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PART 3 IN MOCRA SERIES: FDA GUIDANCE ON COSMETIC PRODUCT LISTINGS

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The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) is is the most significant expansion of FDA's authority to regulate cosmetics since the Federal Food, Drug, and Cosmetic (FD&C) Act was passed in 1938.

As we previously reported, MoCRA requires for the first time that cosmetics manufacturers and brand owners must 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The FDA has provided a draft guidance, "Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry," that provides definitions and clarification on who needs to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 our first post, we provided an overview of the new requirements under MoCRA. Our next post focused on FDA's facility registration requirements. In today's post, we provide more detailed information on providing product listings to the FDA.

WHO MUST SUBMIT PRODUCT LISTINGS?

MoCRA requires that by December 29, 2023, the "responsible person" listed on the label of each cosmetic product must submit product listings to FDA. "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.

WHEN ARE COSMETIC PRODUCT LISTINGS DUE?

The responsible person for a cosmetic product that is being sold as of December 29, 2022 must submit a cosmetic product listing no later than December 29, 2023. For cosmetic products that are

first marketed after December 29, 2022, the deadline is 120 days after the product is first sold in interstate commerce or 120 days after December 29, 2023, whichever is later. Updates must be provided annually, including any update that the product has been discontinued. The electronic submission portal will allow updates and renewals to be made without re-entering all information.

WHAT INFORMATION MUST BE SUBMITTED?

The following information must be submitted as part of a cosmetic product listing:

- the facility registration number of each facility where the cosmetic product is manufactured or processed (for exempt facilities, the facility name and address can be provided instead);
- 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 as specified in Appendix A of the Guide;
- 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 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, or abbreviated renewal).

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.

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

- 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;
- Unique Ingredient Identifiers (UNIIs) ; and

- additional contact information for individuals associated with the listing.

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

HOW ARE COSMETIC PRODUCT LISTINGS SUBMITTED?

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

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

A cosmetic product that is also a drug is not subject to the listing requirements under MoCRA.

WILL THE INFORMATION BE PUBLICLY AVAILABLE?

FDA will not disclose the product listing number or the facility registration number of the facility where the cosmetic product is manufactured or processed in response to a request under the Freedom of Information Act (FOIA) (5 U.S.C. 552). All other information from a cosmetic product listing is subject to public disclosure.

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

RELATED PRACTICE AREAS

- Retail & Consumer Products

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