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