

PART I—NONPRESCRIPTION SUNSCREEN AND
OTHER ACTIVE INGREDIENTS

TERMINATION OF PART

*This part ceased to be effective at the end of
fiscal year 2022, see section 360fff-8 of this title.*

§ 360fff. Definitions

In this part—

(1) the term “Advisory Committee” means the Nonprescription Drug Advisory Committee of the Food and Drug Administration or any successor to such Committee;

(2) the term “final sunscreen order” means an order published by the Secretary in the Federal Register containing information stating that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients—

(A) is GRASE and is not misbranded if marketed in accordance with such order; or

(B) is not GRASE and is misbranded;

(3) the term “GRASE” means generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of a drug as described in section 321(p) of this title;

(4) the term “GRASE determination” means, with respect to a nonprescription active ingredient or a combination of nonprescription active ingredients, a determination of whether such ingredient or combination of ingredients is GRASE;

(5) the term “nonprescription” means not subject to section 353(b)(1) of this title;

(6) the term “pending request” means each request with respect to a nonprescription sunscreen active ingredient submitted under section 330.14 of title 21, Code of Federal Regulations (as in effect on November 26, 2014) for consideration for inclusion in the over-the-counter drug monograph system—

(A) that was determined to be eligible for such review by publication of a notice of eligibility in the Federal Register prior to November 26, 2014; and

(B) for which safety and effectiveness data have been submitted to the Secretary prior to November 26, 2014;

(7) the term “proposed sunscreen order” means an order containing a tentative determination published by the Secretary in the Federal Register containing information proposing that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients—

(A) is GRASE and is not misbranded if marketed in accordance with such order;

(B) is not GRASE and is misbranded; or

(C) is not GRASE and is misbranded because the data are insufficient to classify such ingredient or combination of ingredients as GRASE and not misbranded and additional information is necessary to allow the Secretary to determine otherwise;

(8) the term “sponsor” means the person that submitted—

(A) a request under section 360fff-1 of this title;

(B) a pending request; or

(C) any other application subject to this part;

(9) the term “sunscreen” means a drug containing one or more sunscreen active ingredients; and

(10) the term “sunscreen active ingredient” means an active ingredient that is intended for application to the skin of humans for purposes of absorbing, reflecting, or scattering ultraviolet radiation.

(June 25, 1938, ch. 675, §586, as added Pub. L. 113-195, §2(a), Nov. 26, 2014, 128 Stat. 2035.)

Statutory Notes and Related Subsidiaries

CONSTRUCTION

Pub. L. 113-195, §2(b), Nov. 26, 2014, 128 Stat. 2045, provided that: “Nothing in the amendment made by this section [enacting this section and sections 360fff-1 to [former] 360fff-5 of this title] shall be construed to—

“(1) limit the right of a sponsor (as defined in section 586(8) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360fff(8)], as added by subsection (a)) to request that the Secretary of Health and Human Services convene an advisory committee; or

“(2) limit the authority of the Secretary of Health and Human Services to meet with a sponsor (as defined in section 586(8) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)).”

§ 360fff-1. Submission of requests

Any person may submit a request to the Secretary for a determination of whether a nonprescription sunscreen active ingredient or a combination of nonprescription sunscreen active ingredients, for use under specified conditions, to be prescribed, recommended, or suggested in the labeling thereof (including dosage form, dosage strength, and route of administration) is GRASE and should be included in part 352 of title 21, Code of Federal Regulations (or any successor regulations) concerning nonprescription sunscreen.

(June 25, 1938, ch. 675, §586A, as added Pub. L. 113-195, §2(a), Nov. 26, 2014, 128 Stat. 2036.)

§ 360fff-2. Eligibility determinations; data submission; filing

(a) Eligibility determinations

(1) In general

Not later than 60 calendar days after the date of receipt of a request under section 360fff-1 of this title, the Secretary shall—

(A) determine, in accordance with paragraph (2), whether the request is eligible for further review under subsection (b) and section 360fff-3 of this title;

(B) notify the sponsor of the determination of the Secretary; and

(C) make such determination publicly available in accordance with paragraph (3) and subsection (b)(1).

(2) Criteria for eligibility

(A) In general

To be eligible for review under subsection (b) and section 360fff-3 of this title, a request

shall be for a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients, for use under specified conditions, to be prescribed, recommended, or suggested in the labeling thereof, that—

(i) is not included in part 352 of title 21, Code of Federal Regulations (or any successor regulations) concerning nonprescription sunscreen; and

(ii) has been used to a material extent and for a material time under such conditions, as described in section 321(p)(2) of this title.

(B) Establishment of time and extent

A sponsor shall include in a request under section 360fff-1 of this title the information required under section 330.14 of title 21, Code of Federal Regulations (or any successor regulations) to meet the standard described in subparagraph (A)(ii).

(3) Public availability

(A) Redactions for confidential information

If a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is determined under paragraph (1)(A) to be eligible for further review, the Secretary shall make the request publicly available, with redactions for information that is treated as confidential under section 552(b) of title 5, section 1905 of title 18, or section 331(j) of this title.

(B) Identification of confidential information by sponsor

At the time that a request is made under section 360fff-1 of this title, the sponsor of such request shall identify any information that such sponsor considers to be confidential information described in subparagraph (A).

(C) Confidentiality during eligibility review

The information contained in a request under section 360fff-1 of this title shall remain confidential during the Secretary's consideration under this section of whether the request is eligible for further review consistent with section 330.14 of title 21, Code of Federal Regulations (or any successor regulations).

(b) Data submission and filing of requests

(1) In general

In the case of a request under section 360fff-1 of this title that is determined to be eligible under subsection (a) for further review under this section and section 360fff-3 of this title, the Secretary shall, in notifying the public under subsection (a)(1)(C) of such eligibility determination, post the eligibility determination on the Internet website of the Food and Drug Administration, invite the sponsor of such request and any other interested party to submit comments, and provide a period of not less than 45 calendar days for comments in support of or otherwise relating to a GRASE determination, including published and unpublished data and other information related to the safety and efficacy of such request.

(2) Filing determination

Not later than 60 calendar days after the submission of data and other information described in paragraph (1) by the sponsor, the Secretary shall determine whether the data and other information submitted by the sponsor under this section are sufficiently complete, including being formatted in a manner that enables the Secretary to determine the completeness of such data and information, to enable the Secretary to conduct a substantive review under section 360fff-3 of this title with respect to such request. Not later than 60 calendar days after the submission of data and other information described in paragraph (1) by the sponsor, if the Secretary determines—

(A) that such data and other information are sufficiently complete, the Secretary shall—

(i) issue a written notification to the sponsor of the determination to file such request, and make such notification publicly available; and

(ii) file such request made under section 360fff-1 of this title; or

(B) that such data and other information are not sufficiently complete, the Secretary shall issue a written notification to the sponsor of the determination to refuse to file the request, which shall include the reasons for the refusal, including why such data and other information are not sufficiently complete, and make such notification publicly available.

(3) Refusal to file a request

(A) Request for meetings; submission of additional data or other information

If the Secretary refuses to file a request made under section 360fff-1 of this title, the sponsor may—

(i) within 30 calendar days of receipt of written notification of such refusal, request, in writing, a meeting with the Secretary regarding the filing determination; and

(ii) submit additional data or other information.

(B) Meetings

(i) In general

If a sponsor seeks a meeting under subparagraph (A)(i), the Secretary shall convene the meeting within 30 calendar days of the request for such meeting.

(ii) Actions after meeting

Following any meeting held under clause (i)—

(I) the Secretary may file the request within 60 calendar days;

(II) the sponsor may submit additional data or other information; or

(III) if the sponsor elects, within 120 calendar days, to have the Secretary file the request (with or without amendments to correct any purported deficiencies to the request)—

(aa) the Secretary shall file the request over protest, not later than 30 calendar days after the sponsor makes such election;

- (bb) at the time of filing, the Secretary shall provide written notification of such filing to the sponsor; and
- (cc) the Secretary shall make such notification publicly available.

(iii) Requests filed over protest

The Secretary shall not require the sponsor to resubmit a copy of the request for purposes of filing a request filed over protest, as described in clause (ii)(III).

(C) Submissions of additional data or other information

Within 60 calendar days of any submission of additional data or other information under subparagraph (A)(ii) or (B)(ii)(II), the Secretary shall reconsider the previous determination made under paragraph (2) with respect to the applicable request and make a new determination in accordance with paragraph (2).

(4) Public availability

(A) Redactions for confidential information

After the period of confidentiality described in subsection (a)(3)(C), the Secretary shall make data and other information submitted in connection with a request under section 360fff-1 of this title publicly available, with redactions for information that is treated as confidential under section 552(b) of title 5, section 1905 of title 18, or section 331(j) of this title.

(B) Identification of confidential information by sponsor

A person submitting information under this section shall identify at the time of such submission the portions of such information that the person considers to be confidential information described in subparagraph (A).

(June 25, 1938, ch. 675, §586B, as added Pub. L. 113-195, §2(a), Nov. 26, 2014, 128 Stat. 2036.)

§ 360fff-3. GRASE determination

(a) Review of new request

(1) Proposed sunscreen order

In the case of a request under section 360fff-1 of this title, not later than 300 calendar days after the date on which such request is filed under subsection (b)(2)(A) or (b)(3)(B)(ii)(III) of section 360fff-2 of this title, the Secretary—

- (A) may convene a meeting of the Advisory Committee to review such request; and
- (B) shall complete the review of such request and issue a proposed sunscreen order with respect to such request.

(2) Proposed sunscreen order by Commissioner

If the Secretary does not issue a proposed sunscreen order under paragraph (1)(B) within such 300-day period, the sponsor of such request may notify the Office of the Commissioner of such request and request review by the Office of the Commissioner. If such sponsor so notifies the Office of the Commissioner, the Commissioner shall, not later than 60 calendar days after the date of notification under this paragraph, issue a proposed sunscreen order with respect to such request.

(3) Public comment period

A proposed sunscreen order issued under paragraph (1)(B) or (2) with respect to a request shall provide for a period of 45 calendar days for public comment.

(4) Meeting

A sponsor may request, in writing, a meeting with respect to a proposed sunscreen order issued under this subsection and described in subparagraph (B) or (C) of section 360fff(7) of this title, not later than 30 calendar days after the Secretary issues such order. The Secretary shall convene a meeting with such sponsor not later than 45 calendar days after such request for a meeting.

(5) Final sunscreen order

With respect to a proposed sunscreen order under paragraph (1)(B) or (2)—

(A) the Secretary shall issue a final sunscreen order—

(i) in the case of a proposed sunscreen order described in subparagraph (A) or (B) of section 360fff(7) of this title, not later than 90 calendar days after the end of the public comment period under paragraph (3); or

(ii) in the case of a proposed sunscreen order described in subparagraph (C) of section 360fff(7) of this title, not later than 210 calendar days after the date on which the sponsor submits the additional information requested pursuant to such proposed sunscreen order; or

(B) if the Secretary does not issue such final sunscreen order within such 90- or 210-calendar-day period, as applicable, the sponsor of such request may notify the Office of the Commissioner of such request and request review by the Office of the Commissioner.

(6) Final sunscreen order by Commissioner

The Commissioner shall issue a final sunscreen order with respect to a proposed sunscreen order subject to paragraph (5)(B) not later than 60 calendar days after the date of notification under such paragraph.

(b) Review of pending requests

(1) In general

The review of a pending request shall be carried out by the Secretary in accordance with this subsection.

(2) Inapplicability of sections 360fff-1 and 360fff-2 of this title

Sections 360fff-1 and 360fff-2 of this title shall not apply with respect to any pending request.

(3) Feedback letters as proposed sunscreen order

Notwithstanding the requirements of section 360fff(7) of this title, a letter issued pursuant to section 330.14(g) of title 21, Code of Federal Regulations before November 26, 2014, with respect to a pending request, shall be deemed to be a proposed sunscreen order and displayed on the Internet website of the Food and Drug Administration. Notification of the avail-