

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<sup>1</sup> 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.

<sup>1</sup> So in original. Probably should be “this subsection”.

**§ 364c. Registration and product listing****(a) Submission of registration****(1) Initial registration****(A) Existing facilities**

Every person that, on December 29, 2022, owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States shall register each facility with the Secretary not later than 1 year after December 29, 2022.

**(B) New facilities**

Every person that owns or operates a facility that first engages, after December 29, 2022, in manufacturing or processing of a cosmetic product for distribution in the United States, shall register with the Secretary such facility within 60 days of first engaging in such activity or 60 days after the deadline for registration under subparagraph (A), whichever is later.

**(2) Biennial renewal of registration**

A person required to register a facility under paragraph (1) shall renew such registrations with the Secretary biennially.

**(3) Contract manufacturers**

If a facility manufactures or processes cosmetic products on behalf of a responsible person, the Secretary shall require only a single registration for such facility even if such facility is manufacturing or processing its own cosmetic products or cosmetic products on behalf of more than one responsible person. Such single registration may be submitted to the Secretary by such facility or any responsible person whose products are manufactured or processed at such facility.

**(4) Updates to content**

A person that is required to register under subsection (a)(1) shall notify the Secretary within 60 days of any changes to information required under subsection (b)(2).

**(5) Abbreviated renewal registrations**

The Secretary shall provide for an abbreviated registration renewal process for any person that owns or operates a facility that has not been required to submit updates under paragraph (4) for a registered facility since submission of the most recent registration of such facility under paragraph (1) or (2).

**(b) Format; contents of registration****(1) In general**

Registration information under this section may be submitted at such time and in such manner as the Secretary may prescribe.

**(2) Contents**

The registration under subsection (a) shall contain—

(A) the facility's name, physical address, email address, and telephone number;

(B) with respect to any foreign facility, the contact for the United States agent of the facility, and, if available, the electronic contact information;

(C) the facility registration number, if any, previously assigned by the Secretary under subsection (d);

(D) all brand names under which cosmetic products manufactured or processed in the facility are sold; and

(E) the product category or categories and responsible person for each cosmetic product manufactured or processed at the facility.

**(c) Cosmetic product listing****(1) In general**

For each cosmetic product, the responsible person shall submit to the Secretary a cosmetic product listing, or ensure that such submission is made, at such time and in such manner as the Secretary may prescribe.

**(2) Cosmetic product listing**

The responsible person of a cosmetic product that is marketed on December 29, 2022, shall submit to the Secretary a cosmetic product listing not later than 1 year after December 29, 2022, or for a cosmetic product that is first marketed after December 29, 2022, within 120 days of marketing such product in interstate commerce. Thereafter, any updates to such listing shall be made annually, consistent with paragraphs (4) and (5).

**(3) Abbreviated renewal**

The Secretary shall provide for an abbreviated process for the renewal of any cosmetic product listing under this subsection with respect to which there has been no change since the responsible person submitted the previous listing.

**(4) Contents of listing****(A) In general**

Each such cosmetic product listing shall include—

(i) the facility registration number of each facility where the cosmetic product is manufactured or processed;

(ii) the name and contact number of the responsible person and the name for the cosmetic product, as such name appears on the label;

(iii) the applicable cosmetic category or categories for the cosmetic product;

(iv) a list of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by the name, as required under section 701.3 of title 21, Code of Federal Regulations (or any successor regulations), or by the common or usual name of the ingredient; and

(v) the product listing number, if any previously assigned by the Secretary under subsection (d).

**(B) Flexible listings**

A single listing submission for a cosmetic product may include multiple cosmetic products with identical formulations, or formulations that differ only with respect to colors, fragrances or flavors, or quantity of contents.

**(5) Updates to content**

A responsible person that is required to submit a cosmetic product listing shall submit