

(B) the same drug in the same dosage form for the same intended use is not approved under section 360b or 360ccc of this title or designated under this section at the time the request is made.

(3) Regarding the termination of a designation—

(A) the sponsor of a new animal drug shall notify the Secretary of any decision to discontinue active pursuit of approval under section 360b or 360ccc of this title of an application for a designated new animal drug. The Secretary shall terminate the designation upon such notification;

(B) the Secretary may also terminate designation if the Secretary independently determines that the sponsor is not actively pursuing approval under section 360b or 360ccc of this title with due diligence;

(C) the sponsor of an approved designated new animal drug shall notify the Secretary of any discontinuance of the manufacture of such new animal drug at least one year before discontinuance. The Secretary shall terminate the designation upon such notification; and

(D) the designation shall terminate upon the expiration of any applicable exclusivity period under subsection (c) of this section.

(4) Notice respecting the designation or termination of designation of a new animal drug shall be made available to the public.

(b) Grants and contracts for development of designated new animal drugs

(1) The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in defraying the costs of qualified safety and effectiveness testing expenses and manufacturing expenses incurred in connection with the development of designated new animal drugs.

(2) For purposes of paragraph (1) of this section—

(A) The term “qualified safety and effectiveness testing” means testing—

(i) which occurs after the date such new animal drug is designated under this section and before the date on which an application with respect to such drug is submitted under section 360b of this title; and

(ii) which is carried out under an investigational exemption under section 360b(j) of this title.

(B) The term “manufacturing expenses” means expenses incurred in developing processes and procedures associated with manufacture of the designated new animal drug which occur after the new animal drug is designated under this section and before the date on which an application with respect to such new animal drug is submitted under section 360b or 360ccc of this title.

(c) Exclusivity for designated new animal drugs

(1) Except as provided in subsection (c)(2) of this section, if the Secretary approves or conditionally approves an application for a designated new animal drug, the Secretary may not approve or conditionally approve another application submitted for such new animal drug with

the same intended use as the designated new animal drug for another applicant before the expiration of seven years from the date of approval or conditional approval of the application.

(2) If an application filed pursuant to section 360b of this title or section 360ccc of this title is approved for a designated new animal drug, the Secretary may, during the 7-year exclusivity period beginning on the date of the application approval or conditional approval, approve or conditionally approve another application under section 360b of this title or section 360ccc of this title for such drug for such minor use or minor species for another applicant if—

(A) the Secretary finds, after providing the holder of such an approved application notice and opportunity for the submission of views, that in the granted exclusivity period the holder of the approved application cannot assure the availability of sufficient quantities of the drug to meet the needs for which the drug was designated; or

(B) such holder provides written consent to the Secretary for the approval or conditional approval of other applications before the expiration of such exclusivity period.

(June 25, 1938, ch. 675, §573, as added Pub. L. 108-282, title I, §102(b)(4), Aug. 2, 2004, 118 Stat. 900.)

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.

(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.)

AMENDMENTS

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”.

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 902(a) of act June 25, 1938, set out as a note under section 301 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; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *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.)

AMENDMENTS

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).

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.

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.)

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. Repealed. Pub. L. 86-618, title I, § 103(a)(3), July 12, 1960, 74 Stat. 398

Section, act June 25, 1938, ch. 675, §604, 52 Stat. 1055, directed Secretary to promulgate regulations for listing of coal-tar colors for cosmetics. See section 379e of this title.

EFFECTIVE DATE OF REPEAL

Repeal effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86-618, see section 202 of