

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

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

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

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

5 **“SEC. 524B. PROCEDURES FOR CLASSIFYING SUNSCREEN**
6 **ACTIVE INGREDIENTS.**

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

12 “(b) DEFINITIONS.—

13 “(1) ACTIVE INGREDIENT.—The term ‘active
14 ingredient’ means any component that is intended to
15 furnish pharmacological activity or other direct ef-
16 fect in the diagnosis, cure, mitigation, treatment, or
17 prevention of disease, or to affect the structure or
18 function of the body of humans or animals. The
19 term includes components that may undergo chem-
20 ical change in the manufacture of a drug and may
21 be present in a drug in a modified form intended to
22 furnish the specified activity or effect.

23 “(2) SUNSCREEN ACTIVE INGREDIENT.—The
24 term ‘sunscreen active ingredient’ means an active
25 ingredient that absorbs, reflects, or scatters radi-

1 ation in the ultraviolet range at wavelengths from
2 290 to 400 nanometers.

3 “(3) SUNSCREEN CONDITION.—The term ‘sun-
4 screen condition’ means a sunscreen active ingre-
5 dient (or a combination of sunscreen active ingredi-
6 ents), dosage form, dosage strength, or route of ad-
7 ministration, marketed for a specific nonprescription
8 use.

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

11 “(1) not be included in the stayed sunscreen
12 monograph; and

13 “(2) have been marketed as a nonprescription
14 sunscreen condition in the United States or at least
15 1 other country, or marketed as a cosmetic or die-
16 tary supplement in 1 or more countries other than
17 the United States—

18 “(A) for a minimum of 5 continuous years;

19 and

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

25 “(d) APPLICATION FOR ELIGIBILITY.—

1 “(1) IN GENERAL.—A sponsor of a nonprescrip-
2 tion sunscreen condition described in subsection (c)
3 desiring to market such condition in the United
4 States may submit an application to the Secretary,
5 in such manner and containing such information as
6 required by the Secretary, including the following:

7 “(A) Basic information about the sun-
8 screen condition (including a description of each
9 active ingredient, pharmacologic class, intended
10 nonprescription use, nonprescription strength
11 and dosage form, route of administration, and
12 directions for use).

13 “(B) A detailed chemical description of the
14 sunscreen active ingredient that includes a full
15 description of the drug substance, including its
16 physical and chemical characteristics, the meth-
17 od of synthesis (or isolation) and purification of
18 the drug substance, and any specifications and
19 analytical methods necessary to ensure the
20 identity, strength, quality, and purity of the
21 drug substance, including reference to the cur-
22 rent edition of the official National Formulary,
23 the United States Pharmacopeia, or foreign
24 compendiums, where applicable.

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

3 “(D) The cumulative total number of dos-
4 age units sold for each dosage form of the sun-
5 screen condition, including total weight of the
6 active ingredient, package size for each dosage
7 form in which the condition is marketed as non-
8 prescription, and an estimate of the minimum
9 number of potential consumer exposures to the
10 condition.

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

15 “(F) A list of all countries in which the
16 sunscreen condition has been withdrawn from
17 marketing or in which an application for non-
18 prescription marketing approval has been de-
19 nied and an explanation for such withdrawal or
20 application denial.

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

24 “(A) IN GENERAL.—In the case of an ap-
25 plication with respect to a nonprescription sun-

1 screen condition that has not been marketed in
2 the United States for 5 continuous years, in ad-
3 dition to the information required under para-
4 graph (1), the sponsor shall submit the fol-
5 lowing information for each country in which
6 the sunscreen condition has been marketed:

7 “(i) The manner in which the sun-
8 screen condition has been marketed to con-
9 sumers. If the sunscreen condition is mar-
10 keted to consumers as a nonprescription
11 pharmacy only condition, the Secretary
12 may require supplemental information.

13 “(ii) A description of the population
14 demographics and the source from which
15 this information has been compiled, to en-
16 sure that the sunscreen condition’s use can
17 be reasonably extrapolated to the popu-
18 lation of the United States.

19 “(iii) A description of the country’s
20 system for identifying adverse drug experi-
21 ences, especially those found in non-
22 prescription marketing experience, includ-
23 ing method of collection if applicable.

24 “(iv) A statement of how long the
25 sunscreen condition has been marketed in

1 each country and how long the current
2 product labeling has been in use, accom-
3 panied by a copy of the current product la-
4 beling, including a translation into English
5 of any labeling that is not in English, and
6 a statement of whether the current product
7 labeling has been authorized, accepted, or
8 approved by a regulatory body in each
9 country where the condition is marketed.

10 “(v) A list of all countries where the
11 sunscreen condition is marketed as a pre-
12 scription drug only and an explanation for
13 such restriction.

14 “(B) SUNSCREEN CONDITIONS THAT HAVE
15 BEEN MARKETED IN MORE THAN 5 COUN-
16 TRIES.—

17 “(i) IN GENERAL.—In the case of a
18 sunscreen condition that has been mar-
19 keted as a nonprescription sunscreen in
20 more than 5 countries, with a minimum of
21 5 continuous years of marketing in at least
22 one such country, the sponsor—

23 “(I) may submit information in
24 accordance with clauses (i) through

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

3 “(aa) the country with a
4 minimum of 5 continuous years
5 of nonprescription marketing;

6 “(bb) the country with the
7 longest duration of marketing;
8 and

9 “(cc) the country with the
10 most support for marketing, such
11 as a large volume of sales with
12 cultural diversity among users of
13 the product; and

14 “(II) shall explain the basis for
15 the countries selected under subclause
16 (I); and

17 “(III) shall provide information
18 from more than 5 countries if such in-
19 formation is needed to support the ap-
20 plication.

21 “(ii) REQUIREMENT.—If the sun-
22 screen condition meets the criteria under
23 items (aa) through (cc) of clause (i)(I) in
24 1 or more countries listed in section
25 802(b)(1)(A), at least 1 such country shall

1 be included among the 5 countries selected
2 under such clause (i)(I).

3 “(3) PENDING APPLICATIONS.—The require-
4 ments of this subsection shall not apply to a sun-
5 screen condition deemed eligible for review of safety
6 and effectiveness by publication of a notice of eligi-
7 bility in the Federal Register prior to the date of en-
8 actment of the Sunscreen Innovation Act. Applica-
9 tions for such sunscreen conditions shall be consid-
10 ered in accordance with subsection (g).

11 “(e) PUBLIC AVAILABILITY.—If a condition is found
12 eligible under subsection (d), the Secretary shall make the
13 application publicly available, with redactions for confiden-
14 tial commercial information or trade secret information,
15 and any other information exempt from disclosure pursu-
16 ant to section 1905 of title 18, United States Code, section
17 552(b) of title 5, United States Code, or section 301(j)
18 of this Act. Applications shall remain confidential during
19 the Secretary’s consideration of eligibility.

20 “(f) NEW SUNSCREEN CONDITION APPLICATION.—

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

1 case of a sunscreen condition determined to be eligi-
2 ble, the Secretary shall publish a notice of eligibility
3 in the Federal Register, and provide interested per-
4 sons an opportunity to submit published and unpub-
5 lished data related to the safety and effectiveness of
6 the sunscreen condition for its intended nonprescrip-
7 tion uses, in accordance with paragraph (2). In the
8 case of a sunscreen condition determined not eligi-
9 ble, the Secretary shall issue a letter to the sponsor,
10 which shall be made publicly available.

11 “(2) SAFETY AND EFFECTIVENESS DATA SUB-
12 MISSIONS.—

13 “(A) IN GENERAL.—Within 60 days of the
14 publication in the Federal Register of an appli-
15 cation deemed eligible, as described in para-
16 graph (1), the sponsor and other interested par-
17 ties shall submit safety and effectiveness data
18 to the Secretary for further review, as described
19 in subparagraph (B).

20 “(B) REQUIRED SUBMISSIONS REGARDING
21 DATA.—Submissions under this paragraph shall
22 include the following:

23 “(i) HUMAN SAFETY DATA.—

24 “(I) INDIVIDUAL ACTIVE COMPO-
25 NENTS.—With respect to individual

1 active components, controlled studies,
2 partially controlled or uncontrolled
3 studies, documented case reports, per-
4 tinent marketing experiences that may
5 influence a determination as to the
6 safety of each individual active compo-
7 nent, and pertinent medical and sci-
8 entific literature.

9 “(II) COMBINATIONS OF INDI-
10 VIDUAL ACTIVE COMPONENTS.—With
11 respect to combinations of the indi-
12 vidual active components, controlled
13 studies, partially controlled or uncon-
14 trolled studies, documented case re-
15 ports, pertinent marketing experiences
16 that may influence a determination as
17 to the safety of combinations of the
18 individual active component, and per-
19 tinent medical and scientific lit-
20 erature.

21 “(ii) EFFICACY DATA.—

22 “(I) INDIVIDUAL ACTIVE COMPO-
23 NENTS.—With respect to individual
24 active components, controlled studies,
25 partially controlled or uncontrolled

1 studies, documented case reports, per-
2 tinent marketing experiences that may
3 influence a determination on the effi-
4 cacy of each individual active compo-
5 nent, pertinent medical and scientific
6 literature.

7 “(II) COMBINATIONS OF INDI-
8 VIDUAL ACTIVE COMPONENTS.—With
9 respect to combinations of the indi-
10 vidual active components, controlled
11 studies, partially controlled or uncon-
12 trolled studies, documented case re-
13 ports, pertinent marketing experiences
14 that may influence a determination on
15 the efficacy of combinations of the in-
16 dividual active components, and perti-
17 nent medical and scientific literature.

18 “(iii) DATA SETTING FORTH MEDICAL
19 RATIONALE AND PURPOSE.—A summary of
20 the data and views setting forth the med-
21 ical rationale and purpose (or lack thereof)
22 for the sunscreen condition and the sci-
23 entific basis (or lack thereof) for the con-
24 clusion that the condition has been proven
25 safe and effective for the intended use. If

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

5 “(iv) OFFICIAL DRUG MONOGRAPH.—

6 An applicable United States Pharma-
7 copoeia or National Formulary for the sun-
8 screen active ingredient or a proposed
9 standard for inclusion in an article to be
10 recognized in an official drug monograph
11 for the active ingredient, including infor-
12 mation showing that the official or pro-
13 posed compendial monograph for the active
14 ingredient is consistent with the active in-
15 gredient used in the studies establishing
16 safety and effectiveness and with the active
17 ingredient marketed in the nonprescription
18 product to a material extent and for a ma-
19 terial time. If differences exist between the
20 official or proposed compendial monograph
21 for the active ingredient and the active in-
22 gredient that is the subject of the applica-
23 tion, sponsor shall explain such differences.

24 “(v) ADVERSE DRUG EXPERIENCES.—

25 A list of all serious adverse drug experi-

1 ences, as defined by the Secretary, from
2 each country where the condition has been
3 or is currently marketed as a prescription
4 drug or as a nonprescription drug or prod-
5 uct.

6 “(C) OPTIONAL ANIMAL SAFETY DATA.—

7 In addition to the information required under
8 subparagraph (B), the sponsor may submit in-
9 formation with respect to animal safety data,
10 including controlled studies and partially con-
11 trolled or uncontrolled studies, in the case of an
12 application for individual active components,
13 and controlled studies and partially controlled
14 or uncontrolled studies in the case of an appli-
15 cation for combinations of individual active
16 components.

17 “(D) CONFIDENTIALITY OF SUBMIS-

18 SIONS.—The Secretary shall make data and in-
19 formation submitted by the sponsor, or pursu-
20 ant to a notice requesting safety and effective-
21 ness data published in the Federal Register,
22 publicly available, with redactions for confiden-
23 tial commercial information or trade secret in-
24 formation, and any other information exempt
25 from disclosure pursuant to section 1905 of

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

4 “(3) NEW SUNSCREEN CONDITION APPLICATION
5 SUBMISSION TO THE ADVISORY COMMITTEE.—Not
6 later than 30 days after the end of the public com-
7 ment period described in paragraph (2), the Sec-
8 retary shall submit the application and the safety
9 and effectiveness data submitted under paragraph
10 (2) to the Nonprescription Drugs Advisory Com-
11 mittee (referred to in this section as the ‘advisory
12 committee’) for review.

13 “(g) PENDING SUNSCREEN CONDITION APPLICA-
14 TIONS.—Not later than 30 days after the date of enact-
15 ment of the Sunscreen Innovation Act, the Secretary shall
16 submit to the advisory committee all safety and effective-
17 ness data submitted with respect to each application for
18 review of sunscreen conditions that the Secretary had de-
19 termined, prior to the date of enactment of the Sunscreen
20 Innovation Act, to be eligible for review of safety and ef-
21 fectiveness and for which the information required under
22 subsection (f)(2) has been submitted to the Secretary prior
23 to such date of enactment.

24 “(h) REVIEW AND RECOMMENDATION FOR NON-
25 PRESCRIPTION SUNSCREEN CONDITION.—

1 “(1) IN GENERAL.—The Secretary shall require
2 the advisory committee to evaluate the safety and ef-
3 fectiveness data submitted in accordance with sub-
4 section (f)(2) or (g).

5 “(2) STANDARDS.—In evaluating a non-
6 prescription sunscreen condition under paragraph
7 (1), the advisory committee shall use the regulations
8 in effect at the time of the application, including
9 regulations with respect to—

10 “(A) the safety of the nonprescription sun-
11 screen condition;

12 “(B) the effectiveness of the nonprescrip-
13 tion sunscreen condition;

14 “(C) the benefit-to-risk ratio of the non-
15 prescription sunscreen condition; and

16 “(D) the labeling of the nonprescription
17 sunscreen condition.

18 “(3) COMMUNICATIONS BETWEEN ADVISORY
19 COMMITTEE AND OTHER INDIVIDUALS WHO SUBMIT
20 DATA.—The advisory committee shall have the au-
21 thority to communicate with the sponsor and other
22 individuals who submit data during the advisory
23 committee’s review, including requesting clarification
24 or additional information.

25 “(4) RECOMMENDATIONS.—

1 “(A) IN GENERAL.—For each such sub-
2 mission under subsection (f)(3) or (g), the advi-
3 sory committee shall make one of the following
4 recommendations to the Secretary:

5 “(i) The sunscreen condition is gen-
6 erally recognized as safe and effective (in-
7 cluding any or all indications), including
8 nonprescription sunscreen conditions for
9 which a new drug application has been ap-
10 proved by the Secretary.

11 “(ii) Insufficient information has been
12 provided to support a recommendation that
13 the sunscreen condition is generally recog-
14 nized as safe and effective (including any
15 or all indications).

16 “(iii) The sunscreen condition is not
17 generally recognized as safe and effective
18 to be marketed or sold unless an applica-
19 tion with respect to such condition is ap-
20 proved under section 505(b).

21 “(B) TIMING.—The advisory committee
22 shall make a recommendation under subpara-
23 graph (A) not later than 180 days after the ad-
24 visory committee receives the application and

1 data submitted under subsection (f)(3) or sub-
2 section (g).

3 “(C) RESUBMISSION OF DATA.—If the ad-
4 visory committee recommends that insufficient
5 information has been provided, in accordance
6 with subparagraph (A)(ii), the advisory com-
7 mittee shall make such recommendation not
8 later than 180 days after the date on which
9 such additional information is submitted.

10 “(i) DETERMINATION BY THE CENTER FOR DRUG
11 EVALUATION AND RESEARCH.—

12 “(1) IN GENERAL.—The Center for Drug Eval-
13 uation and Research shall respond to the rec-
14 ommendations of the advisory committee under sub-
15 section (h)(4) as follows:

16 “(A) In the case of a recommendation by
17 the advisory committee described in clause (i)
18 of subsection (h)(4), not later than 45 days
19 after the advisory committee issues the rec-
20 ommendation, the Center for Drug Evaluation
21 and Research shall issue a determination af-
22 firming or denying the recommendation of the
23 advisory committee. If the Center for Drug
24 Evaluation and Research affirms the rec-
25 ommendation of the advisory committee, or if

1 the Center for Drug Evaluation and Research
2 takes no action regarding the recommendation
3 within 45 days of receiving such recommenda-
4 tion, the nonprescription sunscreen condition
5 shall be generally recognized as safe and effec-
6 tive, not misbranded, and permitted to be mar-
7 keted and sold in accordance with all applicable
8 rules and regulations for over-the-counter
9 drugs.

10 “(B) In the case of a recommendation de-
11 scribed in clause (ii) of such subsection, the
12 Center for Drug Evaluation and Research shall
13 issue a determination affirming or denying the
14 recommendation of the advisory committee, to
15 be made publicly available, within 45 days of
16 receiving the recommendation, and inform the
17 sponsor that the sponsor must submit addi-
18 tional information to the advisory committee in
19 order to continue the review by the advisory
20 committee.

21 “(C) In the case of a recommendation de-
22 scribed in clause (iii) of such subsection, the
23 Center for Drug Evaluation and Research shall
24 issue a determination affirming or denying the
25 recommendation of the advisory committee, to

1 be made publicly available, within 45 days of
2 receiving such recommendation, and indicate
3 whether such sunscreen condition determined to
4 be not generally recognized as safe and effective
5 to be marketed and sold unless an application
6 with respect to such condition is approved
7 under section 505(b), or whether additional
8 data must be submitted to the advisory com-
9 mittee.

10 “(2) SUPERVISORY REVIEW OF DETERMINA-
11 TION.—

12 “(A) IN GENERAL.—Any person may re-
13 quest a supervisory review of a determination of
14 the Center for Drug Evaluation and Research
15 to not accept a recommendation of an advisory
16 committee. Such review may be conducted at
17 the next supervisory or higher level above the
18 individual who made the determination.

19 “(B) REQUEST FOR SUPERVISORY RE-
20 VIEW.—A request described in subparagraph
21 (A) shall be made to the Secretary not later
22 than 30 days after such decision and shall indi-
23 cate in the request whether such person seeks
24 an in-person meeting or a teleconference. The
25 Secretary shall schedule an in-person or tele-

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

6 “(C) STANDARD OF SUPERVISORY RE-
7 VIEW.—The Secretary shall be authorized to
8 overturn a determination of the Center for
9 Drug Evaluation and Research not to accept a
10 recommendation of the advisory committee if
11 the supervisory review results in a decision by
12 the reviewer that the individual who made the
13 determination did not provide reasonable and
14 sufficient substantive support for the decision
15 to disregard the advisory committee’s rec-
16 ommendation.

17 “(D) SUPERVISORY REVIEW DECISION.—If
18 the Secretary overturns a determination by the
19 Center for Drug Evaluation and Research not
20 to accept a favorable recommendation of an ad-
21 visory committee, the nonprescription sunscreen
22 condition shall be generally recognized as safe
23 and effective, not misbranded, and permitted to
24 be marketed and sold in accordance with all ap-

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

3 “(E) FINAL AGENCY ACTION.—A decision
4 made through supervisory review shall con-
5 stitute final agency action subject to judicial re-
6 view.

7 “(j) REPORTS.—

8 “(1) IN GENERAL.—Not later than 1 year after
9 the date of enactment of the Sunscreen Innovation
10 Act, on March 1, 2015, and every 2 years thereafter,
11 the Secretary shall issue a report to Congress de-
12 scribing actions taken under this section.

13 “(2) CONTENTS.—The reports under paragraph
14 (1) shall include—

15 “(A) a review of the progress made in
16 issuing in a timely manner decisions on the
17 safety and effectiveness for sunscreen condi-
18 tions for applications pending as of the date of
19 enactment of the Sunscreen Innovation Act, in-
20 cluding the number of pending applications—

21 “(i) reviewed and the decision times
22 for each application, measured from the
23 date of original eligibility application sub-
24 mission by the sponsor;

1 “(ii) resulting in a determination of
2 generally recognized as safe and effective
3 and not misbranded;

4 “(iii) resulting in a determination of
5 not generally recognized as safe and effec-
6 tive and not misbranded and the reasons
7 for such determinations; and

8 “(iv) for which a determination has
9 not been made, an explanation for the
10 delay, a description of the current status of
11 each such application, and the length of
12 time such applications have been pending,
13 measured from the date of original eligi-
14 bility application submission by the spon-
15 sor;

16 “(B) a review of the progress made in
17 issuing in a timely manner a decision on safety
18 and effectiveness for sunscreen condition appli-
19 cations submitted after the date of enactment
20 of the Sunscreen Innovation Act, including the
21 number of such applications—

22 “(i) reviewed and the decision times
23 for each application;

1 “(ii) resulting in a determination of
2 generally recognized as safe and effective
3 and not misbranded; and

4 “(iii) resulting in a determination of
5 not generally recognized as safe and effec-
6 tive and not misbranded and the reasons
7 for such determinations;

8 “(C) a description of the staffing and re-
9 sources relating to the costs associated with the
10 review and decisionmaking pertaining to appli-
11 cations;

12 “(D) a review of the progress in meeting
13 the deadlines with respect to processing applica-
14 tions under this section;

15 “(E) to the extent the Secretary deter-
16 mines appropriate, recommendations for process
17 improvements in the handling of pending and
18 new applications; and

19 “(F) recommendations for expanding the
20 applicability of this section to nonprescription
21 active ingredients or conditions that are not re-
22 lated to the sunscreen category of over-the-
23 counter drugs.

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

1 the Secretary determines to be the most effective for
2 efficiently disseminating the report, including publi-
3 cation of the report on the Internet website of the
4 Food and Drug Administration.

5 “(k) RULES OF CONSTRUCTION.—

6 “(1) AUTHORITY TO WITHDRAW OR SUS-
7 PEND.—Nothing in this section shall be construed to
8 alter the Secretary’s authority to withdraw or sus-
9 pend from the market a drug that the Secretary de-
10 termines to be unsafe or ineffective.

11 “(2) OTHER CONDITIONS.—Nothing in the sec-
12 tion shall affect the Secretary’s authority to review
13 nonprescription conditions other than sunscreen con-
14 ditions.”.

15 **SEC. 3. SUNSCREEN TESTING AND LABELING.**

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

19 (1) the appropriate testing and labeling require-
20 ments for sunscreens sold as an aerosol; and

21 (2) whether sunscreen may contain a label indi-
22 cating a sun protection factor greater than 50.

○