COMMITTEE PRINT

[SHOWING H.R. 4250, AS FAVORABLY FORWARDED BY THE SUBCOMMITTEE ON HEALTH ON JUNE 20, 2014]

113TH CONGRESS
2D SESSION

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.

IN THE HOUSE OF REPRESENTATIVES

MARCH 13, 2014

Mr. WHITFIELD (for himself and Mr. DINGELL) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

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

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.

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 'active ingredient'—

''(A) 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; and

''(B) 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) The term 'Advisory Committee' means the Nonprescription Drug Advisory Committee or any successor to such Committee.

''(3) The terms 'generally recognized as safe and effective' and 'GRASE' mean generally recog-

nized, 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).

''(4) The term 'GRASE determination' means a determination by the Secretary described in section 586A(a).

''(5) The term 'nonprescription' means not subject to section 503(b)(1).

''(6) The term 'pending request' means each request submitted to the Secretary—

''(A) for review of a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients, for a determination of whether such active ingredient or combination of ingredients, for use under specified conditions, to be prescribed, recommended, or suggested in the labeling thereof, is GRASE;

''(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.

''(7) 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 submitting the pending request, for the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients involved.

''(8) 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 in the ultraviolet range at wavelengths from 290 to 400 nanometers.

''(9) 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 **[**_____**]** 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 (e).

''(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) MATERIAL EXTENT AND MATERIAL TIME.—A nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients, for use under the specified condi-

tions, to be prescribed, recommended, or suggested in the labeling thereof, is deemed to meet the standard described in paragraph (1)(B) if such active ingredient or combination of active ingredients has been legally marketed in the United States or at least 1 other country, or marketed as a cosmetic or dietary supplement in 1 or more countries other than the United States—

''(A) for a minimum of 5 continuous years in the same country; and

''(B) in sufficient quantity, as determined by the Secretary based upon the information submitted under subparagraphs (D) and (E) of subsection (c)(1) and, if applicable, subsection (c)(2)(A)(ii).

''(c) TIME AND EXTENT APPLICATION.—

''(1) IN GENERAL.—A sponsor shall include in a request under section 586A(a) a time and extent application including the following:

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

''(B) A detailed chemical description of the active ingredient or combination of active ingredients that includes a full description of the drug substances, including their physical and chemical characteristics, the method of synthesis (or isolation) and purification of the drug substances, and any specifications and analytical methods necessary to ensure the identity, strength, quality, and purity of the drug substances, 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 active ingredient or combination of active ingredients has been marketed.

''(D) The cumulative total number of dosage units sold for each dosage form of the active ingredient or combination of active ingredients, including total weight of the active ingredients and package size for each dosage form in which the active ingredients or combination of active ingredients is marketed as nonprescription. The sponsor shall include an estimate of the minimum number of potential consumer ex-

posures to the active ingredient or combination of active ingredients using one of the following calculations:

"(i) Divide the total number of dosage units sold by the number of dosage units in the largest package size marketed.

"(ii) Divide the total weight of the active ingredients sold by the total weight of the active ingredients in the largest package size marketed.

"(E)(i) The use pattern *(i.e.*, how often the active ingredient or combination of active ingredients is to be used (according to the label) and for how long) for each country in which the active ingredient or combination of active ingredients is marketed.

"(ii) If the use pattern varies between countries based on the active ingredient or combination of active ingredient's packaging and labeling, or changes in use pattern have occurred over time in one or more countries, an explanation of why there are differences or changes.

"(F) A list of all countries in which the active ingredient or combination of active ingredients has been withdrawn from marketing or in

which a request for nonprescription marketing approval has been denied and an explanation for such withdrawal or request denial.

''(2) SUNSCREEN ACTIVE INGREDIENTS THAT HAVE NOT BEEN MARKETED IN THE U.S. FOR 5 CONTINUOUS YEARS.—

''(A) IN GENERAL.—In the case of a time and extent application with respect to a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients 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 active ingredient or combination of active ingredients has been marketed:

''(i) The manner in which the active ingredient or combination of active ingredients has been marketed to consumers (*e.g.*, nonprescription general sales direct-to-consumer; sold only in a pharmacy, with or without the personal involvement of a pharmacist; dietary supplement; or cosmetic), including rules and guidelines for

labeling, and directions for proper use. If the active ingredient or combination of active ingredients is marketed to consumers as nonprescription, pharmacy-only, the sponsor shall establish that this marketing restriction does not indicate safety concerns about its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use.

''(ii) A description of the population demographics (percentage of various racial and ethnic groups) and the source from which this information has been compiled, to ensure that the use of the active ingredient or combination of active ingredients can be reasonably extrapolated to the population of the United States.

''(iii) A description of the country's system for maintenance of approved ingredients, postmarket safety monitoring, and identifying adverse drug experiences, especially those found in nonprescription marketing experience, including method of collection, if applicable.

''(iv) A statement of how long the active ingredient or combination of active ingredients 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) Whether the active ingredient or combination of active ingredients is marketed as a prescription drug only in the country and, if so, an explanation for such restriction.

''(vi) A description of the country's evaluation procedures.

''(vii) A description of the country's rules for grandfathering currently approved sunscreen or cosmetic ingredients, if applicable.

''(B) SUNSCREEN ACTIVE INGREDIENTS THAT HAVE BEEN MARKETED IN MORE THAN 5 COUNTRIES.—

''(i) IN GENERAL.—In the case of a time and extent application with respect to a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients 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 nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients meets the criteria under items (aa) through (cc) of clause (i)(I) in 1 or more countries listed in section 802(b)(1)(A), at least 1 such country shall be included among the 5 countries selected under such clause (i)(I).

"(d) PENDING REQUESTS.—The requirements of subsection (c) shall not apply to pending requests. Pending requests shall be considered in accordance with section 586D(c).

"(e) PUBLIC AVAILABILITY.—

"(1) REDACTIONS FOR CONFIDENTIAL INFORMATION.—If a nonprescription sunscreen active in-

gredient 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 for further review under section 586B—

''(1) the Secretary shall invite the sponsor of the request and any other interested party to submit data in support of or otherwise relating to a GRASE determination in accordance with subsection (b);

''(2) not later than [____] days after the submission of such data under subsection (c) by the sponsor, including any revised submission of such data 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, is complete 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 such refusal if the Secretary finds that such request, together with such data, have not been submitted in accordance with subsection (c) and make such notification publicly available;

''(3) if the Secretary refuses to file the request—

''(A) the sponsor may, within [_____] days of receipt of written notification of such refusal, seek an informal conference with the Secretary regarding whether the Secretary should file the request; and

''(B) the Secretary shall convene the informal conference; and

''(4) following any such informal conference—

''(A) if the sponsor insists 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—

''(i) the date of filing is deemed to be the data that is [____] days after the date on which the sponsor requested the informal conference; and

''(ii) 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) for any of the following reasons:

''(1) The request is not submitted in the form required under subsection (c).

''(2) The request is insufficiently complete because it does not, on its face, contain information required under subsection (c).

''(3) The request does not contain an accurate and complete English translation of each document or data included in the request.

''(4) Documents contained in the request are not legible.

''(5) The request is not indexed or paginated.

''(6) The documents in the request lack adequate bookmarks or other appropriate markers for ease of electronic navigation.

''(7) The request fails to provide assessments of the information required under subsection (c) and fails to provide a justification of why such assessments are not required.

''(8) The request fails to include complete studies, reports, or datasets, where applicable.

''(c) DATA SUBMISSION.—

''(1) IN GENERAL.—In the case of a request under section 586A(a) that is determined to be eligible for further review under section 586B, the Secretary shall provide the sponsor and other interested persons an opportunity to submit published and unpublished data related to the safety and effectiveness

of the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients for its intended nonprescription uses, in accordance with paragraph (2).

''(2) SAFETY AND EFFECTIVENESS DATA SUBMISSIONS.—Submissions under this paragraph shall include the following:

''(A) 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 in-

dividual active component, and pertinent medical and scientific literature.

''(iii) SAFETY CONSIDERATIONS.—With respect to individual active components, all data related to the assessment of skin irritation, eye irritation, sensitization, and human pharmacokinetics, including the rate and amount of absorption of the active components in a variety of different skin types/conditions, human adverse event profileacute toxicity, repeat dose toxicity, genetic toxicity, reproductive toxicity, developmental toxicity, phototoxicity, carcinogenicity, endocrine disruption, toxicokinetics.

''(B) 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, including photo-stability, and chemical stability.

''(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, including photo-stability and chemical stability.

''(iii) SUN PROTECTION.—With respect to individual active components, all data related to the assessment of the sun protection factor (commonly referred to as 'SPF'), broad spectrum protection, and water resistance.

''(C) 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 nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active in-

gredients and the scientific basis (or lack thereof) for the conclusion that the active ingredient or combination of active ingredients has been proven to be generally recognized as 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 shall be included.

"(D) OFFICIAL DRUG MONOGRAPH.—An applicable United States Pharmacopoeia or National Formulary for the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients or a proposed standard for inclusion in an article to be recognized in an official drug monograph for the active ingredient or combination of active ingredients, including information showing that the official or proposed compendial monograph for the active ingredient or combination of active ingredients is consistent with the active ingredient or combination of active ingredients used in the studies establishing safety and effectiveness and with the active ingredient or combination of active ingredients 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 or combination of active ingredients and the active ingredient or combination of active ingredients that is the subject of the request, the sponsor shall explain such differences.

''(E) ADVERSE DRUG EXPERIENCES.—A list of all serious adverse drug experiences, as defined by the Secretary, and any available data regarding such adverse events, from each country where the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients has been or is currently marketed as a prescription drug or as a nonprescription drug or product.

''(F) FORMAT FOR DATA PACKAGE SUBMISSION.—Submissions under this paragraph shall be—

''(i) indexed and paginated for purposes of electronic navigation;

''(ii) legible, in English, or accompanied by an English translation in accordance with applicable regulation; and

''(iii) include—

''(I) a table of contents;

''(II) a background summary of the entire submission;

''(III) separate volumes of data grouped by discipline (*e.g.*, Chemistry, Manufacturing and Controls, Pharmacology and Toxicology, Clinical Safety, Clinical Pharmacology and Human Pharmacokinetics, and Clinical Efficacy); and

''(IV) a summary table listing all studies, and, for each study, a table of contents, summary, and complete data set.

''(G) GUIDANCE FOR NEW REQUESTS SUBMITTED AFTER DATE OF ENACTMENT.—The Secretary may issue guidance on the format and content of a safety and effectiveness data submission under this subsection and on the safety standards for review by the Food and Drug Administration of nonprescription sunscreen active ingredients and combinations of nonprescription sunscreen active ingredients. Issuance of such guidance shall not prevent the

submission and review of new requests under this section prior to issuance of final guidance.

''(d) PUBLIC AVAILABILITY.—

''(1) REDACTIONS FOR CONFIDENTIAL INFORMATION.—The Secretary shall make data and information submitted in connection with a request under section 586(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 shall identify any information which the sponsor considers to be confidential information described in paragraph (1).

''(3) COMPENDIAL INFORMATION.—The information described in subsection (c)(2)(D) shall not be considered confidential for purposes of this subsection.

''SEC. 586D. GRASE DETERMINATION.

''(a) REVIEW OF NEW REQUESTS.—

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

"(A) not later than [_____] 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 whether—

"(i) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the request is GRASE and not misbranded; or

"(ii) 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 [_____]-day period, convene a meeting of the Advisory Committee to review the request; and

"(C) if the Secretary fails to issue such proposed order within the [_____-day] period referred to in subparagraph (A), submit the request to the Commissioner of Food and Drugs for review.

"(2) PROPOSED ORDER BY COMMISSIONER.—With respect to a request submitted to the Commissioner of Food and Drugs under paragraph (1)(C),

the Commissioner shall issue a proposed order with respect to the request not later than [_____] days after the date of such submission.

"(3) PUBLIC COMMENT PERIOD.—Not later than [_____] days after the date on which a proposed order is issued under paragraph (1) with respect to a request, the Director of the Center for Drug Evaluation and Research shall publish a notice in the Federal Register soliciting public comments on the request for a period of not more than [_____] days.

"(4) FINAL ORDER BY CDER.—In the case of a proposed order under paragraph (1) 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 not later than [_____] days after the date on which the proposed order is issued; or

"(B) if the Director fails to issue such final order within such [____-day] period, submit such proposed order to the Commissioner of Food and Drugs for review.

"(5) FINAL ORDER BY COMMISSIONER.—With respect to a proposed order submitted to the Commissioner of Food and Drugs under paragraph

(6)(B), issue a final order with respect to such proposed order not later than [_____] days after the date of such submission.

''(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 (2), unless the sponsor of the pending request, not later than [_____] after the date of the enactment of the Sunscreen Innovation Act, elects to have such review carried out by the Director and the Advisory Committee in accordance with paragraph (3).

''(2) REVIEW BY CDER.—

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

''(i) not later than [_____] days after the date of the enactment of the Sunscreen Innovation Act, issue a proposed order determining whether—

''(I) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen ac-

tive ingredients that is the subject of the pending request is GRASE; or

"(II) additional information is necessary to allow the Director to make such determination;

"(ii) on the date on which the proposed order is issued, publish a notice in the Federal Register soliciting public comments on the proposed order for a period of not more than [_____] days; and

"(iii) if the Director fails to issue such proposed order within the [_____-day] period referred to in clause (i), submit the pending request to the Commissioner of Food and Drugs for review.

"(B) PROPOSED ORDER BY COMMISSIONER.—With respect to a pending request submitted to the Commissioner of Food and Drugs under subparagraph (A)(iii), the Commissioner shall issue a proposed order with respect to the pending request not later than [_____] days after the date of such submission.

"(C) FINAL ORDER BY CDER.—In the case of a proposed order under subparagraph (A) or

(B) with respect to a pending request, the Director of the Center for Drug Evaluation and Research shall—

"(i) issue a final order with respect to the request not later than [_____] days after the date on which the proposed order is issued; or

"(ii) if the Director fails to issue such final order within such [____-day] period, submit such proposed order to the Commissioner of Food and Drugs for review.

"(D) FINAL ORDER BY COMMISSIONER.—With respect to a proposed order submitted to the Commissioner of Food and Drugs under subparagraph (C)(ii), issue a final order with respect to such proposed order not later than [_____] days after the date of such submission.

"(3) REVIEW BY CDER AND ADVISORY COMMITTEE.—In the case of an election under paragraph (1) to have the review of a pending request carried out by the Director of the Center for Drug Evaluation and Research and the Advisory Committee in accordance with this paragraph, the following provisions apply:

"(A) ADVISORY COMMITTEE.—Not later than [_____] days after the date of enactment of the Sunscreen Innovation Act, the Director of the Center for Drug Evaluation and Research shall convene a meeting of the Advisory Committee to review the request.

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

"(i) not later than [_____] days after the date of the enactment of the Sunscreen Innovation Act, issue a proposed order determining whether—

"(I) the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of the pending request is GRASE; or

"(II) additional information is necessary to allow the Director to make such determination;

"(ii) on the date on which the proposed order is issued, publish a notice in the Federal Register soliciting public com-

ments on the proposed order for a period of not more than [_____] days; and

"(iii) if the Director fails to issue such proposed order within the [_____-day] period referred to in clause (i), submit the pending request to the Commissioner of Food and Drugs for review.

"(C) PROPOSED ORDER BY COMMISSIONER.—With respect to a pending request submitted to the Commissioner of Food and Drugs under subparagraph (B)(iii), the Commissioner shall issue a proposed order with respect to the pending request not later than [_____] days after the date of such submission.

"(D) FINAL ORDER BY CDER.—In the case of a proposed order under subparagraph (B) or (C) with respect to a pending request, the Director of the Center for Drug Evaluation and Research shall—

"(i) issue a final order with respect to the request not later than [_____] days after the date on which the proposed order is issued; or

"(ii) if the Director fails to issue such final order within such [____-day] period, submit such proposed order to the Commissioner of Food and Drugs for review.

"(E) FINAL ORDER BY COMMISSIONER.—With respect to a proposed order submitted to the Commissioner of Food and Drugs under subparagraph (D)(ii), issue a final order with respect to such proposed order not later than [_____] days after the date of such submission.

"(c) REVIEW OF ADDITIONAL INFORMATION.—If, after issuance of a proposed order, the Director of the Center for Drug Evaluation and Research or the Commissioner of Food and Drugs determines that additional information is required from the sponsor to complete review of the request under subsection (a) or the pending request under subsection (b) for purposes of issuing a final order pursuant to the respective subsection, the Director or Commissioner (as applicable) shall, upon receipt of such requested additional information—

"(1) review such additional information; and

"(2) issue a final order with respect to the proposed order not later than [_____] days after such receipt.

''(d) PERIOD FOR CONVENING ADVISORY COMMITTEE.—If the Director of the Center for Drug Evaluation and Research or the Commissioner of Food and Drugs requests additional information (pursuant to subsection (c)) during review of a pending request under subsection (b)(2)—

''(1) the sponsor, at the time of submission of the additional information, may indicate in such submission that the sponsor is requesting review by the Advisory Committee; and

''(2) the Director or Commissioner (as applicable) shall convene the Advisory Committee for purposes of such review not later than [____] days after receipt of such submission.

''(e) ADVISORY COMMITTEE.—The Advisory Committee—

''(1) shall not be required to be convened more than twice in any twelve month period with respect to the review of submissions under this section; and

''(2) shall not be required to review more than 3 submissions per meeting.

''(f) NON-DELEGATION.—A determination by the Commissioner of Food and Drugs under this section is non-delegable.

''(g) EFFECT OF FINAL ORDER.—

''(1) 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 in accordance with all requirements applicable to drugs not subject to section 503(b)(1).

''(2) 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 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 [____] days 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 [____] days 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 in a timely manner decisions on the safety and effectiveness for requests for nonprescription sunscreen active ingredients and combinations of nonprescription sunscreen active ingredients pending as of the date of enactment of the Sunscreen Innovation Act, 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 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 request, and the length of time

such requests have been pending, measured from the date of original eligibility request submission by the sponsor;

''(B) a review of the progress made in issuing in a timely manner a decision on safety and effectiveness for requests for nonprescription sunscreen active ingredients and combinations of nonprescription sunscreen active ingredients submitted after the date of enactment of the Sunscreen Innovation Act, including the number of such requests—

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

''(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 requests;

''(D) a review of the progress 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 section to nonprescription active ingredients or conditions 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.''.