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# FDA Issues Draft Guidance on Facility Registration under MoCRA

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The U.S. Food and Drug Administration (FDA) issued draft guidance for industry on the registration and listing of cosmetic products under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) on August 7, 2023. The draft guidance provides details on the submissions process, including the information required and who is responsible for the submission. FDA is accepting comments **until September 7, 2023**. In addition, FDA seeks applications from interested parties to participate in a pilot program to test and evaluate the electronic submission portal. 88 Fed. Reg. 53499. Applications are due **August 22, 2023**, testing will be initiated near **September 15, 2023,** and it will last approximately two weeks.

## Background

On December 29, 2022, Congress passed, and President Biden signed MoCRA into law. MoCRA is the first major amendment to FDA's cosmetics authorities since President Franklin Delano Roosevelt signed the Federal Food, Drug, and Cosmetic Act (FFDCA) into law in 1938. MoCRA seeks to ensure that cosmetic products are safe for their intended use and provides FDA more enforcement authority. This authority includes mandatory recall, if it determines there is a reasonable probability that a cosmetic is adulterated or misbranded, as this would result in a serious adverse event. MoCRA also introduces mandatory facility and product registration, a process that has, until now, been entirely voluntary. This draft guidance provides insights into FDA's current thinking on the mandatory facility and cosmetic product registration.

## Overview of the Draft Guidance

In the draft guidance, FDA defines *facility* to include importers and manufacturers that process cosmetic products. FDA excludes from this definition, among other entities, establishments that label, re-label, pack, re-pack, hold, or distribute cosmetic products, unless packaging and repackaging includes filling the product container with a cosmetic product. FDA defines cosmetic products as "a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product." Under MoCRA, FDA "requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility." Small business provisions are detailed in this guidance. Small businesses are defined as "responsible persons, and owners and operators of facilities, whose average gross

annual sales in the U.S. of cosmetic products for the previous 3-year period is less than $1,000,000, adjusted for inflation, and who do not engage in the manufacturing or processing of certain cosmetic products." The cosmetic products that FDA excludes from the small business definition are the following:

- Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual;
- Cosmetic products that are injected;
- Cosmetic products that are intended for internal use; or
- Cosmetic products that are intended to alter appearance for more than 24 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.

Facility registration involves providing FDA with basic details for each facility, including the location address, contact names, brand names for the cosmetic products sold, the category or categories for each product, the Data Universal Numbering System (DUNS) number for the location, and the type of submission. FDA expects that every person subject to facility registration will renew on a biennial basis. FDA, in Appendix A to the draft guidance, provides the cosmetic product categories and codes.

Facility registration includes the requirement to provide cosmetic product details. The product listing for each facility, involves providing FDA with the following:

- The facility registration number (*i.e.*, the FDA establishment identifier (FEI) obtained from FDA prior to submitting the facility registration) 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 21 C.F.R. Section 701.3 or equivalent;
- The product listing number, if any previously assigned;

- Type of submission;
- Type of business;
- An image of the label;
- A link to the product web page;
- Whether the cosmetic product is for professional use only;
- A responsible person DUNS Number for the address listed on the product label;
- Unique Ingredient Identifiers (UNII); and
- Additional contact information for individuals associated with the listing.

FDA requires an attestation that the information provided for both the facility and products listing is accurate. FDA expects updates to the product listing annually, including information on discontinued products.

In addition, FDA notes that product listing number and details related to facility registration will not be disclosed, including disclosure in response to a request under the Freedom of Information Act (FOIA).

There is no fee for registration.

## Commentary

MoCRA will fundamentally alter how cosmetic products are managed by FDA. Facility and product registration is the first major requirement, and MoCRA established that this process be completed no later than one year from its enactment (*i.e.*, **December 29, 2023**). With FDA issuing draft guidance in August, with 30 days to comment, is within the one-year mandate but does not allow much time for those subject to the registration to collect and complete submission. Importantly, a key piece of the process, the submission portal, is not yet available. FDA includes in the *Federal Register* notice, an opportunity for parties to apply to participate in acceptance testing of the electronic submission portal, but the tight deadline of **August 22, 2023,** for the applications will make it difficult to recruit participants. FDA notes that it intends to initiate acceptance testing on or about **September 15, 2023**, with a two-week duration for testing. It is likely that the submission portal will not be available for facility and product registration until **late 2023**. The draft guidance does give stakeholders insight into the level of detail that will be required and an opportunity to comment before **September 7, 2023**. Product listings include a significant amount of detail, and pulling that information together now will help to alleviate burdens for a potentially rushed submission timeline later this year.

Contract manufacturers should consider if and how this facility and product registration applies to their operations. FDA discusses this nuance in its draft guidance and expects that if the responsible person submits the registration, the contract manufacturer is no longer obligated. These business arrangements and regulatory burdens need to be sorted prior to submission to ensure deadlines are met.



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