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.)

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.

§ 364h. Small businesses

(a) In general

Responsible persons, and owners and operators of facilities, whose average gross annual sales in the United States of cosmetic products for the previous 3-year period is less than $1,000,000, adjusted for inflation, and who do not engage in the manufacturing or processing of the cosmetic products described in subsection (b), shall be considered small businesses and not subject to the requirements of section 364b or 364c of this title.

(b) Requirements applicable to all manufacturers and processors of cosmetics

The exemptions under subsection (a) shall not apply to any responsible person or facility engaged in the manufacturing or processing of any of the following products:

(1) Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual.

(2) Cosmetic products that are injected.

(3) Cosmetic products that are intended for internal use.

(4) Cosmetic products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual.

(June 25, 1938, ch. 675, § 612, as added Pub. L. 117–328, div. FF, title III, § 3502, Dec. 29, 2022, 136 Stat. 5857.)

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.

§ 364i. Exemption for certain products and facilities

(a) In general

Notwithstanding any other provision of law, except as provided in subsection (b), a cosmetic product or facility that is also subject to the requirements of subchapter V shall be exempt from the requirements of sections 364a, 364b, 364c, 364d, 364e(a), 364f, and 364g of this title.

(b) Exception

A facility described in subsection (a) that also manufactures or processes cosmetic products that are not subject to the requirements of subchapter V shall not be exempt from the requirements of sections 364a, 364b, 364c, 364d, 364e(a), 364f, and 364g of this title, with respect to such cosmetic products.

(June 25, 1938, ch. 675, § 613, as added Pub. L. 117–328, div. FF, title III, § 3502, Dec. 29, 2022, 136 Stat. 5857.)

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.

§ 364j. Preemption

(a) In general

No State or political subdivision of a State may establish or continue in effect any law, regulation, order, or other requirement for cosmetics that is different from or in addition to, or otherwise not identical with, any requirement applicable under this subchapter with respect to registration and product listing, good manufacturing practice, records, recalls, adverse event reporting, or safety substantiation.

(b) Limitation

Nothing in the amendments to this chapter made by the Modernization of Cosmetics Regulation Act of 2022 shall be construed to preempt any State statute, public initiative, referendum, regulation, or other State action, except as expressly provided in subsection (a). Notwithstanding subsection (a), nothing in this section shall be construed to prevent any State from prohibiting the use or limiting the amount of an ingredient in a cosmetic product, or from continuing in effect a requirement of any State that is in effect at the time of enactment of the Modernization of Cosmetics Regulation Act of 2022 for the reporting to the State of an ingredient in a cosmetic product.

(c) Savings

Nothing in the amendments to this chapter made by the Modernization of Cosmetics Regulation Act of 2022, nor any standard, rule, requirement, regulation, or adverse event report shall be construed to modify, preempt, or displace any action for damages or the liability of any person under the law of any State, whether statutory or based in common law.

(d) Rule of construction

Nothing in this section shall be construed to amend, expand, or limit the provisions under section 379s of this title.

(June 25, 1938, ch. 675, § 614, as added Pub. L. 117–328, div. FF, title III, § 3502, Dec. 29, 2022, 136 Stat. 5857.)

Editorial Notes

REFERENCES IN TEXT

The amendments to this chapter made by the Modernization of Cosmetics Regulation Act of 2022, referred