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 for[1] 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.

[1] So in original. Probably should be ''of''.

§ 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.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–601 effective Dec. 30, 1970, and regulations establishing special packaging standards effective no sooner than 180 days or later than one year from date regulations are final, or an earlier date published in Federal Register, see section 8 of Pub. L. 91–601, set out as an Effective Date note under section 1471 of Title 15, Commerce and Trade.

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. (b) effective Jan. 1, 1940, and such subsection effective July 1, 1940, as provided by regulations for certain lithographed labeling and containers bearing certain labeling, 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.

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.

Executive Documents

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

§ 363. Regulations making exemptions

The Secretary shall promulgate regulations exempting from any labeling requirement of this chapter cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

(June 25, 1938, ch. 675, § 603, 52 Stat. 1054.)

Executive Documents

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see notes set out under section 321 of this title.

§ 364. Definitions

In this subchapter:

(1) Adverse event

The term ''adverse event'' means any health-related event associated with the use of a cosmetic product that is adverse.

(2) Cosmetic product

The term ''cosmetic product'' means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.

(3) Facility

(A) IN GENERAL.—The term ''facility'' includes any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States.

(B) Such term does not include any of the following:

(i) Beauty shops and salons, unless such establishment manufactures or processes cosmetic products at that location.

(ii) Cosmetic product retailers, including individual sales representatives, direct sellers (as defined in section 3508(b)(2) of title 26), retail distribution facilities, and pharmacies, unless such establishment manufactures or processes cosmetic products that are not sold directly to consumers at that location.

(iii) Hospitals, physicians' offices, and health care clinics.

(iv) Public health agencies and other nonprofit entities that provide cosmetic products directly to the consumer.

(v) Entities (such as hotels and airlines) that provide complimentary cosmetic products to customers incidental to other services.

(vi) Trade shows and other venues where cosmetic product samples are provided free of charge.

(vii) An establishment that manufactures or processes cosmetic products that are solely for use in research or evaluation, including for production testing and not offered for retail sale.

(viii) An establishment that solely performs one or more of the following with respect to cosmetic products:

(I) Labeling.
(II) Relabeling.
(III) Packaging.
(IV) Repackaging.
(V) Holding.
(VI) Distributing.

(C) CLARIFICATION.—For the purposes of subparagraph (B)(viii), the terms ''packaging'' and ''repackaging'' do not include filling a product container with a cosmetic product.

(4) Responsible person

The term ''responsible person'' means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 364e(a) of this title or section 1453(a) of title 15.

(5) Serious adverse event

The term ''serious adverse event'' means an adverse event that—

(A) results in—

(i) death;
(ii) a life-threatening experience;
(iii) inpatient hospitalization;
(iv) a persistent or significant disability or incapacity;
(v) a congenital anomaly or birth defect;
(vi) an infection; or

(vii) significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance), other than as intended, under conditions of use that are customary or usual; or

(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in subparagraph (A).

(June 25, 1938, ch. 675, § 604, as added Pub. L. 117–328, div. FF, title III, § 3502, Dec. 29, 2022, 136 Stat. 5847.)

Editorial Notes

PRIOR PROVISIONS

A prior section 364, act June 25, 1938, ch. 675, § 604, 52 Stat. 1055, directed Secretary to promulgate regulations for listing of coal-tar colors for cosmetics, prior to repeal by Pub. L. 86–618, title I, § 103(a)(3), July 12, 1960, 74 Stat. 398, effective July 12, 1960. See section 379e of this title.

Statutory Notes and Related Subsidiaries

CONSTRUCTION; CONFIDENTIALITY

Pub. L. 117–328, div. FF, title III, § 3503(c), Dec. 29, 2022, 136 Stat. 5859, provided that:

''(1) IN GENERAL.—The Secretary [of Health and Human Services] shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential commercial information that is obtained by the Secretary of Health and Human Services pursuant to this subtitle [subtitle E (§§ 3501–3508) of title III of div. FF of Pub. L. 117–328, see Short Title of 2022 Amendment set out under section 301 of this title], including the amendments made by this subtitle.

''(2) CLARIFICATION.—Nothing in this subtitle, including the amendments made by this subtitle, shall be construed to authorize the disclosure of information that is prohibited from disclosure under section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) or section 1905 of title 18, United States Code, or that is subject to withholding under section 552(b)(4) of title 5, United States Code.''

§ 364a. Adverse events

(a) Serious adverse event reporting requirements

The responsible person shall submit to the Secretary any report received of a serious adverse event associated with the use, in the United States, of a cosmetic product manufactured, packed, or distributed by such person.

(b) Submission of reports

(1) Serious adverse event report

The responsible person shall submit to the Secretary a serious adverse event report accompanied by a copy of the label on or within the retail packaging of such cosmetic product no later than 15 business days after the report is received by the responsible person.

(2) New medical information

The responsible person shall submit to the Secretary any new and material medical information, related to a serious adverse event report submitted to the Secretary in accordance with paragraph (1), that is received by the responsible person within 1 year of the initial report to the Secretary, no later than 15 business days after such information is received by such responsible person.

(3) Consolidation of reports

The Secretary shall develop systems to enable responsible persons to submit a single report that includes duplicate reports of, or new medical information related to, a serious adverse event.

(c) Exemptions

The Secretary may establish by regulation an exemption to any of the requirements of this section if the Secretary determines that such exemption would have no significant adverse effect on public health.

(d) Contact information

The responsible person shall receive reports of adverse events through the domestic address, domestic telephone number, or electronic contact information included on the label in accordance with section 364e(a) of this title.

(e) Maintenance and inspection of adverse event records

(1) Maintenance

The responsible person shall maintain records related to each report of an adverse event associated with the use, in the United States, of a cosmetic product manufactured or distributed by such person received by such person, for a period of 6 years, except that a responsible person that is considered a small business for the purposes of section 364h of this title, who does not engage in the manufacturing or processing of the cosmetic products described in subsection 364h(b) of this title, shall maintain such records for a period of 3 years.

(2) Inspection

(A) In general

The responsible person shall permit an authorized person to have access to records required to be maintained under this section during an inspection pursuant to section 374 of this title.

(B) Authorized person

For purposes of this paragraph, the term ''authorized person'' means an officer or employee of the Department of Health and Human Services who has—

(i) appropriate credentials, as determined by the Secretary; and

(ii) been duly designated by the Secretary to have access to the records required under this section.

(f) Fragrance and flavor ingredients

If the Secretary has reasonable grounds to believe that an ingredient or combination of ingredients in a fragrance or flavor has caused or contributed to a serious adverse event required to be reported under this section, the Secretary may request in writing a list of such ingredients or categories of ingredients in the specific fragrances or flavors in the cosmetic product, from the responsible person. The responsible person shall ensure that the requested information is

submitted to the Secretary within 30 days of such request. In response to a request under section 552 of title 5, information submitted to the Secretary under this subsection shall be withheld under section 552(b)(3) of title 5.

(g) Protected information

A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (b)(2), or an adverse event report, or any new information, voluntarily submitted to the Secretary shall be considered to be—

(1) a safety report under section 379v of this title and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

(2) a record about an individual under section 552a of title 5 (commonly referred to as the ''Privacy Act of 1974'') and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the ''Freedom of Information Act''), and shall not be publicly disclosed unless all personally identifiable information is redacted.

(h) Effect of section

(1) In general

Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

(2) Personally identifiable information

Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not—

(A) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

(B) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

(3) Use of reports

Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with this section.

(4) Rule of construction

The submission of any report in compliance with this section shall not be construed as an admission that the cosmetic product involved caused or contributed to the relevant adverse event.

(June 25, 1938, ch. 675, §605, as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5848.)

Statutory Notes and Related Subsidiaries

CONSTRUCTION; CONFIDENTIALITY

Nothing in section 3502 of Pub. L. 117–328, which enacted this section, 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.

§ 364b. Good manufacturing practice

(a) In general

The Secretary shall by regulation establish good manufacturing practices for facilities that are consistent, to the extent practicable, and appropriate, with national and international standards, in accordance with section 361 of this title. Any such regulations shall be intended to protect the public health and ensure that cosmetic products are not adulterated. Such regulations may allow for the Secretary to inspect records necessary to demonstrate compliance with good manufacturing practices prescribed by the Secretary under this paragraph[1] during an inspection conducted under section 374 of this title.

(b) Considerations

In establishing regulations for good manufacturing practices under this section, the Secretary shall take into account the size and scope of the businesses engaged in the manufacture of cosmetics, and the risks to public health posed by such cosmetics, and provide sufficient flexibility to be practicable for all sizes and types of facilities to which such regulations will apply. Such regulations shall include simplified good manufacturing practice requirements for smaller businesses, as appropriate, to ensure that such regulations do not impose undue economic hardship for smaller businesses, and may include longer compliance times for smaller businesses. Before issuing regulations to implement subsection (a), the Secretary shall consult with cosmetics manufacturers, including smaller businesses, consumer organizations, and other experts selected by the Secretary.

(c) Timeframe

The Secretary shall publish a notice of proposed rulemaking not later than 2 years after December 29, 2022, and shall publish a final such rule not later than 3 years after December 29, 2022.

(June 25, 1938, ch. 675, §606, as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5850.)

Statutory Notes and Related Subsidiaries

CONSTRUCTION; CONFIDENTIALITY

Nothing in section 3502 of Pub. L. 117–328, which enacted this section, 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.

[1] So in original. Probably should be ''this subsection''.

§ 364c. Registration and product listing

(a) Submission of registration

(1) Initial registration

(A) Existing facilities

Every person that, on December 29, 2022, owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States shall register each facility with the Secretary not later than 1 year after December 29, 2022.

(B) New facilities

Every person that owns or operates a facility that first engages, after December 29, 2022, in manufacturing or processing of a cosmetic product for distribution in the United States, shall register with the Secretary such facility within 60 days of first engaging in such activity or 60 days after the deadline for registration under subparagraph (A), whichever is later.

(2) Biennial renewal of registration

A person required to register a facility under paragraph (1) shall renew such registrations with the Secretary biennially.

(3) Contract manufacturers

If a facility manufactures or processes cosmetic products on behalf of a responsible person, the Secretary shall require only a single registration for such facility even if such facility is manufacturing or processing its own cosmetic products or cosmetic products on behalf of more than one responsible person. Such single registration may be submitted to the Secretary by such facility or any responsible person whose products are manufactured or processed at such facility.

(4) Updates to content

A person that is required to register under subsection (a)(1) shall notify the Secretary within 60 days of any changes to information required under subsection (b)(2).

(5) Abbreviated renewal registrations

The Secretary shall provide for an abbreviated registration renewal process for any person that owns or operates a facility that has not been required to submit updates under paragraph (4) for a registered facility since submission of the most recent registration of such facility under paragraph (1) or (2).

(b) Format; contents of registration

(1) In general

Registration information under this section may be submitted at such time and in such manner as the Secretary may prescribe.

(2) Contents

The registration under subsection (a) shall contain—

(A) the facility's name, physical address, email address, and telephone number;

(B) with respect to any foreign facility, the contact for the United States agent of the facility, and, if available, the electronic contact information;

(C) the facility registration number, if any, previously assigned by the Secretary under subsection (d);

(D) all brand names under which cosmetic products manufactured or processed in the facility are sold; and

(E) the product category or categories and responsible person for each cosmetic product manufactured or processed at the facility.

(c) Cosmetic product listing

(1) In general

For each cosmetic product, the responsible person shall submit to the Secretary a cosmetic product listing, or ensure that such submission is made, at such time and in such manner as the Secretary may prescribe.

(2) Cosmetic product listing

The responsible person of a cosmetic product that is marketed on December 29, 2022, shall submit to the Secretary a cosmetic product listing not later than 1 year after December 29, 2022, or for a cosmetic product that is first marketed after December 29, 2022, within 120 days of marketing such product in interstate commerce. Thereafter, any updates to such listing shall be made annually, consistent with paragraphs (4) and (5).

(3) Abbreviated renewal

The Secretary shall provide for an abbreviated process for the renewal of any cosmetic product listing under this subsection with respect to which there has been no change since the responsible person submitted the previous listing.

(4) Contents of listing

(A) In general

Each such cosmetic product listing shall include—

(i) the facility registration number of each facility where the cosmetic product is manufactured or processed;

(ii) the name and contact number of the responsible person and the name for the cosmetic product, as such name appears on the label;

(iii) the applicable cosmetic category or categories for the cosmetic product;

(iv) a list of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by the name, as required under section 701.3 of title 21, Code of Federal Regulations (or any successor regulations), or by the common or usual name of the ingredient; and

(v) the product listing number, if any previously assigned by the Secretary under subsection (d).

(B) Flexible listings

A single listing submission for a cosmetic product may include multiple cosmetic products with identical formulations, or formulations that differ only with respect to colors, fragrances or flavors, or quantity of contents.

(5) Updates to content

A responsible person that is required to submit a cosmetic product listing shall submit

any updates to such cosmetic product listing annually.

(6) Submission

A responsible person may submit product listing information as part of a facility registration or separately.

(d) Facility registration and product listing numbers

At the time of the initial registration of any facility under subsection (a)(1) or initial listing of any cosmetic product under (c)(1),[1] the Secretary shall assign a facility registration number to the facility and a product listing number to each cosmetic product. The Secretary shall not make such product listing number publicly available.

(e) Confidentiality

In response to a request under section 552 of title 5, information described in subsection (b)(2)(D) or (c)(4)(A)(i) that is derived from a registration or listing under this section shall be withheld under section 552(b)(3) of title 5.

(f) Suspensions

(1) Suspension of registration of a facility

The Secretary may suspend the registration of a facility if the Secretary determines that a cosmetic product manufactured or processed by a registered facility and distributed in the United States has a reasonable probability of causing serious adverse health consequences or death to humans and the Secretary has a reasonable belief that other products manufactured or processed by the facility may be similarly affected because of a failure that cannot be isolated to a product or products, or is sufficiently pervasive to raise concerns about other products manufactured in the facility.

(2) Notice of suspension

Before suspending a facility registration under this section, the Secretary shall provide—

(A) notice to the facility registrant of the cosmetic product or other responsible person, as appropriate, of the intent to suspend the facility registration, which shall specify the basis of the determination by the Secretary that the facility registration should be suspended; and

(B) an opportunity, within 5 business days of the notice provided under subparagraph (A), for the responsible person to provide a plan for addressing the reasons for possible suspension of the facility registration.

(3) Hearing on suspension

The Secretary shall provide the registrant subject to an order under paragraph (1) or (2) with an opportunity for an informal hearing, to be held as soon as possible but not later than 5 business days after the issuance of the order, or such other time period agreed upon by the Secretary and the registrant, on the actions required for reinstatement of registration and why the registration that is subject to the suspension should be reinstated. The Secretary shall reinstate a registration if the Secretary determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration.

(4) Post-hearing corrective action plan

If, after providing opportunity for an informal hearing under paragraph (3), the Secretary determines that the suspension of registration remains necessary, the Secretary shall require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by the Secretary. The Secretary shall review such plan not later than 14 business days after the submission of the corrective action plan or such other time period as determined by the Secretary, in consultation with the registrant.

(5) Vacating of order; reinstatement

Upon a determination by the Secretary that adequate grounds do not exist to continue the suspension actions, the Secretary shall promptly vacate the suspension and reinstate the registration of the facility.

(6) Effect of suspension

If the registration of the facility is suspended under this section, no person shall introduce or deliver for introduction into commerce in the United States cosmetic products from such facility.

(7) No delegation

The authority conferred by this section to issue an order to suspend a registration or vacate an order of suspension shall not be delegated to any officer or employee other than the Commissioner.

(June 25, 1938, ch. 675, § 607, as added Pub. L. 117–328, div. FF, title III, § 3502, Dec. 29, 2022, 136 Stat. 5851.)

Statutory Notes and Related Subsidiaries

CONSTRUCTION; CONFIDENTIALITY

Nothing in section 3502 of Pub. L. 117–328, which enacted this section, 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.

§ 364d. Safety substantiation

(a) Substantiation of safety

A responsible person for a cosmetic product shall ensure, and maintain records supporting, that there is adequate substantiation of safety of such cosmetic product.

(b) Coal-tar hair dye

Subsection (a) shall not apply to coal-tar hair dye that otherwise complies with the requirements of section 361(a) of this title. A responsible person for a coal-tar hair dye shall maintain records related to the safety of such product.

(c) Definitions

For purposes of this section:

(1) Adequate substantiation of safety

The term ''adequate substantiation of safety'' means tests or studies, research, analyses,

[1] So in original. Probably should be preceded by ''subsection''.

or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe.

(2) Safe

The term ''safe'' means that the cosmetic product, including any ingredient thereof, is not injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual. The Secretary shall not consider a cosmetic ingredient or cosmetic product injurious to users solely because it can cause minor and transient reactions or minor and transient skin irritations in some users. In determining for purposes of this section whether a cosmetic product is safe, the Secretary may consider, as appropriate and available, the cumulative or other relevant exposure to the cosmetic product, including any ingredient thereof.

(June 25, 1938, ch. 675, § 608, as added Pub. L. 117–328, div. FF, title III, § 3502, Dec. 29, 2022, 136 Stat. 5854.)

Statutory Notes and Related Subsidiaries

CONSTRUCTION; CONFIDENTIALITY

Nothing in section 3502 of Pub. L. 117–328, which enacted this section, 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.

TALC-CONTAINING COSMETICS

Pub. L. 117–328, div. FF, title III, § 3505, Dec. 29, 2022, 136 Stat. 5859, provided that:

''The Secretary of Health and Human Services—

''(1) not later than one year after the date of enactment of this Act [Dec. 29, 2022], shall promulgate proposed regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products; and

''(2) not later than 180 days after the date on which the public comment period on the proposed regulations closes, shall issue such final regulations.''

§ 364e. Labeling

(a) General requirement

Each cosmetic product shall bear a label that includes a domestic address, domestic phone number, or electronic contact information, which may include a website, through which the responsible person can receive adverse event reports with respect to such cosmetic product.

(b) Fragrance allergens

The responsible person shall identify on the label of a cosmetic product each fragrance allergen included in such cosmetic product. Substances that are fragrance allergens for purposes of this subsection shall be determined by the Secretary by regulation. The Secretary shall issue a notice of proposed rulemaking promulgating the regulation implementing this requirement not later than 18 months after December 29, 2022, and not later than 180 days after the date on which the public comment period on the proposed rulemaking closes, shall issue a final rulemaking. In promulgating regulations implementing this subsection, the Secretary shall consider international, State, and local requirements for allergen disclosure, including the substance and format of requirements in the European Union, and may establish threshold levels of amounts of substances subject to disclosure pursuant to such regulations.

(c) Cosmetic products for professional use

(1) Definition of professional

For purposes of this subsection, the term ''professional'' means an individual who is licensed by an official State authority to practice in the field of cosmetology, nail care, barbering, or esthetics.

(2) Professional use labeling

A cosmetic product introduced into interstate commerce and intended to be used only by a professional shall bear a label that—

(A) contains a clear and prominent statement that the product shall be administered or used only by licensed professionals; and

(B) is in conformity with the requirements of the Secretary for cosmetics labeling under this chapter and section 1453(a) of title 15.

(June 25, 1938, ch. 675, § 609, as added Pub. L. 117–328, div. FF, title III, § 3502, Dec. 29, 2022, 136 Stat. 5854.)

DELAYED EFFECTIVE DATE OF SUBSECTION (a)

For delayed effective date of subsection (a) of this section, see Effective Date of 2022 Amendment note below.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2022 AMENDMENT

Pub. L. 117–328, div. FF, title III, § 3503(b)(2), Dec. 29, 2022, 136 Stat. 5859, provided that: ''Section 609(a) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 364e(a)], as added by section 802 [probably should be ''section 3502''], shall take effect on the date that is 2 years after the date of enactment of this Act [Dec. 29, 2022].''

CONSTRUCTION; CONFIDENTIALITY

Nothing in section 3502 of Pub. L. 117–328, which enacted this section, 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.

§ 364f. Records

(a) In general

If the Secretary has a reasonable belief that a cosmetic product, including an ingredient in such cosmetic product, and any other cosmetic product that the Secretary reasonably believes is likely to be affected in a similar manner, is likely to be adulterated such that the use or exposure to such product presents a threat of serious adverse health consequences or death to humans, each responsible person and facility shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate

credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such cosmetic product, and to any other cosmetic product that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether the cosmetic product is adulterated and presents a threat of serious adverse health consequences or death to humans. This subsection shall not be construed to extend to recipes or formulas for cosmetics, financial data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this chapter), research data (other than safety substantiation data for cosmetic products and their ingredients), or sales data (other than shipment data regarding sales).

(b) Rule of construction

Nothing in this section shall be construed to limit the authority of the Secretary to inspect records or require establishment and maintenance of records under any other provision of this chapter, including section 364a or 364b of this title.

(June 25, 1938, ch. 675, § 610, as added Pub. L. 117–328, div. FF, title III, § 3502, Dec. 29, 2022, 136 Stat. 5855.)

Statutory Notes and Related Subsidiaries

CONSTRUCTION; CONFIDENTIALITY

Nothing in section 3502 of Pub. L. 117–328, which enacted this section, 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.

§ 364g. Mandatory recall authority

(a) In general

If the Secretary determines that there is a reasonable probability that a cosmetic is adulterated under section 361 of this title or misbranded under section 362 of this title and the use of or exposure to such cosmetic will cause serious adverse health consequences or death, the Secretary shall provide the responsible person with an opportunity to voluntarily cease distribution and recall such article. If the responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic within the time and manner prescribed by the Secretary (if so prescribed), the Secretary may, by order, require, as the Secretary determines necessary, such person to immediately cease distribution of such article.

(b) Hearing

The Secretary shall provide the responsible person who is subject to an order under subsection (a) with an opportunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order, on whether adequate evidence exists to justify the order.

(c) Order resolution

After an order is issued according to the process under subsections (a) and (b), the Secretary shall, except as provided in subsection (d)—

(1) vacate the order, if the Secretary determines that inadequate grounds exist to support the actions required by the order;

(2) continue the order ceasing distribution of the cosmetic until a date specified in such order; or

(3) amend the order to require a recall of the cosmetic, including any requirements to notify appropriate persons, a timetable for the recall to occur, and a schedule for updates to be provided to the Secretary regarding such recall.

(d) Action following order

Any person who is subject to an order pursuant to paragraph (2) or (3) of subsection (c) shall immediately cease distribution of or recall, as applicable, the cosmetic and provide notification as required by such order.

(e) Notice to persons affected

If the Secretary determines necessary, the Secretary may require the person subject to an order pursuant to subsection (a) or an amended order pursuant to paragraph (2) or (3) of subsection (c) to provide either a notice of a recall order for, or an order to cease distribution of, such cosmetic, as applicable, under this section to appropriate persons, including persons who manufacture, distribute, import, or offer for sale such product that is the subject of an order and to the public.

(f) Public notification

In conducting a recall under this section, the Secretary shall—

(1) ensure that a press release is published regarding the recall, and that alerts and public notices are issued, as appropriate, in order to provide notification—

(A) of the recall to consumers and retailers to whom such cosmetic was, or may have been, distributed; and

(B) that includes, at a minimum—

(i) the name of the cosmetic subject to the recall;

(ii) a description of the risk associated with such article; and

(iii) to the extent practicable, information for consumers about similar cosmetics that are not affected by the recall; and

(2) ensure publication, as appropriate, on the website of the Food and Drug Administration of an image of the cosmetic that is the subject of the press release described in paragraph (1), if available.

(g) No delegation

The authority conferred by this section to order a recall or vacate a recall order shall not be delegated to any officer or employee other than the Commissioner.

(h) Effect

Nothing in this section shall affect the authority of the Secretary to request or participate in a voluntary recall, or to issue an order to cease distribution or to recall under any other provision of this subchapter.

(June 25, 1938, ch. 675, § 611, as added Pub. L. 117–328, div. FF, title III, § 3502, Dec. 29, 2022, 136 Stat. 5855.)

Statutory Notes and Related Subsidiaries

CONSTRUCTION; CONFIDENTIALITY

Nothing in section 3502 of Pub. L. 117–328, which enacted this section, 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.

§ 364h. Small businesses

(a) In general

Responsible persons, and owners and operators of facilities, whose average gross annual sales in the United States of cosmetic products for the previous 3-year period is less than $1,000,000, adjusted for inflation, and who do not engage in the manufacturing or processing of the cosmetic products described in subsection (b), shall be considered small businesses and not subject to the requirements of section 364b or 364c of this title.

(b) Requirements applicable to all manufacturers and processors of cosmetics

The exemptions under subsection (a) shall not apply to any responsible person or facility engaged in the manufacturing or processing of any of the following products:

(1) Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual.

(2) Cosmetic products that are injected.

(3) Cosmetic products that are intended for internal use.

(4) Cosmetic products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual.

(June 25, 1938, ch. 675, § 612, as added Pub. L. 117–328, div. FF, title III, § 3502, Dec. 29, 2022, 136 Stat. 5857.)

Statutory Notes and Related Subsidiaries

CONSTRUCTION; CONFIDENTIALITY

Nothing in section 3502 of Pub. L. 117–328, which enacted this section, 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.

§ 364i. Exemption for certain products and facilities

(a) In general

Notwithstanding any other provision of law, except as provided in subsection (b), a cosmetic product or facility that is also subject to the requirements of subchapter V shall be exempt from the requirements of sections 364a, 364b, 364c, 364d, 364e(a), 364f, and 364g of this title.

(b) Exception

A facility described in subsection (a) that also manufactures or processes cosmetic products that are not subject to the requirements of subchapter V shall not be exempt from the requirements of sections 364a, 364b, 364c, 364d, 364e(a), 364f, and 364g of this title, with respect to such cosmetic products.

(June 25, 1938, ch. 675, § 613, as added Pub. L. 117–328, div. FF, title III, § 3502, Dec. 29, 2022, 136 Stat. 5857.)

Statutory Notes and Related Subsidiaries

CONSTRUCTION; CONFIDENTIALITY

Nothing in section 3502 of Pub. L. 117–328, which enacted this section, 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.

§ 364j. Preemption

(a) In general

No State or political subdivision of a State may establish or continue in effect any law, regulation, order, or other requirement for cosmetics that is different from or in addition to, or otherwise not identical with, any requirement applicable under this subchapter with respect to registration and product listing, good manufacturing practice, records, recalls, adverse event reporting, or safety substantiation.

(b) Limitation

Nothing in the amendments to this chapter made by the Modernization of Cosmetics Regulation Act of 2022 shall be construed to preempt any State statute, public initiative, referendum, regulation, or other State action, except as expressly provided in subsection (a). Notwithstanding subsection (a), nothing in this section shall be construed to prevent any State from prohibiting the use or limiting the amount of an ingredient in a cosmetic product, or from continuing in effect a requirement of any State that is in effect at the time of enactment of the Modernization of Cosmetics Regulation Act of 2022 for the reporting to the State of an ingredient in a cosmetic product.

(c) Savings

Nothing in the amendments to this chapter made by the Modernization of Cosmetics Regulation Act of 2022, nor any standard, rule, requirement, regulation, or adverse event report shall be construed to modify, preempt, or displace any action for damages or the liability of any person under the law of any State, whether statutory or based in common law.

(d) Rule of construction

Nothing in this section shall be construed to amend, expand, or limit the provisions under section 379s of this title.

(June 25, 1938, ch. 675, § 614, as added Pub. L. 117–328, div. FF, title III, § 3502, Dec. 29, 2022, 136 Stat. 5857.)

Editorial Notes

REFERENCES IN TEXT

The amendments to this chapter made by the Modernization of Cosmetics Regulation Act of 2022, referred

to in subsecs. (b) and (c), means the amendments made by subtitle E (§§ 3501–3508) of title III of div. FF of Pub. L. 117–328, which enacted this section and sections 364 to 364i of this title and amended sections 331, 361, 362, 374, and 381 of this title.

The time of enactment of the Modernization of Cosmetics Regulation Act of 2022, referred to in subsec. (b), probably means the date of enactment of subtitle E (§§ 3501–3508) of title III of div. FF of Pub. L. 117–328, which was approved Dec. 29, 2022.

Statutory Notes and Related Subsidiaries

CONSTRUCTION; CONFIDENTIALITY

Nothing in section 3502 of Pub. L. 117–328, which enacted this section, 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.

SUBCHAPTER VII—GENERAL AUTHORITY

PART A—GENERAL ADMINISTRATIVE PROVISIONS

§ 371. Regulations and hearings

(a) Authority to promulgate regulations

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

(b) Regulations for imports and exports

The Secretary of the Treasury and the Secretary of Health and Human Services shall jointly prescribe regulations for the efficient enforcement of the provisions of section 381 of this title, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health and Human Services shall determine.

(c) Conduct of hearings

Hearings authorized or required by this chapter shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) Effectiveness of definitions and standards of identity

The definitions and standards of identity promulgated in accordance with the provisions of this chapter shall be effective for the purposes of the enforcement of this chapter, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) Procedure for establishment

(1) Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title, and any action for the amendment or repeal of any definition and standard of identity under section 341 of this title for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f) Review of order

(1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were