§ 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

any updates to such cosmetic product listing annually.

(6) Submission

A responsible person may submit product listing information as part of a facility registration or separately.

(d) Facility registration and product listing numbers

At the time of the initial registration of any facility under subsection (a)(1) or initial listing of any cosmetic product under (c)(1),[1] the Secretary shall assign a facility registration number to the facility and a product listing number to each cosmetic product. The Secretary shall not make such product listing number publicly available.

(e) Confidentiality

In response to a request under section 552 of title 5, information described in subsection (b)(2)(D) or (c)(4)(A)(i) that is derived from a registration or listing under this section shall be withheld under section 552(b)(3) of title 5.

(f) Suspensions

(1) Suspension of registration of a facility

The Secretary may suspend the registration of a facility if the Secretary determines that a cosmetic product manufactured or processed by a registered facility and distributed in the United States has a reasonable probability of causing serious adverse health consequences or death to humans and the Secretary has a reasonable belief that other products manufactured or processed by the facility may be similarly affected because of a failure that cannot be isolated to a product or products, or is sufficiently pervasive to raise concerns about other products manufactured in the facility.

(2) Notice of suspension

Before suspending a facility registration under this section, the Secretary shall provide—

(A) notice to the facility registrant of the cosmetic product or other responsible person, as appropriate, of the intent to suspend the facility registration, which shall specify the basis of the determination by the Secretary that the facility registration should be suspended; and

(B) an opportunity, within 5 business days of the notice provided under subparagraph (A), for the responsible person to provide a plan for addressing the reasons for possible suspension of the facility registration.

(3) Hearing on suspension

The Secretary shall provide the registrant subject to an order under paragraph (1) or (2) with an opportunity for an informal hearing, to be held as soon as possible but not later than 5 business days after the issuance of the order, or such other time period agreed upon by the Secretary and the registrant, on the actions required for reinstatement of registration and why the registration that is subject to the suspension should be reinstated. The Secretary shall reinstate a registration if the Secretary determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration.

(4) Post-hearing corrective action plan

If, after providing opportunity for an informal hearing under paragraph (3), the Secretary determines that the suspension of registration remains necessary, the Secretary shall require the registrant to submit a corrective action plan to demonstrate how the registrant plans to correct the conditions found by the Secretary. The Secretary shall review such plan not later than 14 business days after the submission of the corrective action plan or such other time period as determined by the Secretary, in consultation with the registrant.

(5) Vacating of order; reinstatement

Upon a determination by the Secretary that adequate grounds do not exist to continue the suspension actions, the Secretary shall promptly vacate the suspension and reinstate the registration of the facility.

(6) Effect of suspension

If the registration of the facility is suspended under this section, no person shall introduce or deliver for introduction into commerce in the United States cosmetic products from such facility.

(7) No delegation

The authority conferred by this section to issue an order to suspend a registration or vacate an order of suspension shall not be delegated to any officer or employee other than the Commissioner.

(June 25, 1938, ch. 675, § 607, as added Pub. L. 117–328, div. FF, title III, § 3502, Dec. 29, 2022, 136 Stat. 5851.)

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.

§ 364d. Safety substantiation

(a) Substantiation of safety

A responsible person for a cosmetic product shall ensure, and maintain records supporting, that there is adequate substantiation of safety of such cosmetic product.

(b) Coal-tar hair dye

Subsection (a) shall not apply to coal-tar hair dye that otherwise complies with the requirements of section 361(a) of this title. A responsible person for a coal-tar hair dye shall maintain records related to the safety of such product.

(c) Definitions

For purposes of this section:

(1) Adequate substantiation of safety

The term ''adequate substantiation of safety'' means tests or studies, research, analyses,

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