

113TH CONGRESS
2^D SESSION

H. R. 4250

AN ACT

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,*

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
19 and experience to evaluate the safety and effective-
20 ness of drugs, as safe and effective for use under the
21 conditions prescribed, recommended, or suggested in
22 the product’s labeling, as described in section
23 201(p).

24 “(3) The term ‘GRASE determination’ means,
25 with respect to a nonprescription sunscreen active
26 ingredient or a combination of nonprescription sun-

1 screen active ingredients, a determination of whether
2 such ingredients or combination of ingredients is
3 generally recognized as safe and effective and not
4 misbranded for use under the conditions prescribed,
5 recommended, or suggested in the product’s labeling,
6 as described in section 201(p).

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

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

11 “(A) for consideration for inclusion in the
12 over-the-counter drug monograph system;

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

17 “(C) for which safety and effectiveness
18 data has been submitted to the Secretary prior
19 to such date of enactment.

20 “(6) The term ‘sponsor’ means the person sub-
21 mitting the request under section 586A(a), including
22 a time and extent application under section 586B, or
23 the person that submitted the pending request.

24 “(7) The term ‘sunscreen active ingredient’
25 means an active ingredient that is intended for ap-

1 plication to the skin of humans for purposes of ab-
2 sorbing, reflecting, or scattering radiation.

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

5 **“SEC. 586A. GENERAL PROVISIONS.**

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

15 “(b) RULES OF CONSTRUCTION.—

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

21 “(2) ENSURING SAFETY AND EFFECTIVE-
22 NESS.—Nothing in this subchapter shall be con-
23 strued to alter the Secretary’s authority to prohibit
24 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 60 days after the date of
12 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 (c).

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) TIME AND EXTENT APPLICATION.—A
10 sponsor shall include in a request under section
11 586A(a) a time and extent application including all
12 the information required to meet the standard de-
13 scribed in paragraph (1)(B).

14 “(c) PUBLIC AVAILABILITY.—

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

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

5 “(3) CONFIDENTIALITY DURING ELIGIBILITY
6 REVIEW.—The information contained in a request
7 under section 586A(a) shall remain confidential dur-
8 ing the Secretary’s consideration under this section
9 of whether the request is eligible for further review.

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

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

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

20 “(A) published and unpublished data and
21 other information related to the safety and ef-
22 fectiveness of the nonprescription sunscreen ac-
23 tive ingredient or combination of nonprescrip-
24 tion sunscreen active ingredients for its in-
25 tended nonprescription uses; or

1 “(B) any other comments; and

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

7 “(A)(i) issue a written notification to the
8 sponsor determining that the request under sec-
9 tion 586A(a), together with such data and
10 other information, is sufficiently complete to
11 conduct a substantive review and make such no-
12 tification publicly available; and

13 “(ii) file such request; or

14 “(B) issue a written notification to the
15 sponsor refusing to file the request and stating
16 the reasons for the refusal and why the data
17 and other information submitted is not suffi-
18 ciently complete to conduct a substantive review
19 and make such notification publicly available;

20 “(3) the Secretary shall, in filing a request
21 under paragraph (2)—

22 “(A) invite the public to submit further
23 comments with respect to such filing; and

24 “(B) limit such public comment, and the
25 comment period under paragraph (1), to the pe-

1 riod ending on the date that is 60 days after
2 such filing;

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

5 “(A) the sponsor may, within 30 days of
6 receipt of written notification of such refusal,
7 seek a meeting with the Secretary regarding
8 whether the Secretary should file the request;
9 and

10 “(B) the Secretary shall convene the meet-
11 ing; and

12 “(5) following any such meeting—

13 “(A) if the sponsor asks that the Secretary
14 file the request (with or without amendments to
15 correct any purported deficiencies to the re-
16 quest) the Secretary shall file the request over
17 protest, issue a written notification of the filing
18 to the sponsor, and make such notification pub-
19 licly available; and

20 “(B) if the request is so filed over protest,
21 the Secretary shall not require the sponsor to
22 resubmit a copy of the request for purposes of
23 such filing.

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

25 The Secretary may refuse to file a request submitted

1 under section 586A(a) if the Secretary determines the
2 data or other information submitted by the sponsor under
3 this section are not sufficiently complete to conduct a sub-
4 stantive review with respect to such request.

5 “(c) PUBLIC AVAILABILITY.—

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

14 “(2) IDENTIFICATION OF CONFIDENTIAL IN-
15 FORMATION BY SPONSOR.—Sponsors or any other
16 individual submitting data or other information
17 under this section shall identify any information
18 which the sponsor or individual considers to be con-
19 fidential information described in paragraph (1).

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

21 “(a) REVIEW OF NEW REQUEST.—

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

1 “(A) not later than 300 days after the date
2 on which the request is filed under section
3 586C(a), complete the review of the request and
4 issue a proposed order determining that—

5 “(i) the nonprescription sunscreen ac-
6 tive ingredient or combination of non-
7 prescription sunscreen active ingredients
8 that is the subject of the request—

9 “(I) is GRASE; and

10 “(II) is not misbranded;

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

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 such request;

21 “(B) within such 300-day period, convene
22 a meeting of the Advisory Committee to review
23 the request under section 586A(a); and

24 “(C) if the Director fails to issue such pro-
25 posed order within the 300-day period referred

1 to in subparagraph (A), transmit the request to
2 the Commissioner of Food and Drugs for re-
3 view.

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

9 “(A) a proposed order described in para-
10 graph (1)(A)(i);

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

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

15 “(3) PUBLICATION IN FEDERAL REGISTER;
16 PUBLIC COMMENT PERIOD.—A proposed order
17 issued under paragraph (1) or (2) with respect to a
18 request shall—

19 “(A) be published in the Federal Register;
20 and

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

23 “(4) FINAL ORDER BY CDER.—In the case of a
24 proposed order under paragraph (1)(A) or (2) 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 (1)(A)
7 or subparagraph (A) or (B) of paragraph
8 (2), 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 (1)(A)(iii) or paragraph
13 (2)(C), not later than 210 days after the
14 date on which the sponsor submits the ad-
15 ditional information requested pursuant to
16 such proposed order; or

17 “(B) if the Director fails to issue such
18 final order within such 90- or 210-day period,
19 as applicable, transmit such proposed order to
20 the Commissioner of Food and Drugs for re-
21 view.

22 “(5) FINAL ORDER BY COMMISSIONER.—With
23 respect to a proposed order transmitted to the Com-
24 missioner of Food and Drugs under paragraph
25 (4)(B), the Commissioner shall issue a final order

1 with respect to such proposed order not later than
2 60 days after the date of such transmission.

3 “(b) REVIEW OF PENDING REQUESTS.—

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

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

11 “(3) PROPOSED ORDER BY CDER.—The Direc-
12 tor of the Center for Drug Evaluation and Research
13 shall—

14 “(A) within the timeframe applicable under
15 paragraph (4), complete the review of the re-
16 quest and issue a proposed order determining
17 that—

18 “(i) the nonprescription sunscreen ac-
19 tive ingredient or combination of non-
20 prescription sunscreen active ingredients
21 that is the subject of the pending re-
22 quest—

23 “(I) is GRASE; and

24 “(II) is not misbranded;

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

6 “(I) is not GRASE; or

7 “(II) is misbranded; or

8 “(iii) additional information is nec-
9 essary to allow the Director of the Center
10 for Drug Evaluation and Research to com-
11 plete the review of the pending request;
12 and

13 “(B) if the Director fails to issue such pro-
14 posed order within the timeframe applicable
15 under paragraph (4), transmit the pending re-
16 quest to the Commissioner of Food and Drugs
17 for review.

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

22 “(A) in the case of a pending request for
23 which the Food and Drug Administration has
24 issued a feedback letter before the date of en-
25 actment of the Sunscreen Innovation Act, not

1 later than 45 days after such date of enact-
2 ment; and

3 “(B) in the case of a pending request for
4 which the Food and Drug Administration has
5 not issued a feedback letter before the date of
6 enactment of the Sunscreen Innovation Act, not
7 later than 90 days after such date of enact-
8 ment.

9 “(5) PROPOSED ORDER BY COMMISSIONER.—
10 With respect to a pending request transmitted to the
11 Commissioner of Food and Drugs under paragraph
12 (3)(B), the Commissioner shall, not later than 60
13 days after the date of such transmission, issue—

14 “(A) a proposed order described in para-
15 graph (3)(A)(i);

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

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

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

24 “(A) be published in the Federal Register;
25 and

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

3 “(7) ADVISORY COMMITTEE.—For a proposed
4 order issued under paragraph (3)(A)(iii) or (5)(C)
5 requesting additional information, an Advisory Com-
6 mittee meeting shall be convened if the sponsor re-
7 quests, or the Director of the Center for Drug Eval-
8 uation and Research or the Commissioner of Food
9 and Drugs decides, to convene such a meeting for
10 the purpose of reviewing the pending request.

11 “(8) FINAL ORDER BY CDER.—In the case of a
12 proposed order under paragraph (3)(A) or (5) with
13 respect to a request, the Director of the Center for
14 Drug Evaluation and Research shall—

15 “(A) issue a final order with respect to the
16 request—

17 “(i) in the case of a proposed order
18 under clause (i) or (ii) of paragraph (3)(A)
19 or subparagraph (A) or (B) of paragraph
20 (5), not later than 90 days after the end
21 of the public comment period under para-
22 graph (3)(B); or

23 “(ii) in the case of a proposed order
24 under paragraph (3)(A)(iii) or paragraph
25 (5)(C)—

1 “(I) if the Advisory Committee is
2 not convened pursuant to paragraph
3 (7), not later than 210 days after the
4 date on which the sponsor submits the
5 additional information requested pur-
6 suant to such proposed order; or

7 “(II) if the Advisory Committee
8 is convened pursuant to paragraph
9 (7), not later than 270 days after date
10 on which the sponsor submits such
11 additional information; or

12 “(B) if the Director fails to issue such
13 final order within such 90-, 210-, and 270-day
14 period, as applicable, transmit such proposed
15 order to the Commissioner of Food and Drugs
16 for review.

17 “(9) FINAL ORDER BY COMMISSIONER.—With
18 respect to a proposed order transmitted to the Com-
19 missioner of Food and Drugs under paragraph
20 (8)(B), the Commissioner shall issue a final order
21 with respect to such proposed order not later than
22 60 days after the date of such transmission.

23 “(c) ADVISORY COMMITTEE.—

24 “(1) LIMITATIONS.—The Food and Drug Ad-
25 ministration—

1 “(A) shall not be required to convene the
2 Advisory Committee—

3 “(i) more than once with respect to
4 any request under section 586A(a) or any
5 pending request; or

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

9 “(B) shall not be required to submit more
10 than 3 submissions to the Advisory Committee
11 per meeting.

12 “(2) MEMBERSHIP.—In appointing the mem-
13 bers of the Advisory Committee, the Secretary may
14 select to serve temporarily as voting members on the
15 Advisory Committee—

16 “(A) members of other Federal advisory
17 committees; or

18 “(B) consultants from outside of the De-
19 partment of Health and Human Services who
20 have substantive expertise regarding sunscreen
21 active ingredients.

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

25 “(e) EFFECT OF FINAL ORDER.—

1 “(1) CONTENT.—A final order under subsection
2 (a)(4), (a)(5), (b)(8), or (b)(9) with respect to a re-
3 quest under section 586A(a) or a pending request
4 shall determine that the nonprescription sunscreen
5 active ingredient or combination of nonprescription
6 sunscreen active ingredients that is the subject of
7 the request—

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

9 “(B) is not GRASE or is misbranded.

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

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

1 branded, the active ingredient or combination of ac-
2 tive ingredients shall not be introduced or delivered
3 into interstate commerce, for use under the condi-
4 tions subject to the final order, unless an application
5 submitted 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 1 year after the
10 date of enactment of the Sunscreen Innovation Act, the
11 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 1 year after
3 the date of enactment of the Sunscreen Innovation
4 Act, and every 2 years thereafter, the Secretary shall
5 issue a report to the Committee on Health, Edu-
6 cation, Labor, and Pensions of the Senate and the
7 Committee on Energy and Commerce of the House
8 of Representatives describing actions taken under
9 this section. Each report under this subsection shall
10 be posted on the Internet site of the Food and Drug
11 Administration.

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

14 “(A) a review of the progress made in
15 issuing GRASE determinations for pending re-
16 quests, including the number of pending re-
17 quests—

18 “(i) reviewed and the decision times
19 for each request, measured from the date
20 of the original request for an eligibility de-
21 termination submitted by the sponsor;

22 “(ii) resulting in a determination that
23 the nonprescription sunscreen active ingre-
24 dient or combination of nonprescription

1 sunscreen active ingredients is GRASE
2 and not misbranded;

3 “(iii) resulting in a determination that
4 the nonprescription sunscreen active ingre-
5 dient or combination of nonprescription
6 sunscreen active ingredients is not GRASE
7 and is misbranded and the reasons for
8 such determinations; and

9 “(iv) for which a determination has
10 not been made, an explanation for the
11 delay, a description of the current status of
12 each such request, and the length of time
13 each such request has been pending, meas-
14 ured from the date of original request for
15 an eligibility determination by the sponsor;

16 “(B) a review of the progress made in
17 issuing in a timely manner GRASE determina-
18 tions for requests submitted under section
19 586A(a), including the number of such re-
20 quests—

21 “(i) reviewed and the decision times
22 for each request;

23 “(ii) resulting in a determination that
24 the nonprescription sunscreen active ingre-
25 dient or combination of nonprescription

1 sunscreen active ingredients is GRASE
2 and not misbranded;

3 “(iii) resulting in a determination that
4 the nonprescription sunscreen active ingre-
5 dient or combination of nonprescription
6 sunscreen active ingredients is not GRASE
7 and is misbranded and the reasons for
8 such determinations; and

9 “(iv) for which a determination has
10 not been made, an explanation for the
11 delay, a description of the current status of
12 each such request, and the length of time
13 each such request has been pending, meas-
14 ured from the date of original request for
15 an eligibility determination by the sponsor;

16 “(C) a description of the staffing and re-
17 sources relating to the costs associated with the
18 review and decisionmaking pertaining to re-
19 quests under this subchapter;

20 “(D) a review of the progress made in
21 meeting the deadlines with respect to processing
22 requests under this subchapter;

23 “(E) to the extent the Secretary deter-
24 mines appropriate, recommendations for process
25 improvements in the handling of pending and

1 new requests, including the advisory committee
2 review process; and

3 “(F) recommendations for expanding the
4 applicability of this subchapter to nonprescrip-
5 tion active ingredients that are not related to
6 the sunscreen category of over-the-counter
7 drugs.

8 “(c) METHOD.—The Secretary shall publish the re-
9 ports required under subsection (b) in the manner the Sec-
10 retary determines to be the most effective for efficiently
11 disseminating the report, including publication of the re-
12 port on the Internet website of the Food and Drug Admin-
13 istration.”.

14 **SEC. 3. GUIDANCE.**

15 (a) IN GENERAL.—

16 (1) ISSUANCE.—Not later than one year after
17 the date of enactment of this Act, the Secretary of
18 Health and Human Services, acting through the
19 Commissioner of Food and Drugs, shall issue guid-
20 ance, in accordance with good guidance practices, on
21 the implementation of, and compliance with, sub-
22 chapter I of chapter V of the Federal Food, Drug,
23 and Cosmetic Act, as added by section 2, including
24 guidance on—

1 (A) the criteria for determining whether a
2 nonprescription sunscreen active ingredient or
3 combination of nonprescription sunscreen active
4 ingredients has been used to a material extent
5 and for a material time, as described in section
6 201(p)(2) of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 321(p)(2));

8 (B) the format and content of a safety and
9 effectiveness data submission; and

10 (C) the safety and efficacy standards for
11 determining whether a nonprescription sun-
12 screen active ingredients or combination of non-
13 prescription sunscreen active ingredients is gen-
14 erally recognized as safe and effective, as de-
15 fined in section 586 of such subchapter I.

16 (2) INAPPLICABILITY OF PAPERWORK REDUC-
17 TION ACT.—Chapter 35 of title 44, United States
18 Code, shall not apply to collections of information
19 made for purposes of guidance under this sub-
20 section.

21 (b) SUBMISSIONS PENDING ISSUANCE OF FINAL
22 GUIDANCE.—Irrespective of whether final guidance under
23 subsection (a) has been issued—

24 (1) persons may, beginning on the date of en-
25 actment of this Act, make submissions under sub-

1 chapter I of chapter V of the Federal Food, Drug,
2 and Cosmetic Act, as added by section 2; and

3 (2) the Secretary of Health and Human Serv-
4 ices, acting through the Commissioner of Food and
5 Drugs, shall review and act upon such submissions
6 in accordance with such subchapter.

Passed the House of Representatives July 28, 2014.

Attest:

Clerk.

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AN ACT

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.