ALSTON & BIRD

WWW.ALSTON.COM

FDA / Food & Beverage ADVISORY ■

AUGUST 9, 2023

Cosmetics Update: FDA Publishes Draft Guidance on Cosmetic Product Facility Registration and Listing

***by* Sam Jockel *and* Alexandra Marzelli**

On August 7, 2023, the U.S. Food and Drug Administration (FDA) published a draft guidance, Registration and Listing of Cosmetic Product Facilities and Products, detailing the who, what, how, and when of cosmetic product facility registration and product listing required under the Modernization of Cosmetics Regulation Act (MoCRA). The FDA intends to launch a registration and listing electronic submission portal for cosmetic products in October 2023, before the statutory compliance date of December 29, 2023.

Described by the FDA as "the most significant expansion of FDA's authority to regulate cosmetics since the Federal Food, Drug, and Cosmetic (FD&C) Act was passed in 1938," MoCRA, enacted on December 29, 2022, as part of the Consolidated Appropriations Act, 2023, represents a significant overhaul of cosmetics regulation in the United States. Bipartisan legislation that was passed with industry support, MoCRA both imposes new requirements on the cosmetics industry, such as the facility registration and cosmetic product listing requirements, and expands the FDA's oversight and enforcement tools.

Facility Registration

Under MoCRA, persons who own or operate a facility that manufactures or processes cosmetic products for distribution in the United States in existence as of the implementation date of MoCRA must register their facilities with the FDA by December 29, 2023. "Facility" is defined to mean "any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States." That definition extends to both foreign and domestic establishments. A number of entities are excluded from the definition of "facility," including beauty shops and salons (unless those establishments manufacture or process cosmetic products at that location), hospitals, physicians' offices and health care clinics, and establishments that solely perform one or more of the following: labeling, relabeling, packaging, repackaging, holding, or distributing (though packaging and repackaging do not include filling a product container with a cosmetic product). In turn, a "cosmetic product" is defined as "a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product."

Under MoCRA, any facility established after December 29, 2022 must register by February 27, 2024, or within 60 days of first engaging in the manufacturing or processing of cosmetic products, whichever is later. The facility registration must be renewed every two years, and any change to the information submitted requires notification to the FDA within 60 days.

Information required to be included in the facility registration includes:

- Facility registration number (if previously assigned).
- Facility name, physical address, email address, and telephone number.
- U.S. agent contact information for foreign facilities.
- All cosmetic brand names manufactured or processed in the facility (this information is not subject to Freedom of Information Act (FOIA) disclosure).
- Cosmetic product category or categories (further specified in the draft guidance).
- Responsible person for each cosmetic product manufactured or processed at the facility.

Product Listing

In addition to facility registration, MoCRA also requires that "responsible persons" submit cosmetic product listings to the FDA. A responsible person is defined as "the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product." For cosmetic products marketed as of December 29, 2022, responsible persons must list each cosmetic product with the FDA by December 29, 2023. For new cosmetic products placed on the market after December 29, 2022, the product listing must be submitted within 120 days of marketing the product in interstate commerce.

Information required to be included in the product listing includes:

- Facility registration number for each facility manufacturing or processing the product.
- Manufacturer, packer, or distributor name and contact information and the cosmetic name (as the name appears on the label).
- Cosmetic categories (further specified in the draft guidance appendix).
- Cosmetic ingredients (fragrances and flavors may be listed this way).
- Product listing number (once assigned).

The product listing submission can be part of a facility registration submission or a separate submission. In addition, a single listing submission can be made for multiple cosmetic products with identical formulas or cosmetic products that only differ in color, fragrances, flavors, or quantity of contents.

Exemptions

Small businesses, defined as those businesses with an average gross annual sale of cosmetic products in the United States for the previous three years of less than $1 million, adjusted for inflation, are exempt from the facility registration and product listing requirements. However, this exemption does not extend to businesses engaged in the manufacturing or processing of cosmetic products used in certain applications, such as those that regularly come into contact with the mucus membrane of the eyes, are injected, are intended for internal use, or are intended to alter the appearance for more than 24 hours under customary or usual conditions of use and removal by the consumer within 24 hours is not customary or usual.

A cosmetic product listing is not required for cosmetic products that are also subject to the requirements of Chapter V of the FD&C Act, which governs drugs and medical devices. Likewise, a facility registration is not required for a facility that manufactures or processes such cosmetic products, provided that all the cosmetic products it manufactures or processes are also subject to Chapter V of the FD&C Act.

Key Takeaways

- **FDA Portal for Registration and Listing Expected October 2023:** Industry should mark its calendar for October 2023, the FDA's estimated "go-live" month for its new electronic submission portal for cosmetic product facility registration and product listing. The FDA is developing an alternative paper form for registration and listing concomitantly but "strongly encourages" electronic submission via the portal. Electronic submissions will be submitted using the structured product labeling format. In addition, the FDA separately announced that it is soliciting applications from members of the cosmetic industry interested in participating in a voluntary pilot program to assist the FDA in evaluating the portal before its October 2023 launch. Applications are due August 22, 2023, and the pilot program is slated to begin on or around September 15, 2023.
- **Prior Voluntary Cosmetic Registration Information Not Transferred to New FDA Portal:** Industry should not rely on any prior submission made to the Voluntary Cosmetic Registration Program (VCRP). In anticipation of MoCRA implementation, the FDA stopped accepting and processing submissions made to the VCRP on March 27, 2023. The FDA will not transfer information submitted to the VCRP to the new system and will not consider prior submissions to the voluntary system to satisfy registration and listing requirements.
- **One Step or More Equals "Manufacturing or Processing of a Cosmetic Product":** For purposes of registration and listing requirements, the FDA interprets "manufacturing or processing" broadly, meaning to engage "in one or more steps in the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the product."
- **Single Registration for Contract Manufacturing Facilities:** If a facility is manufacturing or processing cosmetic products on behalf of more than one responsible person (i.e., acting as contract manufacturer), only one registration is required, and it can be submitted on behalf of the contract manufacturing facility by the responsible person.
- **Cosmetic Product Categories Defined:** The draft guidance sets forth various cosmetic product categories and codes (e.g., baby products, eye makeup preparations, fragrance preparations) that industry should consult when registering facilities and listing products.
- **Allow Time to Obtain Facility Registration Number:** A facility will need to obtain a facility registration number (FDA Establishment Identifier (FEI)) from the FDA before starting its registration submission. Because a product listing submission must include the facility registration number for the facility manufacturing the cosmetic product, responsible persons subject to the listing requirement will need to obtain each facility's FEI before submitting their cosmetic product listing. Companies should build this advance step into their timelines for meeting the December 29, 2023, compliance date.
- **Disclosure of Registration and Listing Information:** The FDA will not disclose the product listing number, the brand names of cosmetic products manufactured or processed at a given registered facility or facilities, or the facility registration numbers referenced in a cosmetic product listing, per MoCRA. However, the FDA will make relevant information from registration and listing publicly available to the extent permitted by law.

The FDA requests that comments on the draft guidance be submitted by September 7, 2023 to ensure they are reviewed by the FDA before the draft guidance is finalized.

You can subscribe to future ***Food & Beverage Digests*** and advisories; ***FDA/Food, Drug & Device*** advisories; and other Alston & Bird publications by completing our **publications subscription form**.

If you have any questions or would like additional information, please contact your Alston & Bird attorney or anyone with our **FDA/Food, Drug & Device** or **Food, Beverage & Agribusiness** teams.

ALSTON & BIRD

WWW.ALSTON.COM

ATLANTA: One Atlantic Center ■ 1201 West Peachtree Street ■ Atlanta, Georgia, USA, 30309-3424 ■ +1 404 881 7000 ■ Fax: +1 404 881 7777
BEIJING: Hanwei Plaza West Wing ■ Suite 21B2 ■ No. 7 Guanghua Road ■ Chaoyang District ■ Beijing, 100004 CN ■ +86 10 8592 7500
BRUSSELS: Rue Guimard 9 et Rue du Commerce 87 ■ 3rd Floor ■ 1000 Brussels ■ Brussels, 1000, BE ■ +32 2 550 3700 ■ Fax: +32 2 550 3719
CHARLOTTE: 1120 South Tryon Street ■ Suite 300 ■ Charlotte, North Carolina, USA 28203-6818 ■ +1 704 444 1000 ■ Fax: +1 704 444 1111
DALLAS: Chase Tower ■ 2200 Ross Avenue ■ Suite 2300 ■ Dallas, Texas, USA, 75201 ■ +1 214 922 3400 ■ Fax: +1 214 922 3899
FORT WORTH: Bank of America Tower ■ 301 Commerce ■ Suite 3635 ■ Fort Worth, Texas, USA, 76102 ■ +1 214 922 3400 ■ Fax: +1 214 922 3899
LONDON: LDN:W ■ 6th Floor ■ 3 Noble Street ■ London ■ EC2V 7DE ■ +44 20 8161 4000
LOS ANGELES: 333 South Hope Street ■ 16th Floor ■ Los Angeles, California, USA, 90071-3004 ■ +1 213 576 1000 ■ Fax: +1 213 576 1100
NEW YORK: 90 Park Avenue ■ 15th Floor ■ New York, New York, USA, 10016-1387 ■ +1 212 210 9400 ■ Fax: +1 212.210.9444
RALEIGH: 555 Fayetteville Street ■ Suite 600 ■ Raleigh, North Carolina, USA, 27601-3034 ■ +1 919 862 2200 ■ Fax: +1 919 862 2260
SAN FRANCISCO: 560 Mission Street ■ Suite 2100 ■ San Francisco, California, USA, 94105-0912 ■ +1 415 243 1000 ■ Fax: +1 415 243 1001
SILICON VALLEY: 755 Page Mill Road ■ Building C - Suite 200 ■ Palo Alto, California, USA 94304-1012 ■ +1 650 838 2000 ■ Fax: +1 650 838 2001
WASHINGTON, DC: The Atlantic Building ■ 950 F Street, NW ■ Washington, DC, USA, 20004-1404 ■ +1 202 239 3300 ■ Fax: +1 202 239 3333