

**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.

