

COMMITTEE PRINT

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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

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 Chapter V of the Federal Food, Drug, and Cosmetic
4 Act (21 U.S.C. 351 et seq.) is amended by adding at the
5 end the following:

6 **“Subchapter I—Nonprescription Sunscreen**
7 **Active Ingredients**

8 **“SEC. 586. DEFINITIONS.**

9 “In this subchapter:

10 “(1) The term ‘active ingredient’—

11 “(A) means any component that is in-
12 tended to furnish pharmacological activity or
13 other direct effect in the diagnosis, cure, miti-
14 gation, treatment, or prevention of disease, or
15 to affect the structure or function of the body
16 of humans or animals; and

17 “(B) includes components that may under-
18 go chemical change in the manufacture of a
19 drug and may be present in a drug in a modi-
20 fied form intended to furnish the specified ac-
21 tivity or effect.

22 “(2) The term ‘Advisory Committee’ means the
23 Nonprescription Drug Advisory Committee or any
24 successor to such Committee.

25 “(3) The terms ‘generally recognized as safe
26 and effective’ and ‘GRASE’ mean generally recog-

1 nized, among experts qualified by scientific training
2 and experience to evaluate the safety and effective-
3 ness of drugs, as safe and effective for use under the
4 conditions prescribed, recommended, or suggested in
5 the product's labeling, as described in section
6 201(p).

7 “(4) The term ‘GRASE determination’ means a
8 determination by the Secretary described in section
9 586A(a).

10 “(5) The term ‘nonprescription’ means not sub-
11 ject to section 503(b)(1).

12 “(6) The term ‘pending request’ means each re-
13 quest submitted to the Secretary—

14 “(A) for review of a nonprescription sun-
15 screen active ingredient or combination of non-
16 prescription sunscreen active ingredients, for a
17 determination of whether such active ingredient
18 or combination of ingredients, for use under
19 specified conditions, to be prescribed, rec-
20 ommended, or suggested in the labeling thereof,
21 is GRASE;

22 “(B) that was deemed eligible for such re-
23 view by publication of a notice of eligibility in
24 the Federal Register prior to the date of enact-
25 ment of the Sunscreen Innovation Act; and

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

4 “(7) The term ‘sponsor’ means the person sub-
5 mitting the request under section 586A(a), including
6 a time and extent application under section 586B, or
7 the person submitting the pending request, for the
8 nonprescription sunscreen active ingredient or com-
9 bination of nonprescription sunscreen active ingredi-
10 ents involved.

11 “(8) The term ‘sunscreen active ingredient’
12 means an active ingredient that is intended for ap-
13 plication to the skin of humans for purposes of ab-
14 sorbing, reflecting, or scattering radiation in the ul-
15 traviolet range at wavelengths from 290 to 400
16 nanometers.

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

19 **“SEC. 586A. GENERAL PROVISIONS.**

20 “(a) REQUESTS.—Any person may submit a request
21 to the Secretary for a determination of whether a non-
22 prescription sunscreen active ingredient or a combination
23 of nonprescription sunscreen active ingredients, for use
24 under specified conditions, to be prescribed, recommended,
25 or suggested in the labeling thereof (including dosage

1 form, dosage strength, and route of administration) is
2 generally recognized as safe and effective and not mis-
3 branded.

4 “(b) RULES OF CONSTRUCTION.—

5 “(1) CURRENTLY MARKETED SUNSCREENS.—

6 Nothing in this subchapter shall be construed to af-
7 fect the marketing of sunscreens that are lawfully
8 marketed in the United States on or before the date
9 of enactment of this subchapter.

10 “(2) ENSURING SAFETY AND EFFECTIVE-

11 NESS.—Nothing in this subchapter shall be con-
12 strued to alter the Secretary’s authority to prohibit
13 the marketing of a sunscreen that is not safe and ef-
14 fective or to impose restrictions on the marketing of
15 a sunscreen to ensure safety and effectiveness.

16 “(3) OTHER PRODUCTS.—Nothing in this sub-

17 chapter shall be construed to affect the Secretary’s
18 regulation of products other than sunscreens.

19 “(c) SUNSET.—This subchapter shall cease to be ef-

20 fective at the end of the 5-year period beginning on the
21 date of enactment of this subchapter.

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

23 “(a) IN GENERAL.—Upon receipt of a request under

24 section 586A(a), not later than **【 _____ 】** days after the

25 date of receipt of such request, the Secretary shall—

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

4 “(2) notify the sponsor of the Secretary’s deter-
5 mination; and

6 “(3) make such determination publicly available
7 in accordance with subsection (e).

8 “(b) CRITERIA FOR ELIGIBILITY.—

9 “(1) IN GENERAL.—To be eligible for review
10 under sections 586C and 586D, a request shall be
11 for a nonprescription sunscreen active ingredient or
12 combination of nonprescription sunscreen active in-
13 gredients, for use under specified conditions, to be
14 prescribed, recommended, or suggested in the label-
15 ing thereof, that—

16 “(A) is not included in the stayed sun-
17 screen monograph in part 352 of title 21, Code
18 of Federal Regulations; and

19 “(B) has been used to a material extent
20 and for a material time, as described in section
21 201(p)(2).

22 “(2) MATERIAL EXTENT AND MATERIAL
23 TIME.—A nonprescription sunscreen active ingre-
24 dient or combination of nonprescription sunscreen
25 active ingredients, for use under the specified condi-

1 tions, to be prescribed, recommended, or suggested
2 in the labeling thereof, is deemed to meet the stand-
3 ard described in paragraph (1)(B) if such active in-
4 gredient or combination of active ingredients has
5 been legally marketed in the United States or at
6 least 1 other country, or marketed as a cosmetic or
7 dietary supplement in 1 or more countries other
8 than the United States—

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

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

16 “(c) TIME AND EXTENT APPLICATION.—

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

20 “(A) Basic information about the active in-
21 gredient or combination of active ingredients
22 (including a description of each pharmacologic
23 class, intended nonprescription use, non-
24 prescription strength and dosage form, route of
25 administration, and directions for use).

1 “(B) A detailed chemical description of the
2 active ingredient or combination of active ingre-
3 dients that includes a full description of the
4 drug substances, including their physical and
5 chemical characteristics, the method of syn-
6 thesis (or isolation) and purification of the drug
7 substances, and any specifications and analyt-
8 ical methods necessary to ensure the identity,
9 strength, quality, and purity of the drug sub-
10 stances, including reference to the current edi-
11 tion of the official National Formulary, the
12 United States Pharmacopeia, or foreign com-
13 pendiums, where applicable.

14 “(C) A list of each country in which the
15 active ingredient or combination of active ingre-
16 dients has been marketed.

17 “(D) The cumulative total number of dos-
18 age units sold for each dosage form of the ac-
19 tive ingredient or combination of active ingredi-
20 ents, including total weight of the active ingre-
21 dients and package size for each dosage form in
22 which the active ingredients or combination of
23 active ingredients is marketed as nonprescrip-
24 tion. The sponsor shall include an estimate of
25 the minimum number of potential consumer ex-

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

4 “(i) Divide the total number of dosage
5 units sold by the number of dosage units
6 in the largest package size marketed.

7 “(ii) Divide the total weight of the ac-
8 tive ingredients sold by the total weight of
9 the active ingredients in the largest pack-
10 age size marketed.

11 “(E)(i) The use pattern (*i.e.*, how often the
12 active ingredient or combination of active ingre-
13 dients is to be used (according to the label) and
14 for how long) for each country in which the ac-
15 tive ingredient or combination of active ingredi-
16 ents is marketed.

17 “(ii) If the use pattern varies between
18 countries based on the active ingredient or com-
19 bination of active ingredient’s packaging and la-
20 beling, or changes in use pattern have occurred
21 over time in one or more countries, an expla-
22 nation of why there are differences or changes.

23 “(F) A list of all countries in which the ac-
24 tive ingredient or combination of active ingredi-
25 ents has been withdrawn from marketing or in

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

4 “(2) SUNSCREEN ACTIVE INGREDIENTS THAT
5 HAVE NOT BEEN MARKETED IN THE U.S. FOR 5 CON-
6 TINUOUS YEARS.—

7 “(A) IN GENERAL.—In the case of a time
8 and extent application with respect to a non-
9 prescription sunscreen active ingredient or com-
10 bination of nonprescription sunscreen active in-
11 gredients that has not been marketed in the
12 United States for 5 continuous years, in addi-
13 tion to the information required under para-
14 graph (1), the sponsor shall submit the fol-
15 lowing information for each country in which
16 the active ingredient or combination of active
17 ingredients has been marketed:

18 “(i) The manner in which the active
19 ingredient or combination of active ingredi-
20 ents has been marketed to consumers (*e.g.*,
21 nonprescription general sales direct-to-con-
22 sumer; sold only in a pharmacy, with or
23 without the personal involvement of a
24 pharmacist; dietary supplement; or cos-
25 metic), including rules and guidelines for

1 labeling, and directions for proper use. If
2 the active ingredient or combination of ac-
3 tive ingredients is marketed to consumers
4 as nonprescription, pharmacy-only, the
5 sponsor shall establish that this marketing
6 restriction does not indicate safety con-
7 cerns about its toxicity or other poten-
8 tiality for harmful effect, the method of its
9 use, or the collateral measures necessary to
10 its use.

11 “(ii) A description of the population
12 demographics (percentage of various racial
13 and ethnic groups) and the source from
14 which this information has been compiled,
15 to ensure that the use of the active ingre-
16 dient or combination of active ingredients
17 can be reasonably extrapolated to the pop-
18 ulation of the United States.

19 “(iii) A description of the country’s
20 system for maintenance of approved ingre-
21 dients, postmarket safety monitoring, and
22 identifying adverse drug experiences, espe-
23 cially those found in nonprescription mar-
24 keting experience, including method of col-
25 lection, if applicable.

1 “(iv) A statement of how long the ac-
2 tive ingredient or combination of active in-
3 gredients has been marketed in each coun-
4 try and how long the current product label-
5 ing has been in use, accompanied by a
6 copy of the current product labeling, in-
7 cluding a translation into English of any
8 labeling that is not in English, and a state-
9 ment of whether the current product label-
10 ing has been authorized, accepted, or ap-
11 proved by a regulatory body in each coun-
12 try where the condition is marketed.

13 “(v) Whether the active ingredient or
14 combination of active ingredients is mar-
15 keted as a prescription drug only in the
16 country and, if so, an explanation for such
17 restriction.

18 “(vi) A description of the country’s
19 evaluation procedures.

20 “(vii) A description of the country’s
21 rules for grandfathering currently ap-
22 proved sunscreen or cosmetic ingredients,
23 if applicable.

1 “(B) SUNSCREEN ACTIVE INGREDIENTS
2 THAT HAVE BEEN MARKETED IN MORE THAN 5
3 COUNTRIES.—

4 “(i) IN GENERAL.—In the case of a
5 time and extent application with respect to
6 a nonprescription sunscreen active ingre-
7 dient or combination of nonprescription
8 sunscreen active ingredients that has been
9 marketed as a nonprescription sunscreen
10 in more than 5 countries, with a minimum
11 of 5 continuous years of marketing in at
12 least one such country, the sponsor—

13 “(I) may submit information in
14 accordance with clauses (i) through
15 (iv) of subparagraph (A) with respect
16 to only 5 such countries, including—

17 “(aa) the country with a
18 minimum of 5 continuous years
19 of nonprescription marketing;

20 “(bb) the country with the
21 longest duration of marketing;
22 and

23 “(cc) the country with the
24 most support for marketing, such
25 as a large volume of sales with

1 cultural diversity among users of
2 the product; and

3 “(II) shall explain the basis for
4 the countries selected under subclause
5 (I); and

6 “(III) shall provide information
7 from more than 5 countries if such in-
8 formation is needed to support the ap-
9 plication.

10 “(ii) REQUIREMENT.—If the non-
11 prescription sunscreen active ingredient or
12 combination of nonprescription sunscreen
13 active ingredients meets the criteria under
14 items (aa) through (cc) of clause (i)(I) in
15 1 or more countries listed in section
16 802(b)(1)(A), at least 1 such country shall
17 be included among the 5 countries selected
18 under such clause (i)(I).

19 “(d) PENDING REQUESTS.—The requirements of
20 subsection (c) shall not apply to pending requests. Pend-
21 ing requests shall be considered in accordance with section
22 586D(c).

23 “(e) PUBLIC AVAILABILITY.—

24 “(1) REDACTIONS FOR CONFIDENTIAL INFOR-
25 MATION.—If a nonprescription sunscreen active in-

1 ingredient or combination of nonprescription sun-
2 screen active ingredients is determined to be eligible
3 for further review under subsection (a)(1), the Sec-
4 retary shall make the request publicly available, with
5 redactions for information that is treated as con-
6 fidential under section 552(b) of title 5, United
7 States Code, section 1905 of title 18, United States
8 Code, or section 301(j) of this Act.

9 “(2) IDENTIFICATION OF CONFIDENTIAL IN-
10 FORMATION BY SPONSOR.—Sponsors shall identify
11 any information which the sponsor considers to be
12 confidential information described in paragraph (1).

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

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

19 “(a) IN GENERAL.—In the case of a request under
20 section 586A(a) that is determined to be eligible for fur-
21 ther review under section 586B—

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

1 “(2) not later than [_____] days after the sub-
2 mission of such data under subsection (c) by the
3 sponsor, including any revised submission of such
4 data following a refusal to file under subparagraph
5 (B), the Secretary shall—

6 “(A)(i) issue a written notification to the
7 sponsor determining that the request under sec-
8 tion 586A(a), together with such data, is com-
9 plete and make such notification publicly avail-
10 able; and

11 “(ii) file such request; or

12 “(B) issue a written notification to the
13 sponsor refusing to file the request and stating
14 the reasons for such refusal if the Secretary
15 finds that such request, together with such
16 data, have not been submitted in accordance
17 with subsection (c) and make such notification
18 publicly available;

19 “(3) if the Secretary refuses to file the re-
20 quest—

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

1 “(B) the Secretary shall convene the infor-
2 mal conference; and

3 “(4) following any such informal conference—

4 “(A) if the sponsor insists that the Sec-
5 retary file the request (with or without amend-
6 ments to correct any purported deficiencies to
7 the request) the Secretary shall file the request
8 over protest, issue a written notification of the
9 filing to the sponsor, and make such notifica-
10 tion publicly available; and

11 “(B) if the request is so filed over pro-
12 test—

13 “(i) the date of filing is deemed to be
14 the date that is **【____】** days after the
15 date on which the sponsor requested the
16 informal conference; and

17 “(ii) the Secretary shall not require
18 the sponsor to resubmit a copy of the re-
19 quest for purposes of such filing.

20 “(b) REASONS FOR REFUSAL TO FILE REQUEST.—

21 The Secretary may refuse to file a request submitted
22 under section 586A(a) for any of the following reasons:

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

1 “(2) The request is insufficiently complete be-
2 cause it does not, on its face, contain information re-
3 quired under subsection (c).

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

7 “(4) Documents contained in the request are
8 not legible.

9 “(5) The request is not indexed or paginated.

10 “(6) The documents in the request lack ade-
11 quate bookmarks or other appropriate markers for
12 ease of electronic navigation.

13 “(7) The request fails to provide assessments of
14 the information required under subsection (c) and
15 fails to provide a justification of why such assess-
16 ments are not required.

17 “(8) The request fails to include complete stud-
18 ies, reports, or datasets, where applicable.

19 “(c) DATA SUBMISSION.—

20 “(1) IN GENERAL.—In the case of a request
21 under section 586A(a) that is determined to be eligi-
22 ble for further review under section 586B, the Sec-
23 retary shall provide the sponsor and other interested
24 persons an opportunity to submit published and un-
25 published data related to the safety and effectiveness

1 of the nonprescription sunscreen active ingredient or
2 combination of nonprescription sunscreen active in-
3 gredients for its intended nonprescription uses, in
4 accordance with paragraph (2).

5 “(2) SAFETY AND EFFECTIVENESS DATA SUB-
6 MISSIONS.—Submissions under this paragraph shall
7 include the following:

8 “(A) SAFETY DATA.—

9 “(i) INDIVIDUAL ACTIVE COMPO-
10 NENTS.—With respect to individual active
11 components, controlled studies, partially
12 controlled or uncontrolled studies, docu-
13 mented case reports, pertinent marketing
14 experiences that may influence a deter-
15 mination as to the safety of each individual
16 active component, and pertinent medical
17 and scientific literature.

18 “(ii) COMBINATIONS OF INDIVIDUAL
19 ACTIVE COMPONENTS.—With respect to
20 combinations of the individual active com-
21 ponents, controlled studies, partially con-
22 trolled or uncontrolled studies, documented
23 case reports, pertinent marketing experi-
24 ences that may influence a determination
25 as to the safety of combinations of the in-

1 individual active component, and pertinent
2 medical and scientific literature.

3 “(iii) SAFETY CONSIDERATIONS.—

4 With respect to individual active compo-
5 nents, all data related to the assessment of
6 skin irritation, eye irritation, sensitization,
7 and human pharmacokinetics, including
8 the rate and amount of absorption of the
9 active components in a variety of different
10 skin types/conditions, human adverse event
11 profileacute toxicity, repeat dose toxicity,
12 genetic toxicity, reproductive toxicity, de-
13 velopmental toxicity, phototoxicity, carcino-
14 genicity, endocrine disruption,
15 toxicokinetics.

16 “(B) EFFICACY DATA.—

17 “(i) INDIVIDUAL ACTIVE COMPO-
18 NENTS.—With respect to individual active
19 components, controlled studies, partially-
20 controlled or uncontrolled studies, docu-
21 mented case reports, pertinent marketing
22 experiences that may influence a deter-
23 mination on the efficacy of each individual
24 active component, pertinent medical and

1 scientific literature, including photo-sta-
2 bility, and chemical stability.

3 “(ii) COMBINATIONS OF INDIVIDUAL
4 ACTIVE COMPONENTS.—With respect to
5 combinations of the individual active com-
6 ponents, controlled studies, partially con-
7 trolled or uncontrolled studies, documented
8 case reports, pertinent marketing experi-
9 ences that may influence a determination
10 on the efficacy of combinations of the indi-
11 vidual active components, and pertinent
12 medical and scientific literature, including
13 photo-stability and chemical stability.

14 “(iii) SUN PROTECTION.—With re-
15 spect to individual active components, all
16 data related to the assessment of the sun
17 protection factor (commonly referred to as
18 ‘SPF’), broad spectrum protection, and
19 water resistance.

20 “(C) DATA SETTING FORTH MEDICAL RA-
21 TIONALE AND PURPOSE.—A summary of the
22 data and views setting forth the medical ration-
23 ale and purpose (or lack thereof) for the non-
24 prescription sunscreen active ingredient or com-
25 bination of nonprescription sunscreen active in-

1 ingredients and the scientific basis (or lack there-
2 of) for the conclusion that the active ingredient
3 or combination of active ingredients has been
4 proven to be generally recognized as safe and
5 effective for the intended use. If there is an ab-
6 sence of controlled studies in the material sub-
7 mitted, an explanation as to why such studies
8 are not considered necessary shall be included.

9 “(D) OFFICIAL DRUG MONOGRAPH.—An
10 applicable United States Pharmacopoeia or Na-
11 tional Formulary for the nonprescription sun-
12 screen active ingredient or combination of non-
13 prescription sunscreen active ingredients or a
14 proposed standard for inclusion in an article to
15 be recognized in an official drug monograph for
16 the active ingredient or combination of active
17 ingredients, including information showing that
18 the official or proposed compendial monograph
19 for the active ingredient or combination of ac-
20 tive ingredients is consistent with the active in-
21 gredient or combination of active ingredients
22 used in the studies establishing safety and ef-
23 fectiveness and with the active ingredient or
24 combination of active ingredients marketed in
25 the nonprescription product to a material extent

1 and for a material time. If differences exist be-
2 tween the official or proposed compendial mono-
3 graph for the active ingredient or combination
4 of active ingredients and the active ingredient
5 or combination of active ingredients that is the
6 subject of the request, the sponsor shall explain
7 such differences.

8 “(E) ADVERSE DRUG EXPERIENCES.—A
9 list of all serious adverse drug experiences, as
10 defined by the Secretary, and any available data
11 regarding such adverse events, from each coun-
12 try where the nonprescription sunscreen active
13 ingredient or combination of nonprescription
14 sunscreen active ingredients has been or is cur-
15 rently marketed as a prescription drug or as a
16 nonprescription drug or product.

17 “(F) FORMAT FOR DATA PACKAGE SUB-
18 MISSION.—Submissions under this paragraph
19 shall be—

20 “(i) indexed and paginated for pur-
21 poses of electronic navigation;

22 “(ii) legible, in English, or accom-
23 panied by an English translation in accord-
24 ance with applicable regulation; and

25 “(iii) include—

1 “(I) a table of contents;

2 “(II) a background summary of
3 the entire submission;

4 “(III) separate volumes of data
5 grouped by discipline (*e.g.*, Chemistry,
6 Manufacturing and Controls, Pharma-
7 cology and Toxicology, Clinical Safety,
8 Clinical Pharmacology and Human
9 Pharmacokinetics, and Clinical Effi-
10 cacy); and

11 “(IV) a summary table listing all
12 studies, and, for each study, a table of
13 contents, summary, and complete data
14 set.

15 “(G) GUIDANCE FOR NEW REQUESTS SUB-
16 MITTED AFTER DATE OF ENACTMENT.—The
17 Secretary may issue guidance on the format
18 and content of a safety and effectiveness data
19 submission under this subsection and on the
20 safety standards for review by the Food and
21 Drug Administration of nonprescription sun-
22 screen active ingredients and combinations of
23 nonprescription sunscreen active ingredients.
24 Issuance of such guidance shall not prevent the

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

3 “(d) PUBLIC AVAILABILITY.—

4 “(1) REDACTIONS FOR CONFIDENTIAL INFOR-
5 MATION.—The Secretary shall make data and infor-
6 mation submitted in connection with a request under
7 section 586(a) publicly available, with redactions for
8 information that is treated as confidential under sec-
9 tion 552(b) of title 5, United States Code, section
10 1905 of title 18, United States Code, or section
11 301(j) of this Act.

12 “(2) IDENTIFICATION OF CONFIDENTIAL IN-
13 FORMATION BY SPONSOR.—Sponsors shall identify
14 any information which the sponsor considers to be
15 confidential information described in paragraph (1).

16 “(3) COMPENDIAL INFORMATION.—The infor-
17 mation described in subsection (c)(2)(D) shall not be
18 considered confidential for purposes of this sub-
19 section.

20 **“SEC. 586D. GRASE DETERMINATION.**

21 “(a) REVIEW OF NEW REQUESTS.—

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

1 “(A) not later than [_____] days after
2 the date on which the request is filed under sec-
3 tion 586C(a), complete the review of the re-
4 quest and issue a proposed order determining
5 whether—

6 “(i) the nonprescription sunscreen ac-
7 tive ingredient or combination of non-
8 prescription sunscreen active ingredients
9 that is the subject of the request is
10 GRASE and not misbranded; or

11 “(ii) additional information is nec-
12 essary to allow the Director of the Center
13 for Drug Evaluation and Research to com-
14 plete the review of such request;

15 “(B) within such [_____] -day period,
16 convene a meeting of the Advisory Committee
17 to review the request; and

18 “(C) if the Secretary fails to issue such
19 proposed order within the [_____] -day] period
20 referred to in subparagraph (A), submit the re-
21 quest to the Commissioner of Food and Drugs
22 for review.

23 “(2) PROPOSED ORDER BY COMMISSIONER.—
24 With respect to a request submitted to the Commis-
25 sioner of Food and Drugs under paragraph (1)(C),

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

4 “(3) PUBLIC COMMENT PERIOD.—Not later
5 than [] days after the date on which a pro-
6 posed order is issued under paragraph (1) with re-
7 spect to a request, the Director of the Center for
8 Drug Evaluation and Research shall publish a notice
9 in the Federal Register soliciting public comments
10 on the request for a period of not more than
11 [] days.

12 “(4) FINAL ORDER BY CDER.—In the case of a
13 proposed order under paragraph (1) or (2) with re-
14 spect to a request, the Director of the Center for
15 Drug Evaluation and Research shall—

16 “(A) issue a final order with respect to the
17 request not later than [] days after the
18 date on which the proposed order is issued; or

19 “(B) if the Director fails to issue such
20 final order within such []-day period, sub-
21 mit such proposed order to the Commissioner of
22 Food and Drugs for review.

23 “(5) FINAL ORDER BY COMMISSIONER.—With
24 respect to a proposed order submitted to the Com-
25 missioner of Food and Drugs under paragraph

1 (6)(B), issue a final order with respect to such pro-
2 posed order not later than [] days after the
3 date of such submission.

4 “(b) REVIEW OF PENDING REQUESTS.—

5 “(1) IN GENERAL.—The review of a pending re-
6 quest shall be carried out by the Director of the
7 Center for Drug Evaluation and Research in accord-
8 ance with paragraph (2), unless the sponsor of the
9 pending request, not later than [] after the
10 date of the enactment of the Sunscreen Innovation
11 Act, elects to have such review carried out by the
12 Director and the Advisory Committee in accordance
13 with paragraph (3).

14 “(2) REVIEW BY CDER.—

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

18 “(i) not later than [] days
19 after the date of the enactment of the Sun-
20 screen Innovation Act, issue a proposed
21 order determining whether—

22 “(I) the nonprescription sun-
23 screen active ingredient or combina-
24 tion of nonprescription sunscreen ac-

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

3 “(II) additional information is
4 necessary to allow the Director to
5 make such determination;

6 “(ii) on the date on which the pro-
7 posed order is issued, publish a notice in
8 the Federal Register soliciting public com-
9 ments on the proposed order for a period
10 of not more than [_____] days; and

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

16 “(B) PROPOSED ORDER BY COMMIS-
17 SIONER.—With respect to a pending request
18 submitted to the Commissioner of Food and
19 Drugs under subparagraph (A)(iii), the Com-
20 missioner shall issue a proposed order with re-
21 spect to the pending request not later than
22 [_____] days after the date of such submis-
23 sion.

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

1 (B) with respect to a pending request, the Di-
2 rector of the Center for Drug Evaluation and
3 Research shall—

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

8 “(ii) if the Director fails to issue such
9 final order within such [_____-day] period,
10 submit such proposed order to the Com-
11 missioner of Food and Drugs for review.

12 “(D) FINAL ORDER BY COMMISSIONER.—
13 With respect to a proposed order submitted to
14 the Commissioner of Food and Drugs under
15 subparagraph (C)(ii), issue a final order with
16 respect to such proposed order not later than
17 [_____] days after the date of such submis-
18 sion.

19 “(3) REVIEW BY CDER AND ADVISORY COM-
20 MITTEE.—In the case of an election under para-
21 graph (1) to have the review of a pending request
22 carried out by the Director of the Center for Drug
23 Evaluation and Research and the Advisory Com-
24 mittee in accordance with this paragraph, the fol-
25 lowing provisions apply:

1 “(A) ADVISORY COMMITTEE.—Not later
2 than [_____] days after the date of enact-
3 ment of the Sunscreen Innovation Act, the Di-
4 rector of the Center for Drug Evaluation and
5 Research shall convene a meeting of the Advi-
6 sory Committee to review the request.

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

10 “(i) not later than [_____] days
11 after the date of the enactment of the Sun-
12 screen Innovation Act, issue a proposed
13 order determining whether—

14 “(I) the nonprescription sun-
15 screen active ingredient or combina-
16 tion of nonprescription sunscreen ac-
17 tive ingredients that is the subject of
18 the pending request is GRASE; or

19 “(II) additional information is
20 necessary to allow the Director to
21 make such determination;

22 “(ii) on the date on which the pro-
23 posed order is issued, publish a notice in
24 the Federal Register soliciting public com-

1 ments on the proposed order for a period
2 of not more than **【_____】** days; and

3 “(iii) if the Director fails to issue such
4 proposed order within the **【_____ -day】**
5 period referred to in clause (i), submit the
6 pending request to the Commissioner of
7 Food and Drugs for review.

8 “(C) PROPOSED ORDER BY COMMIS-
9 SIONER.—With respect to a pending request
10 submitted to the Commissioner of Food and
11 Drugs under subparagraph (B)(iii), the Com-
12 missioner shall issue a proposed order with re-
13 spect to the pending request not later than
14 **【_____】** days after the date of such submis-
15 sion.

16 “(D) FINAL ORDER BY CDER.—In the case
17 of a proposed order under subparagraph (B) or
18 (C) with respect to a pending request, the Di-
19 rector of the Center for Drug Evaluation and
20 Research shall—

21 “(i) issue a final order with respect to
22 the request not later than **【_____】** days
23 after the date on which the proposed order
24 is issued; or

1 “(ii) if the Director fails to issue such
2 final order within such [____-day] period,
3 submit such proposed order to the Com-
4 missioner of Food and Drugs for review.

5 “(E) FINAL ORDER BY COMMISSIONER.—
6 With respect to a proposed order submitted to
7 the Commissioner of Food and Drugs under
8 subparagraph (D)(ii), issue a final order with
9 respect to such proposed order not later than
10 [_____] days after the date of such submis-
11 sion.

12 “(c) REVIEW OF ADDITIONAL INFORMATION.—If,
13 after issuance of a proposed order, the Director of the
14 Center for Drug Evaluation and Research or the Commis-
15 sioner of Food and Drugs determines that additional in-
16 formation is required from the sponsor to complete review
17 of the request under subsection (a) or the pending request
18 under subsection (b) for purposes of issuing a final order
19 pursuant to the respective subsection, the Director or
20 Commissioner (as applicable) shall, upon receipt of such
21 requested additional information—

22 “(1) review such additional information; and

23 “(2) issue a final order with respect to the pro-
24 posed order not later than [_____] days after such
25 receipt.

1 “(d) PERIOD FOR CONVENING ADVISORY COM-
2 MITTEE.—If the Director of the Center for Drug Evalua-
3 tion and Research or the Commissioner of Food and
4 Drugs requests additional information (pursuant to sub-
5 section (c)) during review of a pending request under sub-
6 section (b)(2)—

7 “(1) the sponsor, at the time of submission of
8 the additional information, may indicate in such sub-
9 mission that the sponsor is requesting review by the
10 Advisory Committee; and

11 “(2) the Director or Commissioner (as applica-
12 ble) shall convene the Advisory Committee for pur-
13 poses of such review not later than **[____]** days
14 after receipt of such submission.

15 “(e) ADVISORY COMMITTEE.—The Advisory Com-
16 mittee—

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

20 “(2) shall not be required to review more than
21 3 submissions per meeting.

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

25 “(g) EFFECT OF FINAL ORDER.—

1 “(1) ACTIVE INGREDIENTS DETERMINED TO BE
2 GRASE.—Upon issuance of a final order determining
3 that a nonprescription sunscreen active ingredient or
4 combination of nonprescription sunscreen active in-
5 gredients is GRASE and is not misbranded, the ac-
6 tive ingredient or combination of active ingredients
7 shall be permitted to be introduced or delivered into
8 interstate commerce in accordance with all require-
9 ments applicable to drugs not subject to section
10 503(b)(1).

11 “(2) ACTIVE INGREDIENTS DETERMINED NOT
12 TO BE GRASE.—Upon issuance of a final order de-
13 termining that the nonprescription sunscreen active
14 ingredient or combination of nonprescription sun-
15 screen active ingredients is not GRASE or is mis-
16 branded, the active ingredient or combination of ac-
17 tive ingredients shall not be introduced or delivered
18 into interstate commerce unless an application sub-
19 mitted pursuant to section 505(b) with respect to
20 such active ingredient or combination of active in-
21 gredients is approved.

22 **“SEC. 586E. REPORTS.**

23 “(a) GAO REPORT.—Not later than [_____] days
24 after the date of enactment of the Sunscreen Innovation
25 Act, the Comptroller General of the United States shall—

1 “(1) submit a report reviewing the overall
2 progress of the Secretary in carrying out this sub-
3 chapter to the Committee on Health, Education,
4 Labor, and Pensions of the Senate and the Com-
5 mittee on Energy and Commerce of the House of
6 Representatives; and

7 “(2) include findings on—

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

10 “(B) the role of the Office of the Commis-
11 sioner of Food and Drugs in issuing determina-
12 tions with respect to pending requests, includ-
13 ing the number of requests transferred to the
14 Office of the Commissioner under section 586D.

15 “(b) SECRETARY’S REPORT.—

16 “(1) IN GENERAL.—Not later than **[____]**
17 days after the date of enactment of the Sunscreen
18 Innovation Act, and every 2 years thereafter, the
19 Secretary shall issue a report to the Committee on
20 Health, Education, Labor, and Pensions of the Sen-
21 ate and the Committee on Energy and Commerce of
22 the House of Representatives describing actions
23 taken under this section. Each report under this
24 subsection shall be posted on the Internet site of the
25 Food and Drug Administration.

1 “(2) CONTENTS.—The reports under this sub-
2 section shall include—

3 “(A) a review of the progress made in
4 issuing in a timely manner decisions on the
5 safety and effectiveness for requests for non-
6 prescription sunscreen active ingredients and
7 combinations of nonprescription sunscreen ac-
8 tive ingredients pending as of the date of enact-
9 ment of the Sunscreen Innovation Act, includ-
10 ing the number of pending requests—

11 “(i) reviewed and the decision times
12 for each request, measured from the date
13 of the original request for an eligibility de-
14 termination submitted by the sponsor;

15 “(ii) resulting in a determination of
16 generally recognized as safe and effective
17 and not misbranded;

18 “(iii) resulting in a determination of
19 not generally recognized as safe and effec-
20 tive and not misbranded and the reasons
21 for such determinations; and

22 “(iv) for which a determination has
23 not been made, an explanation for the
24 delay, a description of the current status of
25 each such request, and the length of time

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

4 “(B) a review of the progress made in
5 issuing in a timely manner a decision on safety
6 and effectiveness for requests for nonprescrip-
7 tion sunscreen active ingredients and combina-
8 tions of nonprescription sunscreen active ingre-
9 dients submitted after the date of enactment of
10 the Sunscreen Innovation Act, including the
11 number of such requests—

12 “(i) reviewed and the decision times
13 for each request;

14 “(ii) resulting in a determination of
15 generally recognized as safe and effective
16 and not misbranded; and

17 “(iii) resulting in a determination of
18 not generally recognized as safe and effec-
19 tive and not misbranded and the reasons
20 for such determinations;

21 “(C) a description of the staffing and re-
22 sources relating to the costs associated with the
23 review and decisionmaking pertaining to re-
24 quests;

1 “(D) a review of the progress in meeting
2 the deadlines with respect to processing re-
3 quests under this subchapter;

4 “(E) to the extent the Secretary deter-
5 mines appropriate, recommendations for process
6 improvements in the handling of pending and
7 new requests, including the advisory committee
8 review process; and

9 “(F) recommendations for expanding the
10 applicability of this section to nonprescription
11 active ingredients or conditions that are not re-
12 lated to the sunscreen category of over-the-
13 counter drugs.

14 “(c) METHOD.—The Secretary shall publish the re-
15 ports required under subsection (b) in the manner the Sec-
16 retary determines to be the most effective for efficiently
17 disseminating the report, including publication of the re-
18 port on the Internet website of the Food and Drug Admin-
19 istration.”.