

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

have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.

(f) If it has been manufactured or processed under conditions that do not meet the good manufacturing practice requirements of section 364b of this title.

(g) If it is a cosmetic product, and the cosmetic product, including each ingredient in the cosmetic product, does not have adequate substantiation for¹ safety, as defined in section 364d(c) of this title.

(June 25, 1938, ch. 675, § 601, 52 Stat. 1054; Pub. L. 86-618, title I, § 102(c)(1), July 12, 1960, 74 Stat. 398; Pub. L. 102-571, title I, § 107(11), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103-80, § 3(x), Aug. 13, 1993, 107 Stat. 778; Pub. L. 117-328, div. FF, title III, § 3503(a)(2), Dec. 29, 2022, 136 Stat. 5858.)

Editorial Notes

AMENDMENTS

2022—Subsecs. (f), (g). Pub. L. 117-328 added subsecs. (f) and (g).

1993—Subsec. (a). Pub. L. 103-80 substituted “usual, except that this” for “usual: *Provided, That* this”.

1992—Par. (e). Pub. L. 102-571 substituted “379e(a)” for “376(a)”.

1960—Par. (e). Pub. L. 86-618 substituted “and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 376(a) of this title” for “and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 364 of this title”.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2022 AMENDMENT

Amendment by Pub. L. 117-328 effective on the date that is 1 year after Dec. 29, 2022, see section 3503(b)(1) of Pub. L. 117-328, set out as a note under section 331 of this title.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86-618, see section 202 of Pub. L. 86-618, set out as a note under section 379e of this title.

EFFECTIVE DATE; POSTPONEMENT

Par. (e) effective Jan. 1, 1940, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 of this title.

EFFECTIVE DATE

Section effective twelve months after June 25, 1938, except par. (a), which, with certain exceptions, became effective on June 25, 1938, see section 1002(a) of act June 25, 1938, set out as a note under section 301 of this title.

CONSTRUCTION; CONFIDENTIALITY

Nothing in amendment made by Pub. L. 117-328, to be construed to authorize the disclosure of information

that is prohibited from disclosure under section 331(j) of this title or section 1905 of title 18 or that is subject to withholding under section 552(b)(4) of title 5, see section 3503(c)(2) of Pub. L. 117-328, set out as a note under section 364 of this title.

§ 362. Misbranded cosmetics

A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and (3) the information required under section 364e of this title: *Provided, That* under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 379e of this title. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 361(a) of this title).

(f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of title 15.

(June 25, 1938, ch. 675, § 602, 52 Stat. 1054; Pub. L. 86-618, title I, § 102(c)(2), July 12, 1960, 74 Stat. 398; Pub. L. 91-601, § 6(f), formerly § 7(f), Dec. 30, 1970, 84 Stat. 1673, renumbered Pub. L. 97-35, title XII, § 1205(c), Aug. 13, 1981, 95 Stat. 716; Pub. L. 102-571, title I, § 107(12), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 117-328, div. FF, title III, § 3503(a)(3), Dec. 29, 2022, 136 Stat. 5858.)

Editorial Notes

AMENDMENTS

2022—Subsec. (b)(3). Pub. L. 117-328 added par. (3) before proviso.

1992—Par. (e). Pub. L. 102-571 substituted “379e” for “376”.

1970—Par. (f). Pub. L. 91-601 added par. (f).

1960—Par. (e). Pub. L. 86-618 added par. (e).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2022 AMENDMENT

Amendment by Pub. L. 117-328 effective on the date that is 1 year after Dec. 29, 2022, see section 3503(b)(1) of Pub. L. 117-328, set out as a note under section 331 of this title.

¹ So in original. Probably should be “of”.