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Locke Lord QuickStudy: FDA Issues Draft Guidance on Facilities ?and Product Registration and Listing Under MoCRA

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On August 7, 2023, FDA issued a draft guidance document entitled *Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry* ("The Draft Guidance"), providing FDA's current thoughts on the requirements for facilities and product registration set forth in the Modernization of Cosmetics Regulation Act of 2022 ("MoCRA"). The Draft Guidance seeks comments from industry on FDA's interpretation of MoCRA's registration and listing provisions, as well as additional information FDA intends to seek during the registration and listing process that is not specifically enumerated in those provisions. FDA has requested any comments be submitted within thirty days to docket number FDA-2023-D-1716 on Regulations.gov.

When will the registration system be available?

The Draft Guidance notes that MoCRA requires all covered facilities and products to submit registration and listing information by no later than **December 29, 2023**. FDA intends to make the new electronic submission portal available in **October 2023**, as well as provide a paper form as an alternative submission tool on an unspecified date. (The Draft Guidance at 4.)

What facilities have to register?

MoCRA requires that any facility that manufacturers or processes cosmetics products distributed in the United States must register. FDA proposes several definitions that clarify this requirement in The Draft Guidance:

- Facility – any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States;
- Cosmetic Product – a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product; and
- Manufacturing or Processing of a Cosmetic Product – 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(The Draft Guidance at 4-6.)

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Are any facilities exempt from registration?

MoCRA exempts several types of facilities from registration:

1. Beauty shops and salons, unless such establishment manufactures or processes cosmetic products at that location;
2. Cosmetic product retailers, including individual sales representatives, direct sellers (as defined in section 3508(b)(2) of the Internal Revenue Code of 1986), retail distribution facilities, and pharmacies, unless such establishment manufactures or processes cosmetic products that are not sold directly to consumers at that location;
3. Hospitals, physicians' offices, and health care clinics;
4. Public health agencies and other nonprofit entities that provide cosmetic products directly to the consumer;
5. Entities (such as hotels and airlines) that provide complimentary cosmetic products to customers incidental to other services;
6. Trade shows and other venues where cosmetic product samples are provided free of charge;
7. An establishment that manufactures or processes cosmetic products that are solely for use in research or evaluation, including for production testing and not offered for retail sale;
8. An establishment that solely performs one or more of the following with respect to cosmetic products:

- Labeling,
- Relabeling,
- Packaging,
- Repackaging,
- Holding,
- Distributing.

Who has to register the facility?

The Draft Guidance notes that MoCRA requires the owner or operator of each facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility.

The Draft Guidance suggests that FDA will permit registration via at least two routes.

1. Registration directly by an owner or operator of a facility; or
2. Registration of a facility acting a contract manufacturer by a responsible person.

To clarify these roles, FDA proposes the following definitions of operator, owner, contract manufacturer, and responsible person.

- Operator – a person or company who has management authority over an establishment;
- Owner – a person or company who has an ownership interest in an establishment;
- Contract Manufacturer – a facility that engages in one or more steps in manufacturing or processing a cosmetic product on behalf of a company; and
- Responsible Person – the manufacturer, packer, or distributor of a cosmetics product whose name appears on the label of such cosmetic product in accordance with section 609(a) of the Food, Drug, and Cosmetics Act ("FDCA") or section 4(a) of the Fair Packing and Labeling Act.

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FDA also advises that regardless of whether an owner, operator, or responsible person registers a facility, only a single registration will need to be filed for a facility.

(The Draft Guidance at 7.)

What products have to be listed and by whom?

MoCRA requires the responsible person to register all cosmetic products. Appendix A of The Draft Guidance identifies the various categories of cosmetic products that FDA expects will be listed and provides codes for identifying those categories in registration and listing documents.

Are any operators or owners exempt from registration and listing requirements?

MoCRA exempts two types of owners or operators from facility registration and product listing requirements.

- "Small Business" – a company whose average gross annual sales in the U.S. of cosmetics products from the previous three-year period is less than $1 million adjusted for inflation need not register its facilities or products, unless the facility manufactures cosmetic products:
  - that regularly come into contact with the mucus membrane of the eye under conditions of use that are customary or usual;
  - that are injected;
  - that are intended for internal use; or
  - that are intended to alter appearance for more than twenty-four hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual.
- "Drug manufacturers" – a company that only manufactures or processes cosmetic products that otherwise would qualify as drugs under chapter V of the FDCA need not register its facilities or list its products, unless the facility manufactures or processes any cosmetic product that would not qualify as a drug.

What information will a facilities registration need to include?

MoCRA enumerates several pieces of information that will be required in a facilities 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 and responsible person for each cosmetic product manufactured or processed at the facility; and
- type of submission (initial, amended, biennial renewal, or abbreviated renewal).

The Draft Guidance proposes that the facility registration number be the same as the FDA Establishment Identifier ("FEI") for that facility. If the facility does not already have a FEI, the owner or operator will need to apply for one

through FDA's electronic portal before submitting the registration. FDA also proposes that product categories be provided using the number codes identified in Appendix A of The Draft Guidance.

In The Guidance Document, FDA has also requested that the registration include:

- parent company name (if applicable);
- facility DUNS Number available from Dun & Bradstreet;
- additional contact information for individuals associated with the registration; and
- an attestation as to accuracy and veracity of the information being submitted made by the individuals responsible for the submission.

(The Draft Guidance at 7-8.)

What information will a product listing need to include?

MoCRA requires certain information to be present in any product listing. A single listing submission for a cosmetic product may include multiple cosmetic products with identical formulations, or formulations that differ only with respect to colors, fragrances or flavors, or quantity of contents as long as the following information is present:

- 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;
- a list of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by the name, as required under section 701.3 of title 21, Code of Federal Regulations (or any successor regulations), 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).
- The Draft Guidance proposes that facility registration number and cosmetic category information mirror the format used when making the associated facility registration.

In The Guidance Document, FDA has also requested that the registration include:

- parent company name (if applicable);
- type of business (as listed on the label), i.e., 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;
- FDA's Unique Ingredient Identifiers (UNIIs);
- additional contact information for individuals associated with the listing; and
- an attestation as to accuracy and veracity of the information being submitted made by the individuals

responsible for the submission.

(The Guidance Document at 8-9.)

Will all of the information submitted in facilities registrations and product listings be made public?

The Guidance Document proposes that FDA will keep confidential: (1) the product listing number; (2) brand names identified in a facility registration; and (3) facility registration number identified in a product listing. With respect to a FOIA request for any other information contained in a facility registration or product listing, FDA will consider what information may be considered confidential or may be publicly released under its current regulations and other applicable federal laws such as federal trade secret laws.

What's the next step?

If you or your company have questions or concerns about FDA's proposals in The Draft Guidance, please contact Sharon Blinkoff and Locke Lord's FDA Regulatory and Cosmetics and Personal Care teams. We have experience assisting with both navigating FDA's registration systems and providing comments on pending regulations and guidance documents.

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