

(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 re-

spect 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.)

Editorial Notes

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. Repealed. Pub. L. 116-136, div. A, title III, § 3854(b)(5), Mar. 27, 2020, 134 Stat. 456

Section, June 25, 1938, ch. 675, §586E, as added Pub. L. 113-195, §2(a), Nov. 26, 2014, 128 Stat. 2045, related to sunscreen monograph.

§ 360fff-6. Non-sunscreen time and extent applications

(a) Pending time and extent applications

(1) In general

(A) Request for framework for review

If, prior to November 26, 2014, an application was submitted pursuant to section 330.14 of title 21, Code of Federal Regulations for a GRASE determination for a drug other than a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients and such drug was found to be eligible to be considered for inclusion in the over-the-counter drug monograph system pursuant to section 330.14 of title 21, Code of Federal Regulations, the sponsor of such application may request that the Secretary provide a framework under paragraph (2) for the review of such application.

(B) Request requirements

A request for a framework for review of an application made under subparagraph (A)

shall be made within 180 calendar days of November 26, 2014, and shall include the preference of such sponsor as to whether such application is reviewed by the Secretary in accordance with—

(i) the processes and procedures set forth for pending requests under section 360fff-3(b) of this title, except that specific timelines shall be determined in accordance with other applicable requirements under this section;

(ii) the processes and procedures set forth under part 330 of title 21, Code of Federal Regulations (or any successor regulations);

(iii) an initial filing determination under the processes and procedures described in section 360fff-2(b) of this title and the processes and procedures set forth for pending requests under section 360fff-3(b) of this title, except that specific timelines shall be determined in accordance with other applicable requirements under this section; or

(iv) an initial filing determination under the processes and procedures described in section 360fff-2(b) of this title and the processes and procedures set forth under part 330 of title 21, Code of Federal Regulations (or any successor regulations).

(C) No request

If a sponsor described in subparagraph (A) does not make such request within 180 calendar days of November 26, 2014, such application shall be reviewed by the Secretary in accordance with the timelines of the applicable regulations when such regulations are finalized under subsection (b).

(2) Framework

Not later than 1 year after November 26, 2014, the Secretary shall provide, in writing, a framework to each sponsor that submitted a request under paragraph (1). Such framework shall set forth the various timelines, in calendar days, with respect to the processes and procedures for review under clauses (i), (ii), (iii), and (iv) of paragraph (1)(B) and—

(A) such timelines shall account for the considerations under paragraph (5); and

(B) the timelines for the various processes and procedures shall not be shorter than the timelines set forth for pending requests under sections 360fff-2(b) and 360fff-3(b) of this title, as applicable.

(3) Governing processes and procedures for review

(A) Election

Not later than 60 calendar days after the Secretary provides a framework to a sponsor under paragraph (2), such sponsor may provide an election to the Secretary regarding the processes and procedures for review under clause (i), (ii), (iii), or (iv) of paragraph (1)(B). If such sponsor makes such election, the Secretary shall review the application that is the subject of such election pursuant to the processes and procedures elected by such sponsor and the applicable timelines in calendar days set forth under