

**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 ‘Advisory Committee’ means the
14 Nonprescription Drug Advisory Committee or any
15 successor to such Committee.

16 “(2) The terms ‘generally recognized as safe
17 and effective’ and ‘GRASE’ mean generally recog-
18 nized, among experts qualified by scientific training

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

6 “(3) The term ‘GRASE determination’ means,
7 with respect to a nonprescription sunscreen active
8 ingredient or a combination of nonprescription sun-
9 screen active ingredients, a determination of whether
10 such ingredients or combination of ingredients is
11 generally recognized as safe and effective and not
12 misbranded.

13 “(4) The term ‘nonprescription’ means not sub-
14 ject to section 503(b)(1).

15 “(5) The term ‘pending request’ means each re-
16 quest submitted to the Secretary—

17 “(A) for review of a nonprescription sun-
18 screen active ingredient for a GRASE deter-
19 mination;

20 “(B) that was deemed eligible for such re-
21 view by publication of a notice of eligibility in
22 the Federal Register prior to the date of enact-
23 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 “(6) 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 that submitted the pending request.

8 “(7) The term ‘sunscreen active ingredient’
9 means an active ingredient that is intended for ap-
10 plication to the skin of humans for purposes of ab-
11 sorbing, reflecting, or scattering radiation.

12 “(8) The term ‘sunscreen’ means a product
13 containing one or more sunscreen active ingredients.

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

15 “(a) REQUESTS.—Any person may submit a request
16 to the Secretary for a determination of whether a non-
17 prescription sunscreen active ingredient or a combination
18 of nonprescription sunscreen active ingredients, for use
19 under specified conditions, to be prescribed, recommended,
20 or suggested in the labeling thereof (including dosage
21 form, dosage strength, and route of administration) is
22 generally recognized as safe and effective and not mis-
23 branded.

24 “(b) RULES OF CONSTRUCTION.—

1 “(1) CURRENTLY MARKETED SUNSCREENS.—
2 Nothing in this subchapter shall be construed to af-
3 fect the marketing of sunscreens that are lawfully
4 marketed in the United States on or before the date
5 of enactment of this subchapter.

6 “(2) ENSURING SAFETY AND EFFECTIVE-
7 NESS.—Nothing in this subchapter shall be con-
8 strued to alter the Secretary’s authority to prohibit
9 the marketing of a sunscreen that is not safe and ef-
10 fective or to impose restrictions on the marketing of
11 a sunscreen to ensure safety and effectiveness.

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

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

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

19 “(a) IN GENERAL.—Upon receipt of a request under
20 section 586A(a), not later than 60 days after the date of
21 receipt of such request, the Secretary shall—

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

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

3 “(3) make such determination publicly available
4 in accordance with subsection (c).

5 “(b) CRITERIA FOR ELIGIBILITY.—

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

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

16 “(B) has been used to a material extent
17 and for a material time, as described in section
18 201(p)(2).

19 “(2) TIME AND EXTENT APPLICATION.—A
20 sponsor shall include in a request under section
21 586A(a) a time and extent application including all
22 the information required to meet the standard de-
23 scribed in paragraph (1)(B).

24 “(c) PUBLIC AVAILABILITY.—

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

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

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

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

21 “(a) IN GENERAL.—In the case of a request under
22 section 586A(a) that is determined to be eligible under
23 section 586B for further review under this section and sec-
24 tion 586D—

1 “(1) the Secretary shall, in notifying the public
2 under section 586B(a)(3) of such eligibility deter-
3 mination, invite the sponsor of the request and any
4 other interested party to submit, in support of or
5 otherwise relating to a GRASE determination—

6 “(A) published and unpublished data and
7 other information related to the safety and ef-
8 fectiveness of the nonprescription sunscreen ac-
9 tive ingredient or combination of nonprescrip-
10 tion sunscreen active ingredients for its in-
11 tended nonprescription uses; or

12 “(B) any other comments; and

13 “(2) not later than 60 days after the submis-
14 sion of such data and other information by the spon-
15 sor, including any revised submission of such data
16 and other information following a refusal to file
17 under subparagraph (B), the Secretary shall—

18 “(A)(i) issue a written notification to the
19 sponsor determining that the request under sec-
20 tion 586A(a), together with such data and
21 other information, is complete and make such
22 notification publicly available; and

23 “(ii) file such request; or

24 “(B) issue a written notification to the
25 sponsor refusing to file the request and stating

1 the reasons for the refusal and why the data
2 and other information submitted is inadequate
3 to make a GRASE determination and make
4 such notification publicly available;

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

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

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

12 “(4) if the Secretary refuses to file the re-
13 quest—

14 “(A) the sponsor may, within 30 days of
15 receipt of written notification of such refusal,
16 seek an informal conference with the Secretary
17 regarding whether the Secretary should file the
18 request; and

19 “(B) the Secretary shall convene the infor-
20 mal conference; and

21 “(5) following any such informal conference—

22 “(A) if the sponsor insists that the Sec-
23 retary file the request (with or without amend-
24 ments to correct any purported deficiencies to
25 the request) the Secretary shall file the request

1 over protest, issue a written notification of the
2 filing to the sponsor, and make such notifica-
3 tion publicly available; and

4 “(B) if the request is so filed over protest,
5 the Secretary shall not require the sponsor to
6 resubmit a copy of the request for purposes of
7 such filing.

8 “(b) REASONS FOR REFUSAL TO FILE REQUEST.—
9 The Secretary may refuse to file a request submitted
10 under section 586A(a) if the Secretary determines the
11 data or other information submitted by the sponsor under
12 this section are insufficient to make a GRASE determina-
13 tion with respect to such request.

14 “(c) PUBLIC AVAILABILITY.—

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

23 “(2) IDENTIFICATION OF CONFIDENTIAL IN-
24 FORMATION BY SPONSOR.—Sponsors or any other
25 individual submitting data or other information

1 under this section shall identify any information
2 which the sponsor or individual considers to be con-
3 fidential information described in paragraph (1).

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

5 “(a) REVIEW OF NEW REQUEST.—

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

10 “(A) not later than 300 days after the date
11 on which the request is filed under section
12 586C(a), complete the review of the request and
13 issue a proposed order determining that—

14 “(i) the nonprescription sunscreen ac-
15 tive ingredient or combination of non-
16 prescription sunscreen active ingredients
17 that is the subject of the request—

18 “(I) is GRASE; and

19 “(II) is not misbranded;

20 “(ii) the nonprescription sunscreen ac-
21 tive ingredient or combination of non-
22 prescription sunscreen active ingredients
23 that is the subject of the request—

24 “(I) is not GRASE; or

25 “(II) is misbranded; or

1 “(iii) additional information is nec-
2 essary to allow the Director of the Center
3 for Drug Evaluation and Research to com-
4 plete the review of such request;

5 “(B) within such 300-day period, convene
6 a meeting of the Advisory Committee to review
7 the request under section 586A(a): and

8 “(C) if the Director fails to issue such pro-
9 posed order within the 300-day period referred
10 to in subparagraph (A), transmit the request to
11 the Commissioner of Food and Drugs for re-
12 view.

13 “(2) PROPOSED ORDER BY COMMISSIONER.—
14 With respect to a request transmitted to the Com-
15 missioner of Food and Drugs under paragraph
16 (1)(C), the Commissioner shall, not later than 60
17 days after the date of such transmission, issue—

18 “(A) a proposed order described in para-
19 graph (1)(A)(i);

20 “(B) a proposed order described in para-
21 graph (1)(A)(ii); or

22 “(C) a proposed order described in para-
23 graph (1)(A)(iii).

24 “(3) PUBLICATION IN FEDERAL REGISTER;
25 PUBLIC COMMENT PERIOD.—A proposed order

1 issued under paragraph (1) or (2) with respect to a
2 request shall—

3 “(A) be published in the Federal Register;

4 and

5 “(B) solicit public comments for a period
6 of not more than 45 days.

7 “(4) FINAL ORDER BY CDER.—In the case of a
8 proposed order under paragraph (1)(A) or (2) with
9 respect to a request, the Director of the Center for
10 Drug Evaluation and Research shall—

11 “(A) issue a final order with respect to the
12 request—

13 “(i) in the case of a proposed order
14 under clause (i) or (ii) of paragraph (1)(A)
15 or subparagraph (A) or (B) of paragraph
16 (2), not later than 90 days after the end
17 of the public comment period under para-
18 graph (3)(B); or

19 “(ii) in the case of a proposed order
20 under paragraph (1)(A)(iii) or paragraph
21 (2)(C), not later than 210 days after the
22 date on which the sponsor submits the ad-
23 ditional information requested pursuant to
24 such proposed order; or

1 “(B) if the Director fails to issue such
2 final order within such 90- or 210-day period,
3 as applicable, transmit such proposed order to
4 the Commissioner of Food and Drugs for re-
5 view.

6 “(5) FINAL ORDER BY COMMISSIONER.—With
7 respect to a proposed order transmitted to the Com-
8 missioner of Food and Drugs under paragraph
9 (4)(B), the Commissioner shall issue a final order
10 with respect to such proposed order not later than
11 60 days after the date of such transmission.

12 “(b) REVIEW OF PENDING REQUESTS.—

13 “(1) IN GENERAL.—The review of a pending re-
14 quest shall be carried out by the Director of the
15 Center for Drug Evaluation and Research in accord-
16 ance with paragraph (3).

17 “(2) INAPPLICABILITY OF CERTAIN PROVI-
18 SIONS.—Sections 586B and 586C shall not apply
19 with respect to any pending request.

20 “(3) PROPOSED ORDER BY CDER.—The Direc-
21 tor of the Center for Drug Evaluation and Research
22 shall—

23 “(A) within the timeframe applicable under
24 paragraph (4), complete the review of the re-

1 quest and issue a proposed order determining
2 that—

3 “(i) the nonprescription sunscreen ac-
4 tive ingredient or combination of non-
5 prescription sunscreen active ingredients
6 that is the subject of the pending re-
7 quest—

8 “(I) is GRASE; and

9 “(II) is not misbranded;

10 “(ii) the nonprescription sunscreen ac-
11 tive ingredient or combination of non-
12 prescription sunscreen active ingredients
13 that is the subject of the pending re-
14 quest—

15 “(I) is not GRASE; or

16 “(II) is misbranded; or

17 “(iii) additional information is nec-
18 essary to allow the Director of the Center
19 for Drug Evaluation and Research to com-
20 plete the review of the pending request;
21 and

22 “(B) if the Director fails to issue such pro-
23 posed order within the timeframe applicable
24 under paragraph (4), transmit the pending re-

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

3 “(4) TIMEFRAME FOR ISSUANCE OF PROPOSED
4 ORDER BY CDER.—The Director of the Center for
5 Drug Evaluation and Research shall issue a pro-
6 posed order, as required by paragraph (3)(A)—

7 “(A) in the case of a pending request for
8 which the Food and Drug Administration has
9 issued a feedback letter before the date of en-
10 actment of the Sunscreen Innovation Act, not
11 later than 45 days after such date of enact-
12 ment; and

13 “(B) in the case of a pending request for
14 which the Food and Drug Administration has
15 not issued a feedback letter before the date of
16 enactment of the Sunscreen Innovation Act, not
17 later than 90 days after such date of enact-
18 ment.

19 “(5) PROPOSED ORDER BY COMMISSIONER.—
20 With respect to a pending request transmitted to the
21 Commissioner of Food and Drugs under paragraph
22 (3)(B), the Commissioner shall, not later than 60
23 days after the date of such transmission, issue—

24 “(A) a proposed order described in para-
25 graph (3)(A)(i);

1 “(B) a proposed order described in para-
2 graph (3)(A)(ii); or

3 “(C) a proposed order described in para-
4 graph (3)(A)(iii).

5 “(6) PUBLICATION IN FEDERAL REGISTER;
6 PUBLIC COMMENT PERIOD.—A proposed order
7 issued under paragraph (3) or (5) with respect to a
8 pending request shall—

9 “(A) be published in the Federal Register;
10 and

11 “(B) solicit public comments for a period
12 of not more than 45 days.

13 “(7) ADVISORY COMMITTEE.—If a proposed
14 order is issued under paragraph (3)(A)(iii) or (5)(C)
15 requesting additional information—

16 “(A) the sponsor, the Director of the Cen-
17 ter for Drug Evaluation and Research, or the
18 Commissioner of Food and Drugs may request
19 a meeting of the Advisory Committee for the
20 purpose of reviewing the pending request; and

21 “(B) the Advisory Committee shall be con-
22 vened for such purpose.

23 “(8) FINAL ORDER BY CDER.—In the case of a
24 proposed order under paragraph (3)(A) or (5) with

1 respect 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—

5 “(i) in the case of a proposed order
6 under clause (i) or (ii) of paragraph (3)(A)
7 or subparagraph (A) or (B) of paragraph
8 (5), not later than 90 days after the end
9 of the public comment period under para-
10 graph (3)(B); or

11 “(ii) in the case of a proposed order
12 under paragraph (3)(A)(iii) or paragraph
13 (5)(C)—

14 “(I) if the Advisory Committee is
15 not convened pursuant to paragraph
16 (7), not later than 210 days after the
17 date on which the sponsor submits the
18 additional information requested pur-
19 suant to such proposed order; or

20 “(II) if the Advisory Committee
21 is convened pursuant to paragraph
22 (7), not later than 270 days after date
23 on which the sponsor submits such
24 additional information; or

1 “(B) if the Director fails to issue such
2 final order within such 90-, 210-, and 270-day
3 period, as applicable, transmit such proposed
4 order to the Commissioner of Food and Drugs
5 for review.

6 “(9) FINAL ORDER BY COMMISSIONER.—With
7 respect to a proposed order transmitted to the Com-
8 missioner of Food and Drugs under paragraph
9 (8)(B), the Commissioner shall issue a final order
10 with respect to such proposed order not later than
11 60 days after the date of such transmission.

12 “(c) ADVISORY COMMITTEE.—

13 “(1) LIMITATIONS.—The Advisory Com-
14 mittee—

15 “(A) shall not be required to be con-
16 vened—

17 “(i) more than once with respect to
18 any request under section 586A(a) or any
19 pending request; or

20 “(ii) more than twice in any twelve
21 month period with respect to the review of
22 submissions under this section; and

23 “(B) shall not be required to review more
24 than 3 submissions per meeting.

1 “(2) MEMBERSHIP.—In appointing the mem-
2 bers of the Advisory Committee, the Secretary may
3 select to serve temporarily as voting members on the
4 Advisory Committee—

5 “(A) members of other Federal advisory
6 committees; or

7 “(B) consultants from outside of the De-
8 partment of Health and Human Services who
9 have substantive expertise regarding sunscreen
10 active ingredients.

11 “(d) NO DELEGATION.—Any responsibility vested by
12 this section in the Commissioner of Food and Drugs is
13 not delegable.

14 “(e) EFFECT OF FINAL ORDER.—

15 “(1) CONTENT.—A final order under subsection
16 (a)(4), (a)(5), (b)(8), or (b)(9) with respect to a re-
17 quest under section 586A(a) or a pending request
18 shall determine that the nonprescription sunscreen
19 active ingredient or combination of nonprescription
20 sunscreen active ingredients that is the subject of
21 the request—

22 “(A) is GRASE and is not misbranded; or

23 “(B) is not GRASE or is misbranded.

24 “(2) ACTIVE INGREDIENTS DETERMINED TO BE
25 GRASE.—Upon issuance of a final order determining

1 that a nonprescription sunscreen active ingredient or
2 combination of nonprescription sunscreen active in-
3 gredients is GRASE and is not misbranded, the ac-
4 tive ingredient or combination of active ingredients
5 shall be permitted to be introduced or delivered into
6 interstate commerce in accordance with all require-
7 ments applicable to drugs not subject to section
8 503(b)(1).

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

20 **“SEC. 586E. REPORTS.**

21 “(a) GAO REPORT.—Not later than 1 year after the
22 date of enactment of the Sunscreen Innovation Act, the
23 Comptroller General of the United States shall—

24 “(1) submit a report reviewing the overall
25 progress of the Secretary in carrying out this sub-

1 chapter to the Committee on Health, Education,
2 Labor, and Pensions of the Senate and the Com-
3 mittee on Energy and Commerce of the House of
4 Representatives; and

5 “(2) include findings on—

6 “(A) the progress made in completing the
7 review of pending requests; and

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

13 “(b) SECRETARY’S REPORT.—

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

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

1 “(A) a review of the progress made in
2 issuing GRASE determinations for pending re-
3 quests, including the number of pending re-
4 quests—

5 “(i) reviewed and the decision times
6 for each request, measured from the date
7 of the original request for an eligibility de-
8 termination submitted by the sponsor;

9 “(ii) resulting in a determination that
10 the nonprescription sunscreen active ingre-
11 dient or combination of nonprescription
12 sunscreen active ingredients is GRASE
13 and not misbranded;

14 “(iii) resulting in a determination that
15 the nonprescription sunscreen active ingre-
16 dient or combination of nonprescription
17 sunscreen active ingredients is not GRASE
18 and is misbranded and the reasons for
19 such determinations; and

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

1 ured from the date of original request for
2 an eligibility determination by the sponsor;

3 “(B) a review of the progress made in
4 issuing in a timely manner GRASE determina-
5 tions for requests submitted under section
6 586A(a), including the number of such re-
7 quests—

8 “(i) reviewed and the decision times
9 for each request;

10 “(ii) resulting in a determination that
11 the nonprescription sunscreen active ingre-
12 dient or combination of nonprescription
13 sunscreen active ingredients is GRASE
14 and not misbranded;

15 “(iii) resulting in a determination that
16 the nonprescription sunscreen active ingre-
17 dient or combination of nonprescription
18 sunscreen active ingredients is not GRASE
19 and is misbranded and the reasons for
20 such determinations; and

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

1 ured from the date of original request for
2 an eligibility determination by the sponsor;

3 “(C) a description of the staffing and re-
4 sources relating to the costs associated with the
5 review and decisionmaking pertaining to re-
6 quests under this subchapter;

7 “(D) a review of the progress made in
8 meeting the deadlines with respect to processing
9 requests under this subchapter;

10 “(E) to the extent the Secretary deter-
11 mines appropriate, recommendations for process
12 improvements in the handling of pending and
13 new requests, including the advisory committee
14 review process; and

15 “(F) recommendations for expanding the
16 applicability of this subchapter to nonprescrip-
17 tion active ingredients that are not related to
18 the sunscreen category of over-the-counter
19 drugs.

20 “(c) METHOD.—The Secretary shall publish the re-
21 ports required under subsection (b) in the manner the Sec-
22 retary determines to be the most effective for efficiently
23 disseminating the report, including publication of the re-
24 port on the Internet website of the Food and Drug Admin-
25 istration.”.

1 **SEC. 3. GUIDANCE.**

2 (a) IN GENERAL.—

3 (1) ISSUANCE.—Not later than one year after
4 the date of enactment of this Act, the Secretary of
5 Health and Human Services, acting through the
6 Commissioner of Food and Drugs, shall issue guid-
7 ance, in accordance with good guidance practices, on
8 the implementation of, and compliance with, sub-
9 chapter I of chapter V of the Federal Food, Drug,
10 and Cosmetic Act, as added by section 2, including
11 guidance on—

12 (A) the criteria for determining whether a
13 nonprescription sunscreen active ingredient or
14 combination of nonprescription sunscreen active
15 ingredients has been used to a material extent
16 and for a material time, as described in section
17 201(p)(2) of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 321(p)(2));

19 (B) the format and content of a safety and
20 effectiveness data submission;

21 (C) the safety standards for determining
22 whether a nonprescription sunscreen active in-
23 gredients or combination of nonprescription
24 sunscreen active ingredients is generally recog-
25 nized as safe and effective, as defined in section
26 586 of such subchapter I.

1 (2) INAPPLICABILITY OF PAPERWORK REDUC-
2 TION ACT.—Chapter 35 of title 44, United States
3 Code, shall not apply to collections of information
4 made for purposes of guidance under this sub-
5 section.

6 (b) SUBMISSIONS PENDING ISSUANCE OF FINAL
7 GUIDANCE.—Irrespective of whether final guidance under
8 subsection (a) has been issued—

9 (1) persons may, beginning on the date of en-
10 actment of this Act, make submissions under sub-
11 chapter I of chapter V of the Federal Food, Drug,
12 and Cosmetic Act, as added by section 2; and

13 (2) the Secretary of Health and Human Serv-
14 ices, acting through the Commissioner of Food and
15 Drugs, shall review and act upon such submissions
16 in accordance with such subchapter.

