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Practice Update

FDA Issues First Draft Guidance on MoCRA Registration and Listing of Cosmetic Product Facilities and Products

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On August 7, 2023, the Food and Drug Administration (FDA) published draft guidance regarding the registration and listing of cosmetic products, a new requirement under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). Under this requirement, cosmetic product manufacturers and processors must register their facilities with the FDA and renew these registrations every two years. In addition, a Responsible Person (a manufacturer, packer, or distributor of cosmetic product whose information appears on the label of the product) must list each marketed cosmetic product with the FDA, including product ingredients.

Industry members must register and list by December 29, 2023, and the FDA's draft guidance answers several important questions.

When and where? The FDA intends to make the new electronic submission portal for registration and listing available in October 2023 at https://www.fda.gov/.

How much are the fees? There will be no fees associated with registering and listing cosmetic facilities and products.

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Does a facility need to re-register and re-list if it participated in the voluntary cosmetics registration program? Yes. Information submitted to the FDA as part of its previous voluntary cosmetics registration program will not satisfy the registration and listing requirements under MoCRA, and those registrations and listings must be re-registered and re-listed under MoCRA's new requirements.

What is the first step toward registration and listing? The first step toward registration is to obtain an FDA Establishment Identifier (FEI). Owners and operators should work toward obtaining an FEI now if they do not already have one. The FEI will be used as the facility registration number and is a prerequisite to registering a facility. It is also a prerequisite to listing a cosmetic product, as the owner/operator of the facility will need to share the FEI with the Responsible Person so that the Responsible Person can list the cosmetic products.

In addition to the FEI number, the following information is required 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;
- with respect to any foreign facility, the contact for the United States agent of the facility (name and phone number) and, if available, the electronic contact information (email);
- the facility registration number, if any, previously assigned;
- all brand names under which cosmetic products manufactured or processed in the facility are sold;
- the product category or categories (refer to Appendix A in the draft 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).

And the following information is required to submit a product listing:

- the facility registration number of each facility where the cosmetic product is manufactured or processed;
- the name and contact number of the Responsible Person and the name for the cosmetic product, as such name appears on the label;
- the applicable cosmetic category or categories for the cosmetic product (refer to Appendix A in the draft guidance);
- a list of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by the name, or by the common or usual name of the ingredient;
- the product listing number, if any previously assigned; and
- type of submission (initial, update to content (annual), abbreviated renewal).

What Will Be Subject to Public Disclosure?

As described in the draft guidance, the public listing number will not be available to the public. In addition, information from a facility registration regarding the brand names for the products manufactured or processed at that facility or information from a product listing regarding the facility number where the products are manufactured will not be disclosed under the Freedom of Information Act (FOIA). However, the FDA's draft guidance states that the FDA intends to make "relevant information from cosmetic product facility registration and listing available to the public to the extent permitted by law."

Notably, the draft guidance did not address whether the list of ingredients, which is required to be

disclosed as part of a cosmetic product's listing under MoCRA, will be subject to disclosure. This ambiguity means that it is still yet unknown whether certain fragrance and flavor ingredients that may constitute trade secrets will be subject to public disclosure as part of the product listing process under MoCRA.

Comments on the Draft Guidance

Interested parties may submit comments on the FDA's draft guidance until September 8, 2023. If you have any questions or wish to submit a comment, please do not hesitate to reach out to our team members Felicia Leborgne Nowels or Li X. Massie.