that is determined to be eligible under section 586B for further review under this section and section 586D—*

(1) *the Secretary shall, in notifying the public under section 586B(a)(3) of such eligibility determination, invite the sponsor of the request and any other interested party to submit, in support of or otherwise relating to a GRASE determination—*

(A) *published and unpublished data and other information related to the safety and effectiveness of the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients for its intended nonprescription uses; or*

(B) *any other comments; and*

(2) *not later than 60 days after the submission of such data and other information by the sponsor, including any revised submission of such data and other information following a refusal to file under subparagraph (B), the Secretary shall—*

(A)(i) *issue a written notification to the sponsor determining that the request under section 586A(a), together with such data and other information, is sufficiently complete to conduct a substantive review and make such notification publicly available; and*

(ii) *file such request; or*

(B) *issue a written notification to the sponsor refusing to file the request and stating the reasons for the refusal and why the data and other information submitted is not sufficiently complete to conduct a substantive review and make such notification publicly available;*

(3) *the Secretary shall, in filing a request under paragraph (2)—*

(A) *invite the public to submit further comments with respect to such filing; and*

(B) *limit such public comment, and the comment period under paragraph (1), to the period ending on the date that is 60 days after such filing;*

(4) *if the Secretary refuses to file the request—*

(A) *the sponsor may, within 30 days of receipt of written notification of such refusal, seek a meeting with the Secretary regarding whether the Secretary should file the request; and*

(B) *the Secretary shall convene the meeting; and*

(5) *following any such meeting—*

(A) *if the sponsor asks that the Secretary file the request (with or without amendments to correct any purported deficiencies to the request) the Secretary shall file the request over protest, issue a written notification of the filing to the sponsor, and make such notification publicly available; and*

(B) *if the request is so filed over protest, the Secretary shall not require the sponsor to resubmit a copy of the request for purposes of such filing.*

(b) *REASONS FOR REFUSAL TO FILE REQUEST.*—*The Secretary may refuse to file a request submitted under section 586A(a) if the Secretary determines the data or other information submitted by the*

sponsor under this section are not sufficiently complete to conduct a substantive review with respect to such request.

(c) **PUBLIC AVAILABILITY.**—

(1) **REDACTIONS FOR CONFIDENTIAL INFORMATION.**—The Secretary shall make data and other information submitted in connection with a request under section 586A(a) 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.

(2) **IDENTIFICATION OF CONFIDENTIAL INFORMATION BY SPONSOR.**—Sponsors or any other individual submitting data or other information under this section shall identify any information which the sponsor or individual considers to be confidential information described in paragraph (1).

**SEC. 586D. GRASE DETERMINATION.**

(a) **REVIEW OF NEW REQUEST.**—

(1) **PROPOSED ORDER BY CDER.**—In the case of a request under section 586A(a), the Director of the Center for Drug Evaluation and Research shall—

(A) not later than 300 days after the date on which the request is filed under section 586C(a), complete the review of the request and issue a proposed order determining that—

(i) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the request—

(I) is GRASE; and

(II) is not misbranded;

(ii) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the request—

(I) is not GRASE; or

(II) is misbranded; or

(iii) additional information is necessary to allow the Director of the Center for Drug Evaluation and Research to complete the review of such request;

(B) within such 300-day period, convene a meeting of the Advisory Committee to review the request under section 586A(a); and

(C) if the Director fails to issue such proposed order within the 300-day period referred to in subparagraph (A), transmit the request to the Commissioner of Food and Drugs for review.

(2) **PROPOSED ORDER BY COMMISSIONER.**—With respect to a request transmitted to the Commissioner of Food and Drugs under paragraph (1)(C), the Commissioner shall, not later than 60 days after the date of such transmission, issue—

(A) a proposed order described in paragraph (1)(A)(i);

(B) a proposed order described in paragraph (1)(A)(ii); or

(C) a proposed order described in paragraph (1)(A)(iii).

(3) **PUBLICATION IN FEDERAL REGISTER; PUBLIC COMMENT PERIOD.**—A proposed order issued under paragraph (1) or (2) with respect to a request shall—

(A) be published in the Federal Register; and

(B) solicit public comments for a period of not more than 45 days.

(4) *FINAL ORDER BY CDER.*—In the case of a proposed order under paragraph (1)(A) or (2) with respect to a request, the Director of the Center for Drug Evaluation and Research shall—

(A) issue a final order with respect to the request—

(i) in the case of a proposed order under clause (i) or (ii) of paragraph (1)(A) or subparagraph (A) or (B) of paragraph (2), not later than 90 days after the end of the public comment period under paragraph (3)(B); or

(ii) in the case of a proposed order under paragraph (1)(A)(iii) or paragraph (2)(C), not later than 210 days after the date on which the sponsor submits the additional information requested pursuant to such proposed order; or

(B) if the Director fails to issue such final order within such 90- or 210-day period, as applicable, transmit such proposed order to the Commissioner of Food and Drugs for review.

(5) *FINAL ORDER BY COMMISSIONER.*—With respect to a proposed order transmitted to the Commissioner of Food and Drugs under paragraph (4)(B), the Commissioner shall issue a final order with respect to such proposed order not later than 60 days after the date of such transmission.

(b) *REVIEW OF PENDING REQUESTS.*—

(1) *IN GENERAL.*—The review of a pending request shall be carried out by the Director of the Center for Drug Evaluation and Research in accordance with paragraph (3).

(2) *INAPPLICABILITY OF CERTAIN PROVISIONS.*—Sections 586B and 586C shall not apply with respect to any pending request.

(3) *PROPOSED ORDER BY CDER.*—The Director of the Center for Drug Evaluation and Research shall—

(A) within the timeframe applicable under paragraph (4), complete the review of the request and issue a proposed order determining that—

(i) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the pending request—

(I) is GRASE; and

(II) is not misbranded;

(ii) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the pending request—

(I) is not GRASE; or

(II) is misbranded; or

(iii) additional information is necessary to allow the Director of the Center for Drug Evaluation and Research to complete the review of the pending request; and

(B) if the Director fails to issue such proposed order within the timeframe applicable under paragraph (4), transmit the pending request to the Commissioner of Food and Drugs for review.

(4) *TIMEFRAME FOR ISSUANCE OF PROPOSED ORDER BY CDER.*—The Director of the Center for Drug Evaluation and Re-



search shall issue a proposed order, as required by paragraph (3)(A)—

(A) in the case of a pending request for which the Food and Drug Administration has issued a feedback letter before the date of enactment of the Sunscreen Innovation Act, not later than 45 days after such date of enactment; and

(B) in the case of a pending request for which the Food and Drug Administration has not issued a feedback letter before the date of enactment of the Sunscreen Innovation Act, not later than 90 days after such date of enactment.

(5) **PROPOSED ORDER BY COMMISSIONER.**—With respect to a pending request transmitted to the Commissioner of Food and Drugs under paragraph (3)(B), the Commissioner shall, not later than 60 days after the date of such transmission, issue—

(A) a proposed order described in paragraph (3)(A)(i);

(B) a proposed order described in paragraph (3)(A)(ii); or

(C) a proposed order described in paragraph (3)(A)(iii).

(6) **PUBLICATION IN FEDERAL REGISTER; PUBLIC COMMENT PERIOD.**—A proposed order issued under paragraph (3) or (5) with respect to a pending request shall—

(A) be published in the Federal Register; and

(B) solicit public comments for a period of not more than 45 days.

(7) **ADVISORY COMMITTEE.**—For a proposed order issued under paragraph (3)(A)(iii) or (5)(C) requesting additional information, an Advisory Committee meeting shall be convened if the sponsor requests, or the Director of the Center for Drug Evaluation and Research or the Commissioner of Food and Drugs decides, to convene such a meeting for the purpose of reviewing the pending request.

(8) **FINAL ORDER BY CDER.**—In the case of a proposed order under paragraph (3)(A) or (5) with respect to a request, the Director of the Center for Drug Evaluation and Research shall—

(A) issue a final order with respect to the request—

(i) in the case of a proposed order under clause (i) or (ii) of paragraph (3)(A) or subparagraph (A) or (B) of paragraph (5), not later than 90 days after the end of the public comment period under paragraph (3)(B); or

(ii) in the case of a proposed order under paragraph (3)(A)(iii) or paragraph (5)(C)—

(I) if the Advisory Committee is not convened pursuant to paragraph (7), not later than 210 days after the date on which the sponsor submits the additional information requested pursuant to such proposed order; or

(II) if the Advisory Committee is convened pursuant to paragraph (7), not later than 270 days after date on which the sponsor submits such additional information; or

(B) if the Director fails to issue such final order within such 90-, 210-, and 270-day period, as applicable, transmit such proposed order to the Commissioner of Food and Drugs for review.

(9) **FINAL ORDER BY COMMISSIONER.**—With respect to a proposed order transmitted to the Commissioner of Food and

*Drugs under paragraph (8)(B), the Commissioner shall issue a final order with respect to such proposed order not later than 60 days after the date of such transmission.*

(c) **ADVISORY COMMITTEE.**—

(1) **LIMITATIONS.**—*The Food and Drug Administration—*

(A) *shall not be required to convene the Advisory Committee—*

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

(ii) *more than twice in any twelve month period with respect to the review of submissions under this section; and*

(B) *shall not be required to submit more than 3 submissions to the Advisory Committee per meeting.*

(2) **MEMBERSHIP.**—*In appointing the members of the Advisory Committee, the Secretary may select to serve temporarily as voting members on the Advisory Committee—*

(A) *members of other Federal advisory committees; or*

(B) *consultants from outside of the Department of Health and Human Services who have substantive expertise regarding sunscreen active ingredients.*

(d) **NO DELEGATION.**—*Any responsibility vested by this section in the Commissioner of Food and Drugs is not delegable.*

(e) **EFFECT OF FINAL ORDER.**—

(1) **CONTENT.**—*A final order under subsection (a)(4), (a)(5), (b)(8), or (b)(9) with respect to a request under section 586A(a) or a pending request shall determine that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the request—*

(A) *is GRASE and is not misbranded; or*

(B) *is not GRASE or is misbranded.*

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

(3) **ACTIVE INGREDIENTS DETERMINED NOT TO BE GRASE.**—*Upon issuance of a final order determining that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is not GRASE or is misbranded, the active ingredient or combination of active ingredients shall not be introduced or delivered into interstate commerce, for use under the conditions subject to the final order, unless an application submitted pursuant to section 505(b) with respect to such active ingredient or combination of active ingredients is approved.*

**SEC. 586E. REPORTS.**

(a) **GAO REPORT.**—*Not later than 1 year after the date of enactment of the Sunscreen Innovation Act, the Comptroller General of the United States shall—*

(1) submit a report reviewing the overall progress of the Secretary in carrying out this subchapter to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives; and

(2) include findings on—

(A) the progress made in completing the review of pending requests; and

(B) the role of the Office of the Commissioner of Food and Drugs in issuing determinations with respect to pending requests, including the number of requests transferred to the Office of the Commissioner under section 586D.

(b) SECRETARY'S REPORT.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Sunscreen Innovation Act, and every 2 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 section. Each report under this subsection shall be posted on the Internet site of the Food and Drug Administration.

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

(A) a review of the progress made in issuing GRASE determinations for pending requests, 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 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, 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 in a timely manner GRASE determinations for requests submitted under section 586A(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 or combination of nonprescription sunscreen active ingredients is GRASE and 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, 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) a description of the staffing and resources relating to the costs associated with the review and decisionmaking pertaining to requests under this subchapter;*

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

*(E) to the extent the Secretary determines appropriate, recommendations for process improvements in the handling of pending and new requests, including the advisory committee review process; and*

*(F) recommendations for expanding the applicability of this subchapter to nonprescription active ingredients that are not related to the sunscreen category of over-the-counter drugs.*

*(c) METHOD.—The Secretary shall publish the reports required under subsection (b) 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.*

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