

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.)

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.)