AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 4250

OFFERED BY M__. _____

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.

''(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 review of a nonprescription sunscreen active ingredient for a GRASE determination;

''(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 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 the refusal and why the data and other information submitted is inadequate to make a GRASE determination and make such notification publicly available;

''(3) the Secretary shall, in filing or refusing to file a request under paragraph (2)—

''(A) invite the public to submit comments with respect to such filing or refusal to file; and

''(B) limit such public comment period to the period ending on the date that is 45 days after such filing or refusal to file;

''(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 an informal conference with the Secretary regarding whether the Secretary should file the request; and

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

''(5) 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, 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 insufficient to make a GRASE determination 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 re-

quest 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 re-

quest 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.—If a proposed order is issued under paragraph (3)(A)(iii) or (5)(C) requesting additional information—

''(A) the sponsor, the Director of the Center for Drug Evaluation and Research, or the Commissioner of Food and Drugs may request a meeting of the Advisory Committee for the purpose of reviewing the pending request; and

''(B) the Advisory Committee shall be convened for such purpose.

''(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 Advisory Committee—

''(A) shall not be required to be convened—

''(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 review more than 3 submissions 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 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 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 sub-

chapter 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, meas-

ured 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, meas-

ured 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;

(C) the safety 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.

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