(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

submitted to the Secretary within 30 days of such request. In response to a request under section 552 of title 5, information submitted to the Secretary under this subsection shall be withheld under section 552(b)(3) of title 5.

(g) Protected information

A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (b)(2), or an adverse event report, or any new information, voluntarily submitted to the Secretary shall be considered to be—

(1) a safety report under section 379v of this title and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

(2) a record about an individual under section 552a of title 5 (commonly referred to as the ''Privacy Act of 1974'') and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the ''Freedom of Information Act''), and shall not be publicly disclosed unless all personally identifiable information is redacted.

(h) Effect of section

(1) In general

Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

(2) Personally identifiable information

Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not—

(A) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

(B) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

(3) Use of reports

Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with this section.

(4) Rule of construction

The submission of any report in compliance with this section shall not be construed as an admission that the cosmetic product involved caused or contributed to the relevant adverse event.

(June 25, 1938, ch. 675, §605, as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5848.)

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.

§ 364b. Good manufacturing practice

(a) In general

The Secretary shall by regulation establish good manufacturing practices for facilities that are consistent, to the extent practicable, and appropriate, with national and international standards, in accordance with section 361 of this title. Any such regulations shall be intended to protect the public health and ensure that cosmetic products are not adulterated. Such regulations may allow for the Secretary to inspect records necessary to demonstrate compliance with good manufacturing practices prescribed by the Secretary under this paragraph[1] during an inspection conducted under section 374 of this title.

(b) Considerations

In establishing regulations for good manufacturing practices under this section, the Secretary shall take into account the size and scope of the businesses engaged in the manufacture of cosmetics, and the risks to public health posed by such cosmetics, and provide sufficient flexibility to be practicable for all sizes and types of facilities to which such regulations will apply. Such regulations shall include simplified good manufacturing practice requirements for smaller businesses, as appropriate, to ensure that such regulations do not impose undue economic hardship for smaller businesses, and may include longer compliance times for smaller businesses. Before issuing regulations to implement subsection (a), the Secretary shall consult with cosmetics manufacturers, including smaller businesses, consumer organizations, and other experts selected by the Secretary.

(c) Timeframe

The Secretary shall publish a notice of proposed rulemaking not later than 2 years after December 29, 2022, and shall publish a final such rule not later than 3 years after December 29, 2022.

(June 25, 1938, ch. 675, §606, as added Pub. L. 117–328, div. FF, title III, §3502, Dec. 29, 2022, 136 Stat. 5850.)

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.

[1] So in original. Probably should be ''this subsection''.