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FDA's First Draft Guidance Under MoCRA:
Registration and Listing of Cosmetic Product Facilities and Products[1]

The FDA recently issued its first draft guidance addressing Registration and Listing of Cosmetic Product Facilities and Products (the "**Draft Guidance**"), as required under the Modernization of Cosmetics Regulation Act of 2022 ("**MoCRA**"). This summary provides an initial overview of the Draft Guidance and the steps that cosmetics manufacturers and processors should begin taking to ensure and/or prepare for compliance.

What is the purpose of the Draft Guidance?

The Draft Guidance provides recommendations to assist with the submission of cosmetic product facility registrations and of cosmetic product listings to the FDA and answers the following questions on the topic:

1. What are the MoCRA requirements for submission of cosmetic product facility registrations and product listings?
2. Who is responsible for complying with such requirements?
3. When is compliance required?
4. What information must be included in registration and listings?
5. How must such registration and listing submissions be made?

FDA is accepting both written and electronic comments on the Draft Guidance until September 7, 2023.

What does the Draft Guidance require, and who is responsible for compliance?

1. **"Facilities" must register.** Under MoCRA, registration is required of all non-exempt entities that own or operate any facility in which cosmetic products are manufactured or processed for distribution in the United States.

2. **"Responsible Persons" must list products.** Responsible Persons (i.e., brands) must submit (or ensure submission of) product listings for each cosmetic product marketed in the U.S. in connection with the applicable manufacturing Facility's registration.

Notable Exemptions and Exceptions:

Small Businesses. Certain small businesses are exempt from MoCRA's registration and listing requirements. Responsible persons and facilities may qualify as "small businesses" if they meet the following criteria:

- Average gross annual sales of cosmetic products in the U.S. for the previous three-year period is less than $1,000,000, adjusted for inflation; or
- Not engaged in manufacturing or processing of certain categories of cosmetic products, including cosmetic products that:
    - regularly come into contact with mucus membranes of the eye under customary or usual conditions of use;

[1] Prepared by Suzie Trigg, Kayla Cristales, and Kristi Weisner as of August 31, 2023, based on FDA's Draft Guidance regarding the Registration and Listing of Cosmetic Product Facilities and Products (Aug. 2023), issued under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). This summary is a follow-up to our initial overview of MoCRA, which contains additional information beyond the registration and listing topics covered in the Draft Guidance.

- are injected;
- are intended for internal use; or
- are intended to alter appearance for more than 24 hours under customary or usual conditions of use and where removal by the consumer is not a customary and usual condition of use.

"Cosmeticeuticals." A cosmetic product that also qualifies as a drug is not subject to MoCRA product listing requirements. Neither is a facility that manufactures or processes cosmetic products that are also drugs. But, MoCRA facility registration and product listing submissions can be made using the same electronic portal used to submit drug establishment registrations and drug product listings to the FDA, helping to streamline the process for responsible parties.

What key definitions/terms apply?

- **"Facility"** includes any establishment, including that of an importer, which manufactures or processes cosmetic products distributed in the United States, subject to certain exceptions, including (among others): beauty shops and salons; retailers (that do *not* also engage in manufacturing/processing); establishments that manufacture or process cosmetic products solely for use in research or testing; and establishments that solely label, relabel, package, repackage, hold, and/or distribute cosmetics.[2]

- **"Responsible Person"** means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of the FD&C Act or section 4(a) of the Fair Packaging and Labeling Act.

- **"Manufacturing or processing of a cosmetic product"** means 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.

The Draft Guidance also included an Appendix containing draft Cosmetic Product Categories and Codes, which will presumably be incorporated into the new registration/listing system, similar to FDA's analogous system for medical devices. For convenience, we have attached Appendix A to the Draft Guidance to this summary.

How does the use of contract manufacturers affect compliance responsibilities?

MoCRA defines a "contract manufacturer" as a facility that engages in one or more steps in manufacturing or processing a cosmetic product on behalf of another company. If a facility manufactures or processes cosmetic products on behalf of a responsible person, only a single registration is required for that facility, even if the facility is manufacturing or processing its own cosmetic products or is manufacturing or processing cosmetic products for more than one responsible person.

The responsible person whose products are manufactured or processed by another facility on their behalf (*i.e.*, a responsible person uses a contract manufacturer) may choose to submit that facility's (*i.e.*, the contract manufacturer's) registration. Though, careful contracting will be key in such cases, as facilities and responsible persons remain on the hook for registration and listing, respectively, under MoCRA.

What are the compliance deadlines for registration and listing?

Deadlines to submit the required cosmetic facility registration and product listing information depend on whether the submission is a first-time entry, an update, or a renewal, as well as whether the registrant-facility and products to-be listed were operational and on the market, respectively, as of or after MoCRA's enactment on December 29, 2022.

[2] In determining whether an establishment solely performs one or more of the activities listed, the terms "packaging" and "repackaging" do not include filling a container with a cosmetic product.

Submission Type	Compliance Deadline
Initial registration and listing for facilities and products in operation or on the market, respectively, as of 12/29/22	December 29, 2023
Initial registration for new facilities that started manufacturing of cosmetics after 12/29/22	Within 60 days of starting or by Feb. 27, 2027, whichever is later
Initial product listing for new cosmetics first-marketed on or after 12/29/22	≤ 120 days of later of 12/29/2023 and date of first-marketing
Updates to facility registrations	≤ 60 days of a change to required information
Updates to product listings	Annually
Renewal of facility registrations	Every 2 years

What information must be included with each submission?

Cosmetic Facility Registration. Facility registrations must contain the following information:

- Name of the owner and/or operator of the facility;
- Facility's name, physical address, email address, and telephone number;
- If applicable, the name and phone number for the U.S. agent contact of any foreign facility and, if available, the contact's electronic contact information (*i.e.*, email);
- Facility's previously assigned registration number, if any;
- All brand names under which the cosmetic products manufactured or processed in the facility are sold;
- The product category or categories and the responsible person for each cosmetic product manufactured or processed at the facility; and
- The type of submission (*e.g.*, initial submission, amended submission, biennial renewal, or abbreviated renewal).

FDA also requests submission of the following *optional* information:

- Parent company name, if applicable;
- The facility's Data Universal Numbering System (DUNS) number;
- Additional contact information for individuals associated with the registration; and
- Attestation to the accuracy and veracity of the facility registration information submitted.

Cosmetic Product Listing. Cosmetic product listings must contain the following information:

- Facility registration number for each facility where the cosmetic product is manufactured or processed;
- Name and contact number of the responsible person and the name for the cosmetic product as it appears on the label;
- The applicable cosmetic category or categories for the cosmetic product;
- A list of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by name or by its common or usual name;
- Any previously assigned product listing number, if assigned; and
- The type of submission (*e.g.*, initial submission, annual update, or abbreviated renewal).

FDA also requests submission of the following *optional* information:

- Parent company name, if applicable;

- Type of business, as listed on the label (*i.e.*, manufacturer, packer, or distributor);
- Image of the product label;
- Link to the product webpage;
- An indication of whether the cosmetic product is for professional use only;
- The responsible person's DUNS number for the address listed on the product label;
- The Unique Ingredient Identifiers (UNIIs);
- Additional contact information for individuals associated with the product listing; and
- Attestation to the accuracy and veracity of the product listing information submitted.

Is the information submitted by responsible persons made available to the public?

In response to a Freedom of Information Act (FOIA) request, FDA will not disclose what brand names are manufactured or processed in a facility from the facility's registration, nor will FDA disclose the facility registration number from a cosmetic product listing. All other information from cosmetic product facility registrations and product listings will be available for public disclosure under FOIA, FDA disclosure requirements, and other applicable federal law.

Does FDA charge a fee for submission of the information?

No. There is no fee to submit a facility registration or product listing to FDA under MoCRA requirements.

How are the required submissions made to the FDA?

FDA previously made a voluntary cosmetics registration program available to meet this need. However, the voluntary initiative ended as of March 27, 2023, and the information in the voluntary registration program will not be transferred to the new system. FDA strongly encourages responsible parties to use the new electronic submission portal starting October 2023, but an alternative paper form is also being developed. Both the electronic submission portal and the paper form, and the instructions for each, will be accessible on the FDA's website (once made available). General steps for submitting the information required are described below.

Electronic Cosmetics Facility Registration:

Before registering a facility, the owner or operator of the facility will need to obtain an FDA Establishment Identifier (FEI) if the facility does not already have one.

Electronic Cosmetic Products Listing:

Before submitting product listing, the owner or operator of the facility in which the product is manufactured or processed will need to register the facility and obtain the facility's registration number.

Notice that the last step for each is to print a copy of the submission for recordkeeping purposes. Responsible persons should incorporate submission deadlines into their procedures and training programs to ensure timely compliance with MoCRA requirements well in advance.

Finally, as noted above, brands and contract manufacturers, alike, should start carefully negotiating and/or updating manufacturing agreements to incorporate the above requirements and allocate responsibility and indemnification obligations accordingly in advance of the first compliance deadline (if you have not begun doing so already).

We will continue watching the FDA's website and will circulate an update to this summary upon FDA's issuance of a Final Guidance. In the meantime, contact Suzie Trigg, Kristi Weisner, Kayla Cristales with questions.

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