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