(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-

ability of such letter shall be published in the Federal Register not later than 45 calendar days after November 26, 2014.

**(4) Proposed sunscreen order**

In the case of a pending request for which the Secretary has not issued a letter pursuant to section 330.14(g) of title 21, Code of Federal Regulations before November 26, 2014, the Secretary shall complete review of such request and, not later than 90 calendar days after November 26, 2014, issue a proposed sunscreen order with respect to such request.

**(5) Proposed sunscreen order by Commissioner**

If the Secretary does not issue a proposed sunscreen order under paragraph (4), or the Secretary does not publish a notification of the availability of a letter under paragraph (3), 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. The Commissioner shall, not later than 60 calendar days after the date of notification under this paragraph, issue a proposed order with respect to such request.

**(6) Public comment period**

A proposed sunscreen order issued under paragraph (4) or (5), or a notification of the availability of a letter under paragraph (3), with respect to a pending request shall provide for a period of 45 calendar days for public comment.

**(7) Meeting**

**(A) In general**

A sponsor may request, in writing, a meeting with respect to a proposed sunscreen order issued under this subsection, including a letter deemed to be a proposed sunscreen order under paragraph (3), not later than 30 calendar days after the Secretary issues such order or the date upon which such feedback letter is deemed to be a proposed sunscreen order, as applicable. The Secretary shall convene a meeting with such sponsor not later than 45 calendar days after the date of such request for a meeting.

**(B) Confidential meetings**

A sponsor may request one or more confidential meetings with respect to a proposed sunscreen order, including a letter deemed to be a proposed sunscreen order under paragraph (3), to discuss matters relating to data requirements to support a general recognition of safety and effectiveness involving confidential information and public information related to such proposed sunscreen order, as appropriate. The Secretary shall convene a confidential meeting with such sponsor in a reasonable time period. If a sponsor requests more than one confidential meeting for the same proposed sunscreen order, the Secretary may refuse to grant an additional confidential meeting request if the Secretary determines that such additional confidential meeting is not reasonably necessary for the sponsor to advance its proposed sunscreen order, or if the request for a confidential meeting fails to include sufficient information upon which to base a substantive discussion. The Secretary shall publish a post-meeting summary of each confidential meeting under this subparagraph that does not disclose confidential commercial information or trade secrets. This subparagraph does not authorize the disclosure of confidential commercial information or trade secrets subject to 552(b)(4)[1] of title 5 or section 1905 of title 18.

**(8) Advisory Committee**

In the case of a proposed sunscreen order under paragraph (3), (4), or (5), an Advisory Committee meeting may be convened for the purpose of reviewing and providing recommendations regarding the pending request.

**(9) Final sunscreen order**

In the case of a proposed sunscreen order under paragraph (3), (4), or (5)—

(A) the Secretary shall issue a final sunscreen order with respect to the request—

(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 (6); or

(ii) in the case of a proposed sunscreen order described in subparagraph (C) of section 360fff(7) of this title—

(I) if the Advisory Committee is not convened under paragraph (8), not later than 210 calendar days after the date on which the sponsor submits the additional information requested pursuant to such proposed sunscreen order, which shall include a rationale for not convening such Advisory Committee; or

(II) if the Advisory Committee is convened under paragraph (8), not later than 270 calendar days after the date on which the sponsor submits such additional information; or

(B) if the Secretary does not issue such final sunscreen order within such 90-, 210-, or 270-calendar-day period, as applicable, the sponsor of such request may notify the Office of the Commissioner about such request and request review by the Office of the Commissioner.

**(10) Final sunscreen order by Commissioner**

The Commissioner shall issue a final sunscreen order with respect to a proposed sunscreen order subject to paragraph (9)(B) not later than 60 calendar days after the date of notification under such paragraph.

**(c) Advisory Committee**

The Secretary shall not be required to—

(1) convene the Advisory Committee—

(A) more than once with respect to any request under section 360fff–1 of this title or any pending request; or

(B) more than twice in any calendar year with respect to the review under this section; or

(2) submit more than a total of 3 requests under section 360fff–1 of this title or pending

[1] So in original. Probably should be preceded by ''section''.

requests to the Advisory Committee per meeting.

**(d) No delegation**

Any responsibility vested in the Commissioner by subsection (a)(2), (a)(6), (b)(5), or (b)(10) shall not be delegated.

**(e) Effect of final sunscreen order**

**(1) In general**

**(A) Sunscreen active ingredients determined to be GRASE**

Upon issuance of a final sunscreen order determining that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded, a sunscreen containing such ingredient or combination of ingredients shall be permitted to be introduced or delivered into interstate commerce for use under the conditions described in such final sunscreen order, in accordance with all requirements applicable to drugs not subject to section 353(b)(1) of this title, for so long as such final sunscreen order remains in effect.

**(B) Sunscreen active ingredients determined not to be GRASE**

Upon issuance of a final sunscreen order determining that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is not GRASE and is misbranded, a sunscreen containing such ingredient or combination of ingredients shall not be introduced or delivered into interstate commerce, for use under the conditions described in such final sunscreen order, unless an application is approved pursuant to section 355 of this title with respect to a sunscreen containing such ingredient or combination of ingredients, or unless conditions are later established under which such ingredient or combination of ingredients is later determined to be GRASE and not misbranded under the over-the-counter drug monograph system.

**(2) Amendments to final sunscreen orders**

**(A) Amendments at initiative of Secretary**

In the event that information relevant to a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients becomes available to the Secretary after issuance of a final sunscreen order, the Secretary may amend such final sunscreen order by issuing a new proposed sunscreen order under subsection (a)(1) and following the procedures set forth in this section.

**(B) Petition to amend final order**

Any interested person may petition the Secretary to amend a final sunscreen order under section 10.30, title 21 Code of Federal Regulations (or any successor regulations). If the Secretary grants any petition under such section, the Secretary shall initiate the process for amending a final sunscreen order by issuing a new proposed sunscreen order under subsection (a)(1) and following the procedures set forth in this section.

**(C) Applicability of final orders**

Once the Secretary issues a new proposed sunscreen order to amend a final sunscreen order under subparagraph (A) or (B), such final sunscreen order shall remain in effect and paragraph (3) shall not apply to such final sunscreen order until the Secretary has issued a new final sunscreen order or has determined not to amend the final sunscreen order.

**(3) Relationship to orders under section 355h of this title**

A final sunscreen order shall be deemed to be a final order under section 355h of this title.

**(f) Exclusivity**

**(1) In general**

A final sunscreen order shall have the effect of authorizing solely the order requestor (or the licensees, assignees, or successors in interest of such requestor with respect to the subject of such request and listed under paragraph (5)) for a period of 18 months, to market a sunscreen ingredient under this section incorporating changes described in paragraph (2) subject to the limitations under paragraph (4), beginning on the date the requestor (or any licensees, assignees, or successors in interest of such requestor with respect to the subject of such request and listed under paragraph (5)) may lawfully market such sunscreen ingredient pursuant to the order.

**(2) Changes described**

A change described in this paragraph is a change subject to an order specified in paragraph (1) that permits a sunscreen to contain an active sunscreen ingredient not previously incorporated in a marketed sunscreen listed in paragraph (3).

**(3) Marketed sunscreen**

The marketed sunscreen ingredients described in this paragraph are sunscreen ingredients—

(A) marketed in accordance with a final monograph for sunscreen drug products set forth at part 352 of title 21, Code of Federal Regulations (as published at 64 Fed. Reg. 27687); or

(B) marketed in accordance with a final order issued under this section.

**(4) Limitations on exclusivity**

Only one 18-month period may be granted per ingredient under paragraph (1).

**(5) Listing of licensees, assignees, or successors in interest**

Requestors shall submit to the Secretary at the time when a drug subject to such request is introduced or delivered for introduction into interstate commerce, a list of licensees, assignees, or successors in interest under paragraph (1).

(June 25, 1938, ch. 675, § 586C, as added Pub. L. 113–195, § 2(a), Nov. 26, 2014, 128 Stat. 2039; amended Pub. L. 116–136, div. A, title III, § 3854(b)(1)–(3), Mar. 27, 2020, 134 Stat. 455, 456.)

**Editorial Notes**

AMENDMENTS

2020—Subsec. (b)(7). Pub. L. 116–136, § 3854(b)(2), designated existing provisions as subpar. (A), inserted heading, and added subpar. (B).

Subsec. (e)(3). Pub. L. 116–136, § 3854(b)(1), amended par. (3) generally. Prior to amendment, par. (3) related to inclusion of ingredients that are subjects of final orders in the sunscreen monograph.

Subsec. (f). Pub. L. 116–136, § 3854(b)(3), added subsec. (f).

**Statutory Notes and Related Subsidiaries**

REVIEW OF NONPRESCRIPTION SUNSCREEN ACTIVE INGREDIENTS

Pub. L. 116–136, div. A, title III, § 3854(a), Mar. 27, 2020, 134 Stat. 454, provided that:

''(1) APPLICABILITY OF SECTION 505G FOR PENDING SUBMISSIONS.—

''(A) IN GENERAL.—A sponsor of a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that, as of the date of enactment of this Act [Mar. 27, 2020], is subject to a proposed sunscreen order under section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3) may elect, by means of giving written notification to the Secretary of Health and Human Services within 180 calendar days of the enactment of this Act, to transition into the review of such ingredient or combination of ingredients pursuant to the process set out in section 505G of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355h], as added by section 3851 of this subtitle.

''(B) ELECTION EXERCISED.—Upon receipt by the Secretary of Health and Human Services of a timely notification under subparagraph (A)—

''(i) the proposed sunscreen order involved is deemed to be a request for an order under subsection (b) of section 505G of the Federal Food, Drug, and Cosmetic Act, as added by section 3851 of this subtitle; and

''(ii) such order is deemed to have been accepted for filing under subsection (b)(6)(A)(i) of such section 505G.

''(C) ELECTION NOT EXERCISED.—If a notification under subparagraph (A) is not received by the Secretary of Health and Human Services within 180 calendar days of the date of enactment of this Act, the review of the proposed sunscreen order described in subparagraph (A)—

''(i) shall continue under section 586C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff–3); and

''(ii) shall not be eligible for review under section 505G, added by section 3851 of this subtitle.

''(2) DEFINITIONS.—In this subsection, the terms 'sponsor', 'nonprescription', 'sunscreen active ingredient', and 'proposed sunscreen order' have the meanings given to those terms in section 586 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff).''

### § 360fff–4. Guidance; other provisions

#### (a) Guidance

##### (1) In general

###### (A) Draft guidance

Not later than 1 year after November 26, 2014, the Secretary shall issue draft guidance on the implementation of, and compliance with, the requirements with respect to sunscreen under this part, including guidance on—

(i) the format and content of information submitted by a sponsor in support of a request under section 360fff–1 of this title or a pending request;

(ii) the data required to meet the safety and efficacy standard for determining whether a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded;

(iii) the process by which a request under section 360fff–1 of this title or a pending request is withdrawn; and

(iv) the process by which the Secretary will carry out section 360fff–3(c) of this title, including with respect to how the Secretary will address the total number of requests received under section 360fff–1 of this title and pending requests.

###### (B) Final guidance

The Secretary shall finalize the guidance described in subparagraph (A) not later than 2 years after November 26, 2014.

###### (C) Inapplicability of Paperwork Reduction Act

Chapter 35 of title 44 shall not apply to collections of information made for purposes of guidance under this subsection.

##### (2) Submissions pending issuance of final guidance

Irrespective of whether final guidance under paragraph (1) has been issued—

(A) persons may, beginning on November 26, 2014, make submissions under this part; and

(B) the Secretary shall review and act upon such submissions in accordance with this part.

#### (b) Rules of construction

##### (1) Currently marketed sunscreens

Nothing in this part shall be construed to affect the marketing of sunscreens that are marketed in interstate commerce on or before November 26, 2014, except as otherwise provided in this part.

##### (2) Ensuring safety and effectiveness

Nothing in this part shall be construed to alter the authority of the Secretary with respect to prohibiting the marketing of a sunscreen that is not safe and effective or is misbranded, or with respect to imposing restrictions on the marketing of a sunscreen to ensure safety and effectiveness, except as otherwise provided in this part, including section 360fff–3(e) of this title.

##### (3) Other drugs

Except as otherwise provided in section 360fff–6 of this title, nothing in this part shall be construed to affect the authority of the Secretary under this chapter or the Public Health Service Act (42 U.S.C. 201 et seq.) with respect to a drug other than a nonprescription sunscreen.

##### (4) Effect on drugs otherwise approved

Nothing in this part shall affect the marketing of a drug approved under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262].

#### (c) Timelines

The timelines for the processes and procedures under paragraphs (1), (2), (5), and (6) of section