

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 4250
OFFERED BY M . _____**

Strike all after the enacting clause and insert the following:

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Sunscreen Innovation
3 Act”.

4 **SEC. 2. REGULATION OF NONPRESCRIPTION SUNSCREEN**
5 **ACTIVE INGREDIENTS.**

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

9 **“Subchapter I—Nonprescription Sunscreen**
10 **Active Ingredients**

11 **“SEC. 586. DEFINITIONS.**

12 “In this subchapter:

13 “(1) The term ‘active ingredient’—

14 “(A) means any component that is in-
15 tended to furnish pharmacological activity or
16 other direct effect in the diagnosis, cure, miti-
17 gation, treatment, or prevention of disease, or

1 to affect the structure or function of the body
2 of humans or animals; and

3 “(B) includes components that may under-
4 go chemical change in the manufacture of a
5 drug and may be present in a drug in a modi-
6 fied form intended to furnish the specified ac-
7 tivity or effect.

8 “(2) The term ‘Advisory Committee’ means the
9 Nonprescription Drug Advisory Committee or any
10 successor to such Committee.

11 “(3) The terms ‘generally recognized as safe
12 and effective’ and ‘GRASE’ mean generally recog-
13 nized, among experts qualified by scientific training
14 and experience to evaluate the safety and effective-
15 ness of drugs, as safe and effective for use under the
16 conditions prescribed, recommended, or suggested in
17 the product’s labeling, as described in section
18 201(p).

19 “(4) The term ‘GRASE determination’ means a
20 determination by the Secretary described in section
21 586A(a).

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

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

1 “(A) for review of a nonprescription sun-
2 screen active ingredient or combination of non-
3 prescription sunscreen active ingredients, for a
4 determination of whether such active ingredient
5 or combination of ingredients, for use under
6 specified conditions, to be prescribed, rec-
7 ommended, or suggested in the labeling thereof,
8 is GRASE;

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

13 “(C) for which safety and effectiveness
14 data has been submitted to the Secretary prior
15 to such date of enactment.

16 “(7) The term ‘sponsor’ means the person sub-
17 mitting the request under section 586A(a), including
18 a time and extent application under section 586B, or
19 the person submitting the pending request, for the
20 nonprescription sunscreen active ingredient or com-
21 bination of nonprescription sunscreen active ingredi-
22 ents involved.

23 “(8) The term ‘sunscreen active ingredient’
24 means an active ingredient that is intended for ap-
25 plication to the skin of humans for purposes of ab-

1 sorbing, reflecting, or scattering radiation in the ul-
2 traviolet range at wavelengths from 290 to 400
3 nanometers.

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

6 **“SEC. 586A. GENERAL PROVISIONS.**

7 “(a) REQUESTS.—Any person may submit a request
8 to the Secretary for a determination of whether a non-
9 prescription sunscreen active ingredient or a combination
10 of nonprescription sunscreen active ingredients, for use
11 under specified conditions, to be prescribed, recommended,
12 or suggested in the labeling thereof (including dosage
13 form, dosage strength, and route of administration) is
14 generally recognized as safe and effective and not mis-
15 branded.

16 “(b) RULES OF CONSTRUCTION.—

17 “(1) CURRENTLY MARKETED SUNSCREENS.—
18 Nothing in this subchapter shall be construed to af-
19 fect the marketing of sunscreens that are lawfully
20 marketed in the United States on or before the date
21 of enactment of this subchapter.

22 “(2) ENSURING SAFETY AND EFFECTIVE-
23 NESS.—Nothing in this subchapter shall be con-
24 strued to alter the Secretary’s authority to prohibit
25 the marketing of a sunscreen that is not safe and ef-

1 fective or to impose restrictions on the marketing of
2 a sunscreen to ensure safety and effectiveness.

3 “(3) OTHER PRODUCTS.—Nothing in this sub-
4 chapter shall be construed to affect the Secretary’s
5 regulation of products other than sunscreens.

6 “(c) SUNSET.—This subchapter shall cease to be ef-
7 fective at the end of the 5-year period beginning on the
8 date of enactment of this subchapter.

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

10 “(a) IN GENERAL.—Upon receipt of a request under
11 section 586A(a), not later than **【 _____ 】** days after the
12 date of receipt of such request, the Secretary shall—

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

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

18 “(3) make such determination publicly available
19 in accordance with subsection (e).

20 “(b) CRITERIA FOR ELIGIBILITY.—

21 “(1) IN GENERAL.—To be eligible for review
22 under sections 586C and 586D, a request shall be
23 for a nonprescription sunscreen active ingredient or
24 combination of nonprescription sunscreen active in-
25 gredients, for use under specified conditions, to be

1 prescribed, recommended, or suggested in the label-
2 ing thereof, that—

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

6 “(B) has been used to a material extent
7 and for a material time, as described in section
8 201(p)(2).

9 “(2) MATERIAL EXTENT AND MATERIAL
10 TIME.—A nonprescription sunscreen active ingre-
11 dient or combination of nonprescription sunscreen
12 active ingredients, for use under the specified condi-
13 tions, to be prescribed, recommended, or suggested
14 in the labeling thereof, is deemed to meet the stand-
15 ard described in paragraph (1)(B) if such active in-
16 gredient or combination of active ingredients has
17 been legally marketed in the United States or at
18 least 1 other country, or marketed as a cosmetic or
19 dietary supplement in 1 or more countries other
20 than the United States—

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

23 “(B) in sufficient quantity, as determined
24 by the Secretary based upon the information
25 submitted under subparagraphs (D) and (E) of

1 subsection (c)(1) and, if applicable, subsection
2 (c)(2)(A)(ii).

3 “(c) TIME AND EXTENT APPLICATION.—

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

7 “(A) Basic information about the active in-
8 gredient or combination of active ingredients
9 (including a description of each pharmacologic
10 class, intended nonprescription use, non-
11 prescription strength and dosage form, route of
12 administration, and directions for use).

13 “(B) A detailed chemical description of the
14 active ingredient or combination of active ingre-
15 dients that includes a full description of the
16 drug substances, including their physical and
17 chemical characteristics, the method of syn-
18 thesis (or isolation) and purification of the drug
19 substances, and any specifications and analyt-
20 ical methods necessary to ensure the identity,
21 strength, quality, and purity of the drug sub-
22 stances, including reference to the current edi-
23 tion of the official National Formulary, the
24 United States Pharmacopeia, or foreign com-
25 pendiums, where applicable.

1 “(C) A list of each country in which the
2 active ingredient or combination of active ingre-
3 dients has been marketed.

4 “(D) The cumulative total number of dos-
5 age units sold for each dosage form of the ac-
6 tive ingredient or combination of active ingredi-
7 ents, including total weight of the active ingre-
8 dients and package size for each dosage form in
9 which the active ingredients or combination of
10 active ingredients is marketed as nonprescrip-
11 tion. The sponsor shall include an estimate of
12 the minimum number of potential consumer ex-
13 posures to the active ingredient or combination
14 of active ingredients using one of the following
15 calculations:

16 “(i) Divide the total number of dosage
17 units sold by the number of dosage units
18 in the largest package size marketed.

19 “(ii) Divide the total weight of the ac-
20 tive ingredients sold by the total weight of
21 the active ingredients in the largest pack-
22 age size marketed.

23 “(E)(i) The use pattern (*i.e.*, how often the
24 active ingredient or combination of active ingre-
25 dients is to be used (according to the label) and

1 for how long) for each country in which the ac-
2 tive ingredient or combination of active ingredi-
3 ents is marketed.

4 “(ii) If the use pattern varies between
5 countries based on the active ingredient or com-
6 bination of active ingredient’s packaging and la-
7 beling, or changes in use pattern have occurred
8 over time in one or more countries, an expla-
9 nation of why there are differences or changes.

10 “(F) A list of all countries in which the ac-
11 tive ingredient or combination of active ingredi-
12 ents has been withdrawn from marketing or in
13 which a request for nonprescription marketing
14 approval has been denied and an explanation
15 for such withdrawal or request denial.

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

19 “(A) IN GENERAL.—In the case of a time
20 and extent application with respect to a non-
21 prescription sunscreen active ingredient or com-
22 bination of nonprescription sunscreen active in-
23 gredients that has not been marketed in the
24 United States for 5 continuous years, in addi-
25 tion to the information required under para-

1 graph (1), the sponsor shall submit the fol-
2 lowing information for each country in which
3 the active ingredient or combination of active
4 ingredients has been marketed:

5 “(i) The manner in which the active
6 ingredient or combination of active ingredi-
7 ents has been marketed to consumers (*e.g.*,
8 nonprescription general sales direct-to-con-
9 sumer; sold only in a pharmacy, with or
10 without the personal involvement of a
11 pharmacist; dietary supplement; or cos-
12 metic), including rules and guidelines for
13 labeling, and directions for proper use. If
14 the active ingredient or combination of ac-
15 tive ingredients is marketed to consumers
16 as nonprescription, pharmacy-only, the
17 sponsor shall establish that this marketing
18 restriction does not indicate safety con-
19 cerns about its toxicity or other poten-
20 tiality for harmful effect, the method of its
21 use, or the collateral measures necessary to
22 its use.

23 “(ii) A description of the population
24 demographics (percentage of various racial
25 and ethnic groups) and the source from

1 which this information has been compiled,
2 to ensure that the use of the active ingre-
3 dient or combination of active ingredients
4 can be reasonably extrapolated to the pop-
5 ulation of the United States.

6 “(iii) A description of the country’s
7 system for maintenance of approved ingre-
8 dients, postmarket safety monitoring, and
9 identifying adverse drug experiences, espe-
10 cially those found in nonprescription mar-
11 keting experience, including method of col-
12 lection, if applicable.

13 “(iv) A statement of how long the ac-
14 tive ingredient or combination of active in-
15 gredients has been marketed in each coun-
16 try and how long the current product label-
17 ing has been in use, accompanied by a
18 copy of the current product labeling, in-
19 cluding a translation into English of any
20 labeling that is not in English, and a state-
21 ment of whether the current product label-
22 ing has been authorized, accepted, or ap-
23 proved by a regulatory body in each coun-
24 try where the condition is marketed.

1 “(v) Whether the active ingredient or
2 combination of active ingredients is mar-
3 keted as a prescription drug only in the
4 country and, if so, an explanation for such
5 restriction.

6 “(vi) A description of the country’s
7 evaluation procedures.

8 “(vii) A description of the country’s
9 rules for grandfathering currently ap-
10 proved sunscreen or cosmetic ingredients,
11 if applicable.

12 “(B) SUNSCREEN ACTIVE INGREDIENTS
13 THAT HAVE BEEN MARKETED IN MORE THAN 5
14 COUNTRIES.—

15 “(i) IN GENERAL.—In the case of a
16 time and extent application with respect to
17 a nonprescription sunscreen active ingre-
18 dient or combination of nonprescription
19 sunscreen active ingredients that has been
20 marketed as a nonprescription sunscreen
21 in more than 5 countries, with a minimum
22 of 5 continuous years of marketing in at
23 least one such country, the sponsor—

24 “(I) may submit information in
25 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 non-
22 prescription sunscreen active ingredient or
23 combination of nonprescription sunscreen
24 active ingredients meets the criteria under
25 items (aa) through (cc) of clause (i)(I) in

1 1 or more countries listed in section
2 802(b)(1)(A), at least 1 such country shall
3 be included among the 5 countries selected
4 under such clause (i)(I).

5 “(d) PENDING REQUESTS.—The requirements of
6 subsection (c) shall not apply to pending requests. Pend-
7 ing requests shall be considered in accordance with section
8 586D(e).

9 “(e) PUBLIC AVAILABILITY.—

10 “(1) REDACTIONS FOR CONFIDENTIAL INFOR-
11 MATION.—If a nonprescription sunscreen active in-
12 gredient or combination of nonprescription sun-
13 screen active ingredients is determined to be eligible
14 for further review under subsection (a)(1), the Sec-
15 retary shall make the request publicly available, with
16 redactions for information that is treated as con-
17 fidential under section 552(b) of title 5, United
18 States Code, section 1905 of title 18, United States
19 Code, or section 301(j) of this Act.

20 “(2) IDENTIFICATION OF CONFIDENTIAL IN-
21 FORMATION BY SPONSOR.—Sponsors shall identify
22 any information which the sponsor considers to be
23 confidential information described in paragraph (1).

24 “(3) CONFIDENTIALITY DURING ELIGIBILITY
25 REVIEW.—The information contained in a request

1 under section 586A(a) shall remain confidential dur-
2 ing the Secretary's consideration under this section
3 of whether the request is eligible for further review.

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

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

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

12 “(2) not later than [____] days after the sub-
13 mission of such data under subsection (c) by the
14 sponsor, including any revised submission of such
15 data following a refusal to file under subparagraph
16 (B), the Secretary shall—

17 “(A)(i) issue a written notification to the
18 sponsor determining that the request under sec-
19 tion 586A(a), together with such data, is com-
20 plete and make such notification publicly avail-
21 able; and

22 “(ii) file such request; or

23 “(B) issue a written notification to the
24 sponsor refusing to file the request and stating
25 the reasons for such refusal if the Secretary

1 finds that such request, together with such
2 data, have not been submitted in accordance
3 with subsection (c) and make such notification
4 publicly available;

5 “(3) if the Secretary refuses to file the re-
6 quest—

7 “(A) the sponsor may, within **【_____】**
8 days of receipt of written notification of such
9 refusal, seek an informal conference with the
10 Secretary regarding whether the Secretary
11 should file the request; and

12 “(B) the Secretary shall convene the infor-
13 mal conference; and

14 “(4) following any such informal conference—

15 “(A) if the sponsor insists that the Sec-
16 retary file the request (with or without amend-
17 ments to correct any purported deficiencies to
18 the request) the Secretary shall file the request
19 over protest, issue a written notification of the
20 filing to the sponsor, and make such notifica-
21 tion publicly available; and

22 “(B) if the request is so filed over pro-
23 test—

24 “(i) the date of filing is deemed to be
25 the date that is **【_____】** days after the

1 date on which the sponsor requested the
2 informal conference; and

3 “(ii) the Secretary shall not require
4 the sponsor to resubmit a copy of the re-
5 quest for purposes of such filing.

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

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

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

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

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

17 “(4) Documents contained in the request are
18 not legible.

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

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

23 “(7) The request fails to provide assessments of
24 the information required under subsection (c) and

1 fails to provide a justification of why such assess-
2 ments are not required.

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

5 “(c) DATA SUBMISSION.—

6 “(1) IN GENERAL.—In the case of a request
7 under section 586A(a) that is determined to be eligi-
8 ble for further review under section 586B, the Sec-
9 retary shall provide the sponsor and other interested
10 persons an opportunity to submit published and un-
11 published data related to the safety and effectiveness
12 of the nonprescription sunscreen active ingredient or
13 combination of nonprescription sunscreen active in-
14 gredients for its intended nonprescription uses, in
15 accordance with paragraph (2).

16 “(2) SAFETY AND EFFECTIVENESS DATA SUB-
17 MISSIONS.—Submissions under this paragraph shall
18 include the following:

19 “(A) SAFETY DATA.—

20 “(i) INDIVIDUAL ACTIVE COMPO-
21 NENTS.—With respect to individual active
22 components, controlled studies, partially
23 controlled or uncontrolled studies, docu-
24 mented case reports, pertinent marketing
25 experiences that may influence a deter-

1 mination as to the safety of each individual
2 active component, and pertinent medical
3 and scientific literature.

4 “(ii) COMBINATIONS OF INDIVIDUAL
5 ACTIVE COMPONENTS.—With respect to
6 combinations of the individual active com-
7 ponents, controlled studies, partially con-
8 trolled or uncontrolled studies, documented
9 case reports, pertinent marketing experi-
10 ences that may influence a determination
11 as to the safety of combinations of the in-
12 dividual active component, and pertinent
13 medical and scientific literature.

14 “(iii) SAFETY CONSIDERATIONS.—
15 With respect to individual active compo-
16 nents, all data related to the assessment of
17 skin irritation, eye irritation, sensitization,
18 and human pharmacokinetics, including
19 the rate and amount of absorption of the
20 active components in a variety of different
21 skin types/conditions, human adverse event
22 profileacute toxicity, repeat dose toxicity,
23 genetic toxicity, reproductive toxicity, de-
24 velopmental toxicity, phototoxicity, carcino-

1 genicity, endocrine disruption,
2 toxicokinetics.

3 “(B) EFFICACY DATA.—

4 “(i) INDIVIDUAL ACTIVE COMPO-
5 NENTS.—With respect to individual active
6 components, controlled studies, partially-
7 controlled or uncontrolled studies, docu-
8 mented case reports, pertinent marketing
9 experiences that may influence a deter-
10 mination on the efficacy of each individual
11 active component, pertinent medical and
12 scientific literature, including photo-sta-
13 bility, and chemical stability.

14 “(ii) COMBINATIONS OF INDIVIDUAL
15 ACTIVE COMPONENTS.—With respect to
16 combinations of the individual active com-
17 ponents, controlled studies, partially con-
18 trolled or uncontrolled studies, documented
19 case reports, pertinent marketing experi-
20 ences that may influence a determination
21 on the efficacy of combinations of the indi-
22 vidual active components, and pertinent
23 medical and scientific literature, including
24 photo-stability and chemical stability.

1 “(iii) SUN PROTECTION.—With re-
2 spect to individual active components, all
3 data related to the assessment of the sun
4 protection factor (commonly referred to as
5 ‘SPF’), broad spectrum protection, and
6 water resistance.

7 “(C) DATA SETTING FORTH MEDICAL RA-
8 TIONALE AND PURPOSE.—A summary of the
9 data and views setting forth the medical ration-
10 ale and purpose (or lack thereof) for the non-
11 prescription sunscreen active ingredient or com-
12 bination of nonprescription sunscreen active in-
13 gredients and the scientific basis (or lack there-
14 of) for the conclusion that the active ingredient
15 or combination of active ingredients has been
16 proven to be generally recognized as safe and
17 effective for the intended use. If there is an ab-
18 sence of controlled studies in the material sub-
19 mitted, an explanation as to why such studies
20 are not considered necessary shall be included.

21 “(D) OFFICIAL DRUG MONOGRAPH.—An
22 applicable United States Pharmacopoeia or Na-
23 tional Formulary for the nonprescription sun-
24 screen active ingredient or combination of non-
25 prescription sunscreen active ingredients or a

1 proposed standard for inclusion in an article to
2 be recognized in an official drug monograph for
3 the active ingredient or combination of active
4 ingredients, including information showing that
5 the official or proposed compendial monograph
6 for the active ingredient or combination of ac-
7 tive ingredients is consistent with the active in-
8 gredient or combination of active ingredients
9 used in the studies establishing safety and ef-
10 fectiveness and with the active ingredient or
11 combination of active ingredients marketed in
12 the nonprescription product to a material extent
13 and for a material time. If differences exist be-
14 tween the official or proposed compendial mono-
15 graph for the active ingredient or combination
16 of active ingredients and the active ingredient
17 or combination of active ingredients that is the
18 subject of the request, the sponsor shall explain
19 such differences.

20 “(E) ADVERSE DRUG EXPERIENCES.—A
21 list of all serious adverse drug experiences, as
22 defined by the Secretary, and any available data
23 regarding such adverse events, from each coun-
24 try where the nonprescription sunscreen active
25 ingredient or combination of nonprescription

1 sunscreen active ingredients has been or is cur-
2 rently marketed as a prescription drug or as a
3 nonprescription drug or product.

4 “(F) FORMAT FOR DATA PACKAGE SUB-
5 MISSION.—Submissions under this paragraph
6 shall be—

7 “(i) indexed and paginated for pur-
8 poses of electronic navigation;

9 “(ii) legible, in English, or accom-
10 panied by an English translation in accord-
11 ance with applicable regulation; and

12 “(iii) include—

13 “(I) a table of contents;

14 “(II) a background summary of
15 the entire submission;

16 “(III) separate volumes of data
17 grouped by discipline (*e.g.*, Chemistry,
18 Manufacturing and Controls, Pharma-
19 cology and Toxicology, Clinical Safety,
20 Clinical Pharmacology and Human
21 Pharmacokinetics, and Clinical Effi-
22 cacy); and

23 “(IV) a summary table listing all
24 studies, and, for each study, a table of

1 contents, summary, and complete data
2 set.

3 “(G) GUIDANCE FOR NEW REQUESTS SUB-
4 MITTED AFTER DATE OF ENACTMENT.—The
5 Secretary may issue guidance on the format
6 and content of a safety and effectiveness data
7 submission under this subsection and on the
8 safety standards for review by the Food and
9 Drug Administration of nonprescription sun-
10 screen active ingredients and combinations of
11 nonprescription sunscreen active ingredients.
12 Issuance of such guidance shall not prevent the
13 submission and review of new requests under
14 this section prior to issuance of final guidance.

15 “(d) PUBLIC AVAILABILITY.—

16 “(1) REDACTIONS FOR CONFIDENTIAL INFOR-
17 MATION.—The Secretary shall make data and infor-
18 mation submitted in connection with a request under
19 section 586(a) publicly available, with redactions for
20 information that is treated as confidential under sec-
21 tion 552(b) of title 5, United States Code, section
22 1905 of title 18, United States Code, or section
23 301(j) of this Act.

24 “(2) IDENTIFICATION OF CONFIDENTIAL IN-
25 FORMATION BY SPONSOR.—Sponsors shall identify

1 any information which the sponsor considers to be
2 confidential information described in paragraph (1).

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

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

8 “(a) REVIEW OF NEW REQUESTS.—

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

12 “(A) not later than [_____] days after
13 the date on which the request is filed under sec-
14 tion 586C(a), complete the review of the re-
15 quest and issue a proposed order determining
16 whether—

17 “(i) the nonprescription sunscreen ac-
18 tive ingredient or combination of non-
19 prescription sunscreen active ingredients
20 that is the subject of the request is
21 GRASE and not misbranded; or

22 “(ii) additional information is nec-
23 essary to allow the Director of the Center
24 for Drug Evaluation and Research to com-
25 plete the review of such request;

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

4 “(C) if the Secretary fails to issue such
5 proposed order within the [_____] -day] period
6 referred to in subparagraph (A), submit the re-
7 quest to the Commissioner of Food and Drugs
8 for review.

9 “(2) PROPOSED ORDER BY COMMISSIONER.—
10 With respect to a request submitted to the Commis-
11 sioner of Food and Drugs under paragraph (1)(C),
12 the Commissioner shall issue a proposed order with
13 respect to the request not later than [_____] days
14 after the date of such submission.

15 “(3) PUBLIC COMMENT PERIOD.—Not later
16 than [_____] days after the date on which a pro-
17 posed order is issued under paragraph (1) with re-
18 spect to a request, the Director of the Center for
19 Drug Evaluation and Research shall publish a notice
20 in the Federal Register soliciting public comments
21 on the request for a period of not more than
22 [_____] days.

23 “(4) FINAL ORDER BY CDER.—In the case of a
24 proposed order under paragraph (1) or (2) with re-

1 spect to a request, the Director of the Center for
2 Drug Evaluation and Research shall—

3 “(A) issue a final order with respect to the
4 request not later than **【_____】** days after the
5 date on which the proposed order is issued; or

6 “(B) if the Director fails to issue such
7 final order within such **【_____-day】** period, sub-
8 mit such proposed order to the Commissioner of
9 Food and Drugs for review.

10 “(5) FINAL ORDER BY COMMISSIONER.—With
11 respect to a proposed order submitted to the Com-
12 missioner of Food and Drugs under paragraph
13 (6)(B), issue a final order with respect to such pro-
14 posed order not later than **【_____】** days after the
15 date of such submission.

16 “(b) REVIEW OF PENDING REQUESTS.—

17 “(1) IN GENERAL.—The review of a pending re-
18 quest shall be carried out by the Director of the
19 Center for Drug Evaluation and Research in accord-
20 ance with paragraph (2), unless the sponsor of the
21 pending request, not later than **【_____】** after the
22 date of the enactment of the Sunscreen Innovation
23 Act, elects to have such review carried out by the
24 Director and the Advisory Committee in accordance
25 with paragraph (3).

1 “(2) REVIEW BY CDER.—

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

5 “(i) not later than **【_____】** days
6 after the date of the enactment of the Sun-
7 screen Innovation Act, issue a proposed
8 order determining whether—

9 “(I) the nonprescription sun-
10 screen active ingredient or combina-
11 tion of nonprescription sunscreen ac-
12 tive ingredients that is the subject of
13 the pending request is GRASE; or

14 “(II) additional information is
15 necessary to allow the Director to
16 make such determination;

17 “(ii) on the date on which the pro-
18 posed order is issued, publish a notice in
19 the Federal Register soliciting public com-
20 ments on the proposed order for a period
21 of not more than **【_____】** days; and

22 “(iii) if the Director fails to issue such
23 proposed order within the **【_____ -day】**
24 period referred to in clause (i), submit the

1 pending request to the Commissioner of
2 Food and Drugs for review.

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

11 “(C) FINAL ORDER BY CDER.—In the case
12 of a proposed order under subparagraph (A) or
13 (B) with respect to a pending request, the Di-
14 rector of the Center for Drug Evaluation and
15 Research shall—

16 “(i) issue a final order with respect to
17 the request not later than **【_____】** days
18 after the date on which the proposed order
19 is issued; or

20 “(ii) if the Director fails to issue such
21 final order within such **【_____-day】** period,
22 submit such proposed order to the Com-
23 missioner of Food and Drugs for review.

24 “(D) FINAL ORDER BY COMMISSIONER.—
25 With respect to a proposed order submitted to

1 the Commissioner of Food and Drugs under
2 subparagraph (C)(ii), issue a final order with
3 respect to such proposed order not later than
4 **【_____】** days after the date of such submis-
5 sion.

6 “(3) REVIEW BY CDER AND ADVISORY COM-
7 MITTEE.—In the case of an election under para-
8 graph (1) to have the review of a pending request
9 carried out by the Director of the Center for Drug
10 Evaluation and Research and the Advisory Com-
11 mittee in accordance with this paragraph, the fol-
12 lowing provisions apply:

13 “(A) ADVISORY COMMITTEE.—Not later
14 than **【_____】** days after the date of enact-
15 ment of the Sunscreen Innovation Act, the Di-
16 rector of the Center for Drug Evaluation and
17 Research shall convene a meeting of the Advi-
18 sory Committee to review the request.

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

22 “(i) not later than **【_____】** days
23 after the date of the enactment of the Sun-
24 screen Innovation Act, issue a proposed
25 order determining whether—

1 “(I) the nonprescription sun-
2 screen active ingredient or combina-
3 tion of nonprescription sunscreen ac-
4 tive ingredients that is the subject of
5 the pending request is GRASE; or

6 “(II) additional information is
7 necessary to allow the Director to
8 make such determination;

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

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

19 “(C) PROPOSED ORDER BY COMMIS-
20 SIONER.—With respect to a pending request
21 submitted to the Commissioner of Food and
22 Drugs under subparagraph (B)(iii), the Com-
23 missioner shall issue a proposed order with re-
24 spect to the pending request not later than

1 【_____】 days after the date of such submis-
2 sion.

3 “(D) FINAL ORDER BY CDER.—In the case
4 of a proposed order under subparagraph (B) or
5 (C) with respect to a pending request, the Di-
6 rector of the Center for Drug Evaluation and
7 Research shall—

8 “(i) issue a final order with respect to
9 the request not later than 【_____】 days
10 after the date on which the proposed order
11 is issued; or

12 “(ii) if the Director fails to issue such
13 final order within such 【_____-day】 period,
14 submit such proposed order to the Com-
15 missioner of Food and Drugs for review.

16 “(E) FINAL ORDER BY COMMISSIONER.—
17 With respect to a proposed order submitted to
18 the Commissioner of Food and Drugs under
19 subparagraph (D)(ii), issue a final order with
20 respect to such proposed order not later than
21 【_____】 days after the date of such submis-
22 sion.

23 “(c) REVIEW OF ADDITIONAL INFORMATION.—If,
24 after issuance of a proposed order, the Director of the
25 Center for Drug Evaluation and Research or the Commis-

1 sioner of Food and Drugs determines that additional in-
2 formation is required from the sponsor to complete review
3 of the request under subsection (a) or the pending request
4 under subsection (b) for purposes of issuing a final order
5 pursuant to the respective subsection, the Director or
6 Commissioner (as applicable) shall, upon receipt of such
7 requested additional information—

8 “(1) review such additional information; and

9 “(2) issue a final order with respect to the pro-
10 posed order not later than **【_____】** days after such
11 receipt.

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

18 “(1) the sponsor, at the time of submission of
19 the additional information, may indicate in such sub-
20 mission that the sponsor is requesting review by the
21 Advisory Committee; and

22 “(2) the Director or Commissioner (as applica-
23 ble) shall convene the Advisory Committee for pur-
24 poses of such review not later than **【____】** days
25 after receipt of such submission.

1 “(e) ADVISORY COMMITTEE.—The Advisory Com-
2 mittee—

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

6 “(2) shall not be required to review more than
7 3 submissions per meeting.

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

11 “(g) EFFECT OF FINAL ORDER.—

12 “(1) ACTIVE INGREDIENTS DETERMINED TO BE
13 GRASE.—Upon issuance of a final order determining
14 that a nonprescription sunscreen active ingredient or
15 combination of nonprescription sunscreen active in-
16 gredients is GRASE and is not misbranded, the ac-
17 tive ingredient or combination of active ingredients
18 shall be permitted to be introduced or delivered into
19 interstate commerce in accordance with all require-
20 ments applicable to drugs not subject to section
21 503(b)(1).

22 “(2) ACTIVE INGREDIENTS DETERMINED NOT
23 TO BE GRASE.—Upon issuance of a final order de-
24 termining that the nonprescription sunscreen active
25 ingredient or combination of nonprescription sun-

1 screen active ingredients is not GRASE or is mis-
2 branded, the active ingredient or combination of ac-
3 tive ingredients shall not be introduced or delivered
4 into interstate commerce unless an application sub-
5 mitted pursuant to section 505(b) with respect to
6 such active ingredient or combination of active in-
7 gredients is approved.

8 **“SEC. 586E. REPORTS.**

9 “(a) GAO REPORT.—Not later than [____] days
10 after the date of enactment of the Sunscreen Innovation
11 Act, the Comptroller General of the United States shall—

12 “(1) submit a report reviewing the overall
13 progress of the Secretary in carrying out this sub-
14 chapter to the Committee on Health, Education,
15 Labor, and Pensions of the Senate and the Com-
16 mittee on Energy and Commerce of the House of
17 Representatives; and

18 “(2) include findings on—

19 “(A) the progress made in completing the
20 review of pending requests; and

21 “(B) the role of the Office of the Commis-
22 sioner of Food and Drugs in issuing determina-
23 tions with respect to pending requests, includ-
24 ing the number of requests transferred to the
25 Office of the Commissioner under section 586D.

1 “(b) SECRETARY’S REPORT.—

2 “(1) IN GENERAL.—Not later than []
3 days after the date of enactment of the Sunscreen
4 Innovation Act, and every 2 years thereafter, the
5 Secretary shall issue a report to the Committee on
6 Health, Education, Labor, and Pensions of the Sen-
7 ate and the Committee on Energy and Commerce of
8 the House of Representatives describing actions
9 taken under this section. Each report under this
10 subsection shall be posted on the Internet site of the
11 Food and Drug Administration.

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

14 “(A) a review of the progress made in
15 issuing in a timely manner decisions on the
16 safety and effectiveness for requests for non-
17 prescription sunscreen active ingredients and
18 combinations of nonprescription sunscreen ac-
19 tive ingredients pending as of the date of enact-
20 ment of the Sunscreen Innovation Act, includ-
21 ing the number of pending requests—

22 “(i) reviewed and the decision times
23 for each request, measured from the date
24 of the original request for an eligibility de-
25 termination submitted 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 request, and the length of time
12 such requests have been pending, measured
13 from the date of original eligibility request
14 submission by the sponsor;

15 “(B) a review of the progress made in
16 issuing in a timely manner a decision on safety
17 and effectiveness for requests for nonprescrip-
18 tion sunscreen active ingredients and combina-
19 tions of nonprescription sunscreen active ingre-
20 dients submitted after the date of enactment of
21 the Sunscreen Innovation Act, including the
22 number of such requests—

23 “(i) reviewed and the decision times
24 for each request;

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 re-
11 quests;

12 “(D) a review of the progress in meeting
13 the deadlines with respect to processing re-
14 quests under this subchapter;

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

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

1 “(c) METHOD.—The Secretary shall publish the re-
2 ports required under subsection (b) in the manner the Sec-
3 retary determines to be the most effective for efficiently
4 disseminating the report, including publication of the re-
5 port on the Internet website of the Food and Drug Admin-
6 istration.”.

