

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

to in subsecs. (b) and (c), means the amendments made by subtitle E (§§ 3501–3508) of title III of div. FF of Pub. L. 117–328, which enacted this section and sections 364 to 364i of this title and amended sections 331, 361, 362, 374, and 381 of this title.

The time of enactment of the Modernization of Cosmetics Regulation Act of 2022, referred to in subsec. (b), probably means the date of enactment of subtitle E (§§ 3501–3508) of title III of div. FF of Pub. L. 117–328, which was approved Dec. 29, 2022.

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SUBCHAPTER VII—GENERAL AUTHORITY

PART A—GENERAL ADMINISTRATIVE PROVISIONS

§ 371. Regulations and hearings

(a) Authority to promulgate regulations

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

(b) Regulations for imports and exports

The Secretary of the Treasury and the Secretary of Health and Human Services shall jointly prescribe regulations for the efficient enforcement of the provisions of section 381 of this title, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health and Human Services shall determine.

(c) Conduct of hearings

Hearings authorized or required by this chapter shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) Effectiveness of definitions and standards of identity

The definitions and standards of identity promulgated in accordance with the provisions of this chapter shall be effective for the purposes of the enforcement of this chapter, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e) Procedure for establishment

(1) Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title, and any action for the amendment or repeal of any definition and standard of identity under section 341 of this title for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all

interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f) Review of order

(1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were