

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<sup>1</sup> 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.

<sup>1</sup> So in original. Probably should be “of”.

## 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 repackaging 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 quali-

tatively 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 non-profit 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