

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.)

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§ 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 sub-

chapter 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.)

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§ 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