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# MoCRA Registration and Product Listing Enforcement Coming Before Year's End: Start Preparing Now

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The Modernization of Cosmetics Regulation Act's (MoCRA) **December 29, 2023** enforcement deadline for facility registration and product listing is fast approaching. On August 7, the U.S. Food and Drug Administration (FDA) posted [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for the Industry \(Draft\)](#) ("FDA draft guidance"). The FDA draft guidance revealed that the FDA intends to open the online submission portal for facility registration and product listing in October 2023. The FDA recently published [Electronic Submissions Portal Screenshots for Commenting September 2023](#), which provides step-by-step instructions for facility registration and product listing in the new FDA Cosmetics Direct online portal.

While cosmetic companies await final guidance from the FDA and the opening of the FDA Cosmetics Direct online portal, companies should be proactive in collecting the information required to complete their facility registrations and product listings.

## Facility Registration

Any establishment that manufactures or processes cosmetic products distributed in the United States is a cosmetic facility and **must be registered with the FDA by December 29, 2023**. Per the FDA draft guidance, "manufacturing or processing of a cosmetic product," is defined as "engaging in one or more steps in the making of any cosmetic product by chemical, physical,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."

Sections 607(a) and 607 (b)(2) of the Food, Drug and Cosmetics Act (FD&C) detail the information needed for the facility registration, but in the FDA draft guidance, the FDA also requested submission of the following optional information:

- Parent company name (if applicable);
- Facility DUNS Number; and
- Additional contact information for individuals associated with the registration.

#### Steps to Prepare for Facility Registration

- Determine if your cosmetic company manufactures or processes a cosmetic product per the definition in the FDA draft guidance.
- If so, obtain a FDA Establishment Identifier (FEI), visit [here](#) to check if your company already has a FEI or for information on how to obtain a FEI.
- If you are a foreign facility, engage a U.S. agent (if not already completed).
- Review records to identify all cosmetic brands manufactured or processed at your facility and the responsible person for those brands. If you cannot determine this information from your records, reach out to your vendors or business partners for clarification.
- Review your records and [Appendix A to the FDA draft guidance](#) to determine which product categories are manufactured/processed at your facility.

#### Product Listing

All responsible persons must provide a product listing for each cosmetic product that is commercially distributed. Under FD&C § 604(4), a responsible person is “the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product.” A cosmetic product listing is required for all cosmetic products unless the responsible person qualifies as a small business or the product in question is subject to Chapter V of FD&C (ex. cosmetic products with SPF).

FD&C § 607(c) details the information needed for the product listing, but in the FDA draft guidance, the FDA also requested submission of the following optional information:

- Parent company name (if applicable);
- Type of business (as listed on label, ex. manufacturer, packer, or distributor);
- Image of the label;
- Product webpage link;
- Whether the cosmetic product is for professional use only;
- Responsible person DUNS Number for address listed on product label;
- Unique Ingredient Identifiers (UNIs); and
- Additional contact information for individuals associated with the listing.

#### Steps to Prepare for Product Listing

- Identify if you are the responsible person for any cosmetic products.
- Identify all facilities involved in the manufacturing and processing of cosmetic products for which you are a responsible person.
- Reach out to all identified facilities to obtain their Facility Registration Number (when available).
- Collect information for all cosmetic products, including product category (as described in [Appendix A of the FDA draft guidance](#)) and list of ingredients (including any fragrances, flavors, or colors).
- Determine which cosmetic products have identical formulations, or formulations that differ only with respect to colors, fragrances or flavors, or quantity of contents.

MoCRA enforcement will be here before you know it. Start preparing today to make the transition as smooth as possible.

If you have any questions about MoCRA or compliance with FDA regulations, please any attorney with Frost Brown Todd's [Consumable Goods](#) team.

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***Frost Brown Todd's Consumable Goods team is closely watching the MoCRA regulations. For more coverage, click***

***below.***

***Modernization of Cosmetics Act of 2022 Overhauls FDA Regulation  
of the Cosmetics Industry***

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