

113<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4250

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IN THE SENATE OF THE UNITED STATES

JULY 29, 2014

Received

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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.

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:

KAREN L. HAAS,

*Clerk.*