

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—