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113TH CONGRESS
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H. R. 4250

[Report No. 113–558]

To amend the Federal Food, Drug, and Cosmetic Act to provide an alternative process for review of safety and effectiveness of nonprescription sunscreen active ingredients and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 13, 2014

Mr. WHITFIELD (for himself and Mr. DINGELL) introduced the following bill; which was referred to the Committee on Energy and Commerce

JULY 24, 2014

Additional sponsors: Mr. FARR, Mr. GUTHRIE, Mr. TIBERI, Mr. STIVERS, Mr. ROGERS of Kentucky, Mr. BARR, Mr. FORBES, Mr. CARNEY, Mr. LANCE, Mrs. ELLMERS, Mrs. BLACKBURN, Mrs. CAROLYN B. MALONEY of New York, Mr. GRIFFIN of Arkansas, Mr. CRENSHAW, Mr. LANKFORD, Mr. DENT, Mr. ROONEY, Mr. BARROW of Georgia, Mr. KINGSTON, Mrs. NOEM, Mr. LATTA, Mr. GRAVES of Georgia, Mr. ROSS, Mr. BISHOP of New York, Mr. PERLMUTTER, Mr. MURPHY of Pennsylvania, Mr. DIAZ-BALART, Mr. JOHNSON of Ohio, Mr. MATHESON, Mr. ROSKAM, Mr. FLEISCHMANN, Mr. CHABOT, and Mr. RENACCI

JULY 24, 2014

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

[For text of introduced bill, see copy of bill as introduced on March 13, 2014]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide an alternative process for review of safety and effectiveness of nonprescription sunscreen active ingredients and for other purposes.

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

3 **SECTION 1. SHORT TITLE.**

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

6 **SEC. 2. REGULATION OF NONPRESCRIPTION SUNSCREEN**
7 **ACTIVE INGREDIENTS.**

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

11 **“Subchapter I—Nonprescription Sunscreen**
12 **Active Ingredients**

13 **“SEC. 586. DEFINITIONS.**

14 *“In this subchapter:*

15 *“(1) The term ‘Advisory Committee’ means the*
16 *Nonprescription Drug Advisory Committee or any*
17 *successor to such Committee.*

18 *“(2) The terms ‘generally recognized as safe and*
19 *effective’ and ‘GRASE’ mean generally recognized,*
20 *among experts qualified by scientific training and ex-*
21 *perience to evaluate the safety and effectiveness of*
22 *drugs, as safe and effective for use under the condi-*
23 *tions prescribed, recommended, or suggested in the*
24 *product’s labeling, as described in section 201(p).*

1 “(3) *The term ‘GRASE determination’ means,*
2 *with respect to a nonprescription sunscreen active in-*
3 *redient or a combination of nonprescription sun-*
4 *screen active ingredients, a determination of whether*
5 *such ingredients or combination of ingredients is gen-*
6 *erally recognized as safe and effective and not mis-*
7 *branded for use under the conditions prescribed, rec-*
8 *ommended, or suggested in the product’s labeling, as*
9 *described in section 201(p).*

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

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

14 “(A) *for consideration for inclusion in the*
15 *over-the-counter drug monograph system;*

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

20 “(C) *for which safety and effectiveness data*
21 *has been submitted to the Secretary prior to such*
22 *date of enactment.*

23 “(6) *The term ‘sponsor’ means the person sub-*
24 *mitting the request under section 586A(a), including*

1 *a time and extent application under section 586B, or*
2 *the person that submitted the pending request.*

3 “(7) *The term ‘sunscreen active ingredient’*
4 *means an active ingredient that is intended for appli-*
5 *cation to the skin of humans for purposes of absorb-*
6 *ing, reflecting, or scattering radiation.*

7 “(8) *The term ‘sunscreen’ means a product con-*
8 *taining one or more sunscreen active ingredients.*

9 **“SEC. 586A. GENERAL PROVISIONS.**

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

18 “(b) *RULES OF CONSTRUCTION.—*

19 “(1) *CURRENTLY MARKETED SUNSCREENS.—*
20 *Nothing in this subchapter shall be construed to affect*
21 *the marketing of sunscreens that are lawfully mar-*
22 *keted in the United States on or before the date of en-*
23 *actment of this subchapter.*

24 “(2) *ENSURING SAFETY AND EFFECTIVENESS.—*
25 *Nothing in this subchapter shall be construed to alter*

1 *the Secretary’s authority to prohibit the marketing of*
2 *a sunscreen that is not safe and effective or to impose*
3 *restrictions on the marketing of a sunscreen to ensure*
4 *safety and effectiveness.*

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

8 “(c) *SUNSET.—This subchapter shall cease to be effec-*
9 *tive at the end of the 5-year period beginning on the date*
10 *of enactment of this subchapter.*

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

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

15 “(1) *determine whether the request is eligible for*
16 *further review under sections 586C and 586D, as de-*
17 *scribed in subsection (b);*

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

20 “(3) *make such determination publicly available*
21 *in accordance with subsection (c).*

22 “(b) *CRITERIA FOR ELIGIBILITY.—*

23 “(1) *IN GENERAL.—To be eligible for review*
24 *under sections 586C and 586D, a request shall be for*
25 *a nonprescription sunscreen active ingredient or com-*

1 *combination of nonprescription sunscreen active ingredi-*
2 *ents, for use under specified conditions, to be pre-*
3 *scribed, recommended, or suggested in the labeling*
4 *thereof, that—*

5 *“(A) is not included in the stayed sunscreen*
6 *monograph in part 352 of title 21, Code of Fed-*
7 *eral Regulations; and*

8 *“(B) has been used to a material extent and*
9 *for a material time, as described in section*
10 *201(p)(2).*

11 *“(2) TIME AND EXTENT APPLICATION.—A spon-*
12 *sor shall include in a request under section 586A(a)*
13 *a time and extent application including all the infor-*
14 *mation required to meet the standard described in*
15 *paragraph (1)(B).*

16 *“(c) PUBLIC AVAILABILITY.—*

17 *“(1) REDACTIONS FOR CONFIDENTIAL INFORMA-*
18 *TION.—If a nonprescription sunscreen active ingre-*
19 *dient or combination of nonprescription sunscreen ac-*
20 *tive ingredients is determined to be eligible for further*
21 *review under subsection (a)(1), the Secretary shall*
22 *make the request publicly available, with redactions*
23 *for information that is treated as confidential under*
24 *section 552(b) of title 5, United States Code, section*

1 1905 of title 18, United States Code, or section 301(j)
2 of this Act.

3 “(2) *IDENTIFICATION OF CONFIDENTIAL INFOR-*
4 *MATION BY SPONSOR.*—Sponsors shall identify any
5 information which the sponsor considers to be con-
6 fidential information described in paragraph (1).

7 “(3) *CONFIDENTIALITY DURING ELIGIBILITY RE-*
8 *VIEW.*—The information contained in a request under
9 section 586A(a) shall remain confidential during the
10 Secretary’s consideration under this section of wheth-
11 er the request is eligible for further review.

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

13 “(a) *IN GENERAL.*—In the case of a request under sec-
14 tion 586A(a) that is determined to be eligible under section
15 586B for further review under this section and section
16 586D—

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

22 “(A) published and unpublished data and
23 other information related to the safety and effec-
24 tiveness of the nonprescription sunscreen active
25 ingredient or combination of nonprescription

1 *sunscreen active ingredients for its intended non-*
2 *prescription uses; or*

3 “(B) *any other comments; and*

4 “(2) *not later than 60 days after the submission*
5 *of such data and other information by the sponsor,*
6 *including any revised submission of such data and*
7 *other information following a refusal to file under*
8 *subparagraph (B), the Secretary shall—*

9 “(A)(i) *issue a written notification to the*
10 *sponsor determining that the request under sec-*
11 *tion 586A(a), together with such data and other*
12 *information, is sufficiently complete to conduct a*
13 *substantive review and make such notification*
14 *publicly available; and*

15 “(i) *file such request; or*

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

22 “(3) *the Secretary shall, in filing a request*
23 *under paragraph (2)—*

24 “(A) *invite the public to submit further*
25 *comments with respect to such filing; and*

1 “(B) limit such public comment, and the
2 comment period under paragraph (1), to the pe-
3 riod ending on the date that is 60 days after
4 such filing;

5 “(4) if the Secretary refuses to file the request—

6 “(A) the sponsor may, within 30 days of re-
7 ceipt of written notification of such refusal, seek
8 a meeting with the Secretary regarding whether
9 the Secretary should file the request; 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 request)
16 the Secretary shall file the request over protest,
17 issue a written notification of the filing to the
18 sponsor, and make such notification publicly
19 available; and

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

24 “(b) REASONS FOR REFUSAL TO FILE REQUEST.—The
25 Secretary may refuse to file a request submitted under sec-

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

5 *“(c) PUBLIC AVAILABILITY.—*

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

14 *“(2) IDENTIFICATION OF CONFIDENTIAL INFOR-*
15 *MATION BY SPONSOR.—Sponsors or any other indi-*
16 *vidual submitting data or other information under*
17 *this section shall identify any information which the*
18 *sponsor or individual considers to be confidential in-*
19 *formation described in paragraph (1).*

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

21 *“(a) REVIEW OF NEW REQUEST.—*

22 *“(1) PROPOSED ORDER BY CDER.—In the case of*
23 *a request under section 586A(a), the Director of the*
24 *Center for Drug Evaluation and Research 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 a
22 meeting of the Advisory Committee to review the
23 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 to

1 *in subparagraph (A), transmit the request to the*
2 *Commissioner of Food and Drugs for review.*

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

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

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

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

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

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

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

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

1 “(A) issue a final order with respect to the
2 request—

3 “(i) in the case of a proposed order
4 under clause (i) or (ii) of paragraph (1)(A)
5 or subparagraph (A) or (B) of paragraph
6 (2), not later than 90 days after the end of
7 the public comment period under paragraph
8 (3)(B); or

9 “(ii) in the case of a proposed order
10 under paragraph (1)(A)(iii) or paragraph
11 (2)(C), not later than 210 days after the
12 date on which the sponsor submits the addi-
13 tional information requested pursuant to
14 such proposed order; or

15 “(B) if the Director fails to issue such final
16 order within such 90- or 210-day period, as ap-
17 plicable, transmit such proposed order to the
18 Commissioner of Food and Drugs for review.

19 “(5) FINAL ORDER BY COMMISSIONER.—With re-
20 spect to a proposed order transmitted to the Commis-
21 sioner of Food and Drugs under paragraph (4)(B),
22 the Commissioner shall issue a final order with re-
23 spect to such proposed order not later than 60 days
24 after the date of such transmission.

25 “(b) REVIEW OF PENDING REQUESTS.—

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

5 “(2) *INAPPLICABILITY OF CERTAIN PROVI-*
6 *SIONS.*—*Sections 586B and 586C shall not apply*
7 *with respect to any pending request.*

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

11 “(A) *within the timeframe applicable under*
12 *paragraph (4), complete the review of the request*
13 *and 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 pending 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 pending 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 the pending request; and

5 “(B) if the Director fails to issue such pro-
6 posed order within the timeframe applicable
7 under paragraph (4), transmit the pending re-
8 quest to the Commissioner of Food and Drugs for
9 review.

10 “(4) TIMEFRAME FOR ISSUANCE OF PROPOSED
11 ORDER BY CDER.—The Director of the Center for
12 Drug Evaluation and Research shall issue a proposed
13 order, as required by paragraph (3)(A)—

14 “(A) in the case of a pending request for
15 which the Food and Drug Administration has
16 issued a feedback letter before the date of enact-
17 ment of the Sunscreen Innovation Act, not later
18 than 45 days after such date of enactment; and

19 “(B) in the case of a pending request for
20 which the Food and Drug Administration has
21 not issued a feedback letter before the date of en-
22 actment of the Sunscreen Innovation Act, not
23 later than 90 days after such date of enactment.

24 “(5) PROPOSED ORDER BY COMMISSIONER.—
25 With respect to a pending request transmitted to the

1 *Commissioner of Food and Drugs under paragraph*
2 *(3)(B), the Commissioner shall, not later than 60*
3 *days after the date of such transmission, issue—*

4 *“(A) a proposed order described in para-*
5 *graph (3)(A)(i);*

6 *“(B) a proposed order described in para-*
7 *graph (3)(A)(ii); or*

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

10 *“(6) PUBLICATION IN FEDERAL REGISTER; PUB-*
11 *LIC COMMENT PERIOD.—A proposed order issued*
12 *under paragraph (3) or (5) with respect to a pending*
13 *request shall—*

14 *“(A) be published in the Federal Register;*

15 *and*

16 *“(B) solicit public comments for a period of*
17 *not more than 45 days.*

18 *“(7) ADVISORY COMMITTEE.—For a proposed*
19 *order issued under paragraph (3)(A)(iii) or (5)(C) re-*
20 *questing additional information, an Advisory Com-*
21 *mittee meeting shall be convened if the sponsor re-*
22 *quests, or the Director of the Center for Drug Evalua-*
23 *tion and Research or the Commissioner of Food and*
24 *Drugs decides, to convene such a meeting for the pur-*
25 *pose of reviewing the pending request.*

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

5 “(A) *issue a final order with respect to the*
6 *request—*

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

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

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

22 “(II) *if the Advisory Committee is*
23 *convened pursuant to paragraph (7),*
24 *not later than 270 days after date on*

1 *which the sponsor submits such addi-*
2 *tional information; or*

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

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

13 *“(c) ADVISORY COMMITTEE.—*

14 *“(1) LIMITATIONS.—The Food and Drug Admin-*
15 *istration—*

16 *“(A) shall not be required to convene the*
17 *Advisory Committee—*

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

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

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

4 “(2) MEMBERSHIP.—In appointing the members
5 of the Advisory Committee, the Secretary may select
6 to serve temporarily as voting members on the Advi-
7 sory Committee—

8 “(A) members of other Federal advisory
9 committees; or

10 “(B) consultants from outside of the Depart-
11 ment of Health and Human Services who have
12 substantive expertise regarding sunscreen active
13 ingredients.

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

17 “(e) EFFECT OF FINAL ORDER.—

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

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

1 “(B) is not GRASE or is misbranded.

2 “(2) ACTIVE INGREDIENTS DETERMINED TO BE
3 GRASE.—Upon issuance of a final order determining
4 that a nonprescription sunscreen active ingredient or
5 combination of nonprescription sunscreen active in-
6 gredients is GRASE and is not misbranded, the ac-
7 tive ingredient or combination of active ingredients
8 shall be permitted to be introduced or delivered into
9 interstate commerce, for use under the conditions sub-
10 ject to the final order, in accordance with all require-
11 ments applicable to drugs not subject to section
12 503(b)(1).

13 “(3) ACTIVE INGREDIENTS DETERMINED NOT TO
14 BE GRASE.—Upon issuance of a final order deter-
15 mining that the nonprescription sunscreen active in-
16 gredient or combination of nonprescription sunscreen
17 active ingredients is not GRASE or is misbranded,
18 the active ingredient or combination of active ingredi-
19 ents shall not be introduced or delivered into inter-
20 state commerce, for use under the conditions subject
21 to the final order, unless an application submitted
22 pursuant to section 505(b) with respect to such active
23 ingredient or combination of active ingredients is ap-
24 proved.

1 **“SEC. 586E. REPORTS.**

2 “(a) *GAO REPORT.*—Not later than 1 year after the
3 date of enactment of the Sunscreen Innovation Act, the
4 Comptroller General of the United States shall—

5 “(1) submit a report reviewing the overall
6 progress of the Secretary in carrying out this sub-
7 chapter to the Committee on Health, Education,
8 Labor, and Pensions of the Senate and the Committee
9 on Energy and Commerce of the House of Representa-
10 tives; and

11 “(2) include findings on—

12 “(A) the progress made in completing the
13 review of pending requests; and

14 “(B) the role of the Office of the Commis-
15 sioner of Food and Drugs in issuing determina-
16 tions with respect to pending requests, including
17 the number of requests transferred to the Office
18 of the Commissioner under section 586D.

19 “(b) *SECRETARY’S REPORT.*—

20 “(1) *IN GENERAL.*—Not later than 1 year after
21 the date of enactment of the Sunscreen Innovation
22 Act, and every 2 years thereafter, the Secretary shall
23 issue a report to the Committee on Health, Edu-
24 cation, Labor, and Pensions of the Senate and the
25 Committee on Energy and Commerce of the House of
26 Representatives describing actions taken under this

1 *section. Each report under this subsection shall be*
2 *posted on the Internet site of the Food and Drug Ad-*
3 *ministration.*

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

6 “(A) *a review of the progress made in*
7 *issuing GRASE determinations for pending re-*
8 *quests, including the number of pending re-*
9 *quests—*

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

14 “(ii) *resulting in a determination that*
15 *the nonprescription sunscreen active ingre-*
16 *dient or combination of nonprescription*
17 *sunscreen active ingredients is GRASE and*
18 *not misbranded;*

19 “(iii) *resulting in a determination that*
20 *the nonprescription sunscreen active ingre-*
21 *dient or combination of nonprescription*
22 *sunscreen active ingredients is not GRASE*
23 *and is misbranded and the reasons for such*
24 *determinations; and*

1 “(iv) for which a determination has
2 not been made, an explanation for the
3 delay, a description of the current status of
4 each such request, and the length of time
5 each such request has been pending, meas-
6 ured from the date of original request for an
7 eligibility determination by the sponsor;

8 “(B) a review of the progress made in
9 issuing in a timely manner GRASE determina-
10 tions for requests submitted under section
11 586A(a), including the number of such re-
12 quests—

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

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

20 “(iii) resulting in a determination that
21 the nonprescription sunscreen active ingre-
22 dient or combination of nonprescription
23 sunscreen active ingredients is not GRASE
24 and is misbranded and the reasons for such
25 determinations; and

1 “(iv) for which a determination has
2 not been made, an explanation for the
3 delay, a description of the current status of
4 each such request, and the length of time
5 each such request has been pending, meas-
6 ured from the date of original request for an
7 eligibility determination by the sponsor;

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 under this subchapter;

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

15 “(E) to the extent the Secretary determines
16 appropriate, recommendations for process im-
17 provements in the handling of pending and new
18 requests, including the advisory committee re-
19 view process; and

20 “(F) recommendations for expanding the
21 applicability of this subchapter to nonprescrip-
22 tion active ingredients that are not related to the
23 sunscreen category of over-the-counter drugs.

24 “(c) *METHOD.*—The Secretary shall publish the re-
25 ports required under subsection (b) in the manner the Sec-

1 *retary determines to be the most effective for efficiently dis-*
2 *seminating the report, including publication of the report*
3 *on the Internet website of the Food and Drug Administra-*
4 *tion.”.*

5 **SEC. 3. GUIDANCE.**

6 (a) *IN GENERAL.*—

7 (1) *ISSUANCE.*—*Not later than one year after the*
8 *date of enactment of this Act, the Secretary of Health*
9 *and Human Services, acting through the Commis-*
10 *sioner of Food and Drugs, shall issue guidance, in ac-*
11 *cordance with good guidance practices, on the imple-*
12 *mentation of, and compliance with, subchapter I of*
13 *chapter V of the Federal Food, Drug, and Cosmetic*
14 *Act, as added by section 2, including guidance on—*

15 (A) *the criteria for determining whether a*
16 *nonprescription sunscreen active ingredient or*
17 *combination of nonprescription sunscreen active*
18 *ingredients has been used to a material extent*
19 *and for a material time, as described in section*
20 *201(p)(2) of the Federal Food, Drug, and Cos-*
21 *metic Act (21 U.S.C. 321(p)(2));*

22 (B) *the format and content of a safety and*
23 *effectiveness data submission; and*

24 (C) *the safety and efficacy standards for de-*
25 *termining whether a nonprescription sunscreen*

1 *active ingredients or combination of non-*
2 *prescription sunscreen active ingredients is gen-*
3 *erally recognized as safe and effective, as defined*
4 *in section 586 of such subchapter I.*

5 (2) *INAPPLICABILITY OF PAPERWORK REDUCTION*
6 *ACT.—Chapter 35 of title 44, United States Code,*
7 *shall not apply to collections of information made for*
8 *purposes of guidance under this subsection.*

9 (b) *SUBMISSIONS PENDING ISSUANCE OF FINAL GUID-*
10 *ANCE.—Irrespective of whether final guidance under sub-*
11 *section (a) has been issued—*

12 (1) *persons may, beginning on the date of enact-*
13 *ment of this Act, make submissions under subchapter*
14 *I of chapter V of the Federal Food, Drug, and Cos-*
15 *metic Act, as added by section 2; and*

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

Union Calendar No. 418

113TH CONGRESS
2^D SESSION

H. R. 4250

[Report No. 113-558]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide an alternative process for review of safety and effectiveness of nonprescription sunscreen active ingredients and for other purposes.

JULY 24, 2014

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed