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# PART 2 IN MOCRA SERIES: FDA GUIDANCE ON FACILITY REGISTRATIONS

Aug 23, 2023

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) is significantly changing regulation of the cosmetics industry in the U.S. For the first time, cosmetics manufacturers and brand owners will need to register facilities with FDA, list products with FDA, and comply with specified requirements relating to safety substantiation, good manufacturing practices, adverse event reporting and recordkeeping, and product labeling. Notably, the definition of cosmetics is broad and includes many personal care products.

The FDA has provided a draft guidance, "Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry," that provides definitions and clarification on who needs to register as a facility, who needs to list their cosmetic products and what information needs to be provided.

In a prior post, we provided an overview of the new requirements under MoCRA. Today's post focuses on the facility registration requirements. In tomorrow's post, we provide more detailed information on providing product listings to the FDA.

## WHO MUST REGISTER AS A FACILITY?

MoCRA requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product[1] for distribution in the United States to register each facility with FDA. "Facility" means "any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States."

The Guide further defines "manufactures or processes" to mean "engaging 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."

While the facility registration requirement applies to foreign facilities, domestic and foreign establishments that solely perform labeling, relabeling, holding, distributing, packaging and repackaging (but not filling containers with product) are not required to register. Similarly, establishments such as retailers, retail distribution facilities, beauty shops and salons, pharmacies,

hospitals, physicians' offices, and health care clinics are also not required to register, so long as they do not manufacture or process cosmetic products.

Small businesses with average gross annual sales less than $1,000,000 for the previous 3-year period are exempt from the facility registration and product listing requirements, so long as they do not manufacture cosmetics that come in contact with the mucus membrane of the eye, are injected, are intended for internal use, or are intended to alter the appearance for more than 24 hours.

## WHAT INFORMATION MUST BE PROVIDED?

The first step in a facility submission is to obtain a facility registration number from the FDA. The Guidance specifies that the facility registration number will be the FDA Establishment Identifier (FEI). To learn how to request an FEI number or determine if an entity already has an FEI number, refer to the FDA's FEI Search Portal.

Once an FEI is obtained, the following information must be provided as part of a facility registration:

- the name of the owner and/or operator of the facility;
- the facility's name, physical address, email address, and telephone number;
- for a foreign facility, the contact for the United States agent of the facility (name and phone number), and, if available, the electronic contact information (email);
- all brand names under which cosmetic products manufactured or processed in the facility are sold;
- the product category or categories as listed in Appendix A of the Guidance and responsible person for each cosmetic product manufactured or processed at the facility; and
- type of submission (initial, amended, biennial renewal, or abbreviated renewal).

FDA also requests that the following additional optional information be submitted:

- parent company name (if applicable);
- facility DUNS Number; and
- additional contact information for individuals associated with the registration.

FDA requires that individuals submitting registration and listing information attest to the accuracy and veracity of the information submitted.

## HOW IS A FACILITY REGISTRATION SUBMITTED?

FDA is developing an electronic submission portal to streamline submission and receipt of registration and product listing information and expects the portal to be available in October 2023. Although FDA strongly encourages electronic submission, it is developing a paper form as an alternative . Both the electronic submission portal and the paper form will be accessible at the FDA website. There will not be any fee to submit a facility registration.

## WHEN MUST A FACILITY REGISTRATION BE SUBMITTED?

Initial facility registration is due no later than December 29, 2023. For companies that first started to manufacture or process a cosmetic product for distribution in the United States after December 20, 2022, the registration deadline is extended to February 27, 2024. Any changes to the registration information must be updated within 60 days. Registrations must be updated every two years. The electronic submission portal will allow updates and renewals to be made without re-entering all information.

## WHAT IF A PRODUCT IS BOTH A DRUG AND A COSMETIC?

A facility that manufactures or processes cosmetic products that are also drugs is not subject to the facility registration requirement under MoCRA unless it manufactures or processes cosmetic products that are not also drugs.

## WILL THE INFORMATION SUBMITTED VIA THE FACILITY REGISTRATION PROCESS BE PUBLICLY AVAILABLE?

FDA will not disclose information from a facility registration on the brand names under which cosmetic products manufactured or processed in the facility are sold in response to a request under the Freedom of Information Act (FOIA) (5 U.S.C. 552). All other information from facility registration submissions are subject to public disclosure.

*For questions or information, or to schedule a free webinar on complying with MoCRA, contact one of the authors listed.*

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[1] A "cosmetic" is defined as any "article[] intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and. . .articles intended for use as a component of any such articles." FDCA Sec. 201(i). The term "cosmetic product" means a "preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product." FDCA Sec. 604(2).

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