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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.

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

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

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

''(b) DEFINITIONS.—

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

''(2) SUNSCREEN ACTIVE INGREDIENT.—The term 'sunscreen active ingredient' means an active ingredient that absorbs, reflects, or scatters radi-

ation in the ultraviolet range at wavelengths from 290 to 400 nanometers.

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

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

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

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

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

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

''(d) APPLICATION FOR ELIGIBILITY.—

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

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

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

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

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

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

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

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

"(A) IN GENERAL.—In the case of an application with respect to a nonprescription sun-

screen condition that has not been marketed in the United States for 5 continuous years, in addition to the information required under paragraph (1), the sponsor shall submit the following information for each country in which the sunscreen condition has been marketed:

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

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

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

''(iv) A statement of how long the sunscreen condition has been marketed in

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

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

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

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

''(I) may submit information in accordance with clauses (i) through

(iv) of subparagraph (A) with respect to only 5 such countries, including—

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

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

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

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

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

"(ii) REQUIREMENT.—If the sunscreen condition meets the criteria under items (aa) through (cc) of clause (i)(I) in 1 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).

''(3) PENDING APPLICATIONS.—The requirements of this subsection shall not apply to a sunscreen condition deemed eligible for review of safety and effectiveness by publication of a notice of eligibility in the Federal Register prior to the date of enactment of the Sunscreen Innovation Act. Applications for such sunscreen conditions shall be considered in accordance with subsection (g).

''(e) PUBLIC AVAILABILITY.—If a condition is found eligible under subsection (d), the Secretary shall make the application publicly available, with redactions for confidential commercial information or trade secret information, and any other information exempt from disclosure pursuant to section 1905 of title 18, United States Code, section 552(b) of title 5, United States Code, or section 301(j) of this Act. Applications shall remain confidential during the Secretary's consideration of eligibility.

''(f) NEW SUNSCREEN CONDITION APPLICATION.—

''(1) ELIGIBILITY DETERMINATION.—Not later than 60 days after the submission of an eligibility application under subsection (d), the Secretary shall determine if the sunscreen condition is eligible for further review for safety and effectiveness. In the

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

''(2) SAFETY AND EFFECTIVENESS DATA SUBMISSIONS.—

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

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

''(i) HUMAN SAFETY DATA.—

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

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

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

''(ii) EFFICACY DATA.—

''(I) INDIVIDUAL ACTIVE COMPONENTS.—With respect to individual active components, controlled studies, partially controlled or uncontrolled

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

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

"(iii) DATA SETTING FORTH MEDICAL RATIONALE AND PURPOSE.—A summary of the data and views setting forth the medical rationale and purpose (or lack thereof) for the sunscreen condition and the scientific basis (or lack thereof) for the conclusion that the condition has been proven safe and effective for the intended use. If

there is an absence of controlled studies in the material submitted, an explanation as to why such studies are not considered necessary must be included.

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

''(v) ADVERSE DRUG EXPERIENCES.—A list of all serious adverse drug experi-

ences, as defined by the Secretary, from each country where the condition has been or is currently marketed as a prescription drug or as a nonprescription drug or product.

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

''(D) CONFIDENTIALITY OF SUBMISSIONS.—The Secretary shall make data and information submitted by the sponsor, or pursuant to a notice requesting safety and effectiveness data published in the Federal Register, publicly available, with redactions for confidential commercial information or trade secret information, and any other information exempt from disclosure pursuant to section 1905 of

title 18, United States Code, section 552(b) of title 5, United States Code, or section 301(j) of this Act.

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

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

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

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

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

''(A) the safety of the nonprescription sunscreen condition;

''(B) the effectiveness of the nonprescription sunscreen condition;

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

''(D) the labeling of the nonprescription sunscreen condition.

''(3) COMMUNICATIONS BETWEEN ADVISORY COMMITTEE AND OTHER INDIVIDUALS WHO SUBMIT DATA.—The advisory committee shall have the authority to communicate with the sponsor and other individuals who submit data during the advisory committee's review, including requesting clarification or additional information.

''(4) RECOMMENDATIONS.—

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

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

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

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

"(B) TIMING.—The advisory committee shall make a recommendation under subparagraph (A) not later than 180 days after the advisory committee receives the application and

data submitted under subsection (f)(3) or subsection (g).

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

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

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

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

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

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

''(C) In the case of a recommendation described in clause (iii) of such subsection, the Center for Drug Evaluation and Research shall issue a determination affirming or denying the recommendation of the advisory committee, to

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

''(2) SUPERVISORY REVIEW OF DETERMINATION.—

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

''(B) REQUEST FOR SUPERVISORY REVIEW.—A request described in subparagraph (A) shall be made to the Secretary not later than 30 days after such decision and shall indicate in the request whether such person seeks an in-person meeting or a teleconference. The Secretary shall schedule an in-person or tele-

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

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

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

plicable rules and regulations for over-the-counter drugs.

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

''(j) REPORTS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

''(k) RULES OF CONSTRUCTION.—

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

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

SEC. 3. SUNSCREEN TESTING AND LABELING.

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

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

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

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