(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 availability 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 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.

(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 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 de-

scribed 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) Inclusion of ingredients that are subjects of final orders in the sunscreen monograph

(A) Amending regulations

(i) Requirement

At any time that the Secretary proposes to amend part 352 of title 21, Code of Federal Regulations (or any successor regulations) concerning nonprescription sunscreen, including pursuant to section 360fff–5 of this title, except as provided in clause (iv), the Secretary shall include in such part 352 (or any successor regulations) any nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients that is the subject of an effective final sunscreen order of the type described in section 360fff(2)(A) of this title and issued since the time that the Secretary last amended such regulations. Such regulation shall set forth conditions of use under which each such ingredient or combination of ingredients is GRASE and not misbranded. If these conditions differ from, or are in addition to, those previously set forth in the applicable final sunscreen order, the Secretary shall provide notice and opportunity for comment on such conditions in the rulemaking, and the applicable final sunscreen order shall continue in effect until the effective date of a final regulation, as set forth in clause (iii).

(ii) Inclusion of orders

In proposing to amend the regulations as described in clause (i), the Secretary shall include in the proposed regulations a list of final sunscreen orders that shall cease to be effective on the effective date of a resulting final regulation. Such list shall include all final sunscreen orders of the type described in section 360fff(2)(A) of this title that are in effect on the date that such regulations are proposed, with the exception that such list shall not include any final sunscreen orders that, on the date that the regulations are proposed, the Secretary is in the process of amending under paragraph (2).

(iii) Orders no longer effective

Any final sunscreen order included by the Secretary in a list described in clause (ii) and in a list included in resulting final regulations shall cease to be effective on the date that such final regulations including such order in such list become effective.

(iv) Ingredients not GRASE

If, notwithstanding a final sunscreen order stating that a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded if marketed in accordance with such order, while amending the regulations as described in clause (i), the Secretary concludes that such ingredient or combination of ingredients is no longer GRASE for use in nonprescription sunscreen, the Secretary shall, at the discretion of the Secretary, either initiate the process for amending the final sunscreen order set forth in paragraph (2) of this subsection or include in a proposed regulation an explanation and information supporting the determination of the Secretary that such ingredient or combination of ingredients is no longer GRASE for use in nonprescription sunscreen.

(B) Procedure for updating regulations

After the Secretary amends and finalizes the regulations under part 352 of title 21, Code of Federal Regulations under section 360fff–5 of this title and such regulations become effective, the Secretary may use direct final rulemaking to include in such regulations any nonprescription sunscreen active ingredients that are the subject of effective final sunscreen orders.

(June 25, 1938, ch. 675, § 586C, as added Pub. L. 113–195, § 2(a), Nov. 26, 2014, 128 Stat. 2039.)

§ 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 360fff–3(a) of this title shall not apply to any requests submitted to the Secretary under section 360fff–1 of this title after the date that is 6 years after November 26, 2014.

(June 25, 1938, ch. 675, § 586D, as added Pub. L. 113–195, § 2(a), Nov. 26, 2014, 128 Stat. 2044.)

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (b)(3), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§ 201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

§ 360fff–5. Sunscreen monograph

(a) In general

Not later than 5 years after November 26, 2014, the Secretary shall amend and finalize regulations under part 352 of title 21, Code of Federal Regulations concerning nonprescription sunscreen that are effective not later than 5 years after November 26, 2014. The Secretary shall publish such regulations not less than 30 calendar days before the effective date of such regulations.

(b) Reports

If the regulations promulgated under subsection (a) do not include provisions related to the effectiveness of various sun protection factor levels, and do not address all dosage forms known to the Secretary to be used in sunscreens marketed in the United States without a new drug approval under section 355 of this title, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the rationale for such provisions not being in-