

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 Repealed.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 such framework, which the Secretary shall confirm in writing to the sponsor not later than the date upon which the Secretary provides a report under paragraph (4). If such sponsor does not make such election, 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).

###### **(B) Different processes and procedures**

At any time during review of an application, the Secretary may review such application under different processes and procedures under clause (i), (ii), (iii), or (iv) of paragraph (1)(B) than the processes and procedures elected by the sponsor in accordance with subparagraph (A), so long as the Secretary proposes, in writing, the change and the sponsor agrees, in writing, to such change.

##### **(C) Inclusion of ingredients in monographs**

If the sponsor elects to use the processes and procedures for review in accordance

with clause (i) or (iii) of paragraph (1)(B), the Secretary may incorporate any resulting final order into a regulation addressing the conditions under which other drugs in the same therapeutic category are GRASE and not misbranded, including through direct final rulemaking, and the final order so incorporated shall cease to be effective on the effective date of the final regulation that addresses such drug.

#### (4) Letter regarding pending applications

Not later than 18 months after November 26, 2014, the Secretary shall 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, in writing, regarding all pending applications subject to paragraph (1). In such letter, the Secretary shall provide a report on the review of such applications, including the timelines, in calendar days, for the review and GRASE determination for each application. Such timelines shall account for the considerations under paragraph (5).

#### (5) Timelines

The timelines in calendar days established by the Secretary pursuant to this subsection—

(A) may vary based on the content, complexity, and format of the application submitted to the Secretary; and

(B) shall—

(i) reflect the public health priorities of the Food and Drug Administration, including the potential public health benefits posed by the inclusion of additional drugs in the over-the-counter drug monograph system;

(ii) take into consideration the resources available to the Secretary for carrying out such priorities and the processes and procedures described in paragraphs (1)(B) and (2); and

(iii) be reasonable, taking into consideration the requirements described in clauses (i) and (ii).

#### (b) New time and extent applications

##### (1) In general

Not later than 18 months after November 26, 2014, the Secretary shall issue proposed regulations establishing timelines for the review of applications for GRASE determinations for drugs other than nonprescription sunscreen active ingredients or combinations of nonprescription sunscreen active ingredients that are submitted to the Secretary after November 26, 2014, under section 330.14 of title 21, Code of Federal Regulations (or any successor regulations), and that are 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 (or any successor regulations), or that are subject to this subsection pursuant to paragraph (1) or (3) of subsection (a), as applicable, providing—

(A) timely and efficient completion of evaluations of applications under section 330.14 of title 21, Code of Federal Regulations (or any successor regulations) for drugs other than sunscreens; and

(B) timely and efficient completion of the review of the safety and effectiveness submissions pursuant to such applications, including establishing—

(i) reasonable timelines, in calendar days, for the applicable proposed and final regulations for applications of various content, complexity, and format, and timelines for internal procedures related to such processes; and

(ii) measurable metrics for tracking the extent to which the timelines set forth in the regulations are met.

#### (2) Timelines

The timelines in calendar days established in the regulations under paragraph (1)—

(A) may vary based on the content, complexity, and format of the application submitted to the Secretary; and

(B) shall—

(i) reflect the public health priorities of the Food and Drug Administration, including the potential public health benefits posed by the inclusion of additional drugs in the over-the-counter drug monograph system;

(ii) take into consideration the resources available to the Secretary for carrying out such priorities and the processes and procedures described in paragraph (1); and

(iii) be reasonable, taking into consideration the requirements described in clauses (i) and (ii).

#### (3) Procedure

In promulgating regulations under this subsection, the Secretary shall issue a notice of proposed rulemaking that includes a copy of the proposed regulation, provide a period of not less than 60 calendar days for comments on the proposed regulation, and publish the final regulation not less than 30 calendar days before the effective date of the regulation.

#### (4) Restrictions

Notwithstanding any other provision of law, the Secretary shall promulgate regulations implementing this section only as described in paragraphs (1), (2), and (3).

#### (5) Final regulations

The Secretary shall finalize the regulations under this section not later than 27 months after November 26, 2014.

(June 25, 1938, ch. 675, §586F, as added Pub. L. 113-195, §3, Nov. 26, 2014, 128 Stat. 2046.)

#### Statutory Notes and Related Subsidiaries

##### TREATMENT OF NON-SUNSCREEN TIME AND EXTENT APPLICATIONS

Pub. L. 116-136, div. A, title III, §3854(d), Mar. 27, 2020, 134 Stat. 457, provided that:

“(1) IN GENERAL.—Any application described in section 586F of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360fff-6) that was submitted to the Secretary pursuant to section 330.14 of title 21, Code of Federal Regulations, as such provisions were in effect immediately prior to the date of enactment date of this Act [Mar. 27, 2020], shall be extinguished as of such date of enactment, subject to paragraph (2).

“(2) ORDER REQUEST.—Nothing in paragraph (1) precludes the submission of an order request under section

505G(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355h(b)], as added by section 3851 of this subtitle, with respect to a drug that was the subject of an application extinguished under paragraph (1).”

### § 360fff-7. Report

#### (a) In general

##### (1) In general

Not later than 18 months after November 26, 2014, and on the dates that are 2 and 4 years thereafter, the Secretary shall issue 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 describing actions taken under this part.

##### (2) Contents

The reports under this subsection shall include—

(A) a review of the progress made in issuing GRASE determinations for pending requests, including the number of pending requests—

(i) reviewed and the decision times for each request, measured from the date of the original request for an eligibility determination submitted by the sponsor;

(ii) resulting in a determination that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded;

(iii) resulting in a determination that the nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is not GRASE and is misbranded and the reasons for such determinations; and

(iv) for which a determination has not been made, and an explanation for the delay, a description of the current status of each such request, and the length of time each such request has been pending, measured from the date of original request for an eligibility determination by the sponsor;

(B) a review of the progress made in issuing GRASE determinations for requests not included in the reporting under subparagraph (A), including the number of such requests—

(i) reviewed and the decision times for each request;

(ii) resulting in a determination that the nonprescription sunscreen active ingredient, combination of nonprescription sunscreen active ingredients, or other ingredient is GRASE and is not misbranded;

(iii) resulting in a determination that the nonprescription sunscreen active ingredient, combination of nonprescription sunscreen active ingredients, or other ingredient is not GRASE and is misbranded and the reasons for such determinations; and

(iv) for which a determination has not been made, and an explanation for the delay, a description of the current status of each such request, and the length of

time each such request has been pending, measured from the date of original request for an eligibility determination by the sponsor;

(C) an annual accounting (including information from years prior to November 26, 2014, where such information is available) of the total number of requests submitted, pending, or completed under this part, including whether such requests were the subject of an advisory committee convened by the Secretary;

(D) a description of the staffing and resources relating to the costs associated with the review and decisionmaking pertaining to requests under this part;

(E) a review of the progress made in meeting the deadlines with respect to processing requests under this part; and

(F) to the extent the Secretary determines appropriate, recommendations for process improvements in the handling of requests under this part, including the advisory committee review process.

#### (b) Method

The Secretary shall publish the reports under subsection (a) in the manner the Secretary determines to be the most effective for efficiently disseminating the report, including publication of the report on the Internet website of the Food and Drug Administration.

(June 25, 1938, ch. 675, §586G, as added Pub. L. 113–195, §4(c), Nov. 26, 2014, 128 Stat. 2050.)

### § 360fff-8. Sunset

This part shall cease to be effective at the end of fiscal year 2022.

(June 25, 1938, ch. 675, §586H, as added Pub. L. 116–136, div. A, title III, §3854(b)(4), Mar. 27, 2020, 134 Stat. 456.)

## SUBCHAPTER VI—COSMETICS

### § 361. Adulterated cosmetics

A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual, except that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: “Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.”, and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term “hair dye” shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may