

# Cosmetic Regulation: Update on U.S. FDA Registration and Listing, and Serious Adverse Event Reporting

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*December 28, 2023*

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) is the most significant expansion of U.S. Food and Drug Administration (FDA) authority to regulate cosmetics since passage of the Federal Food, Drug, and Cosmetic Act (FDCA) Act in 1938. Although MoCRA directed FDA to implement many provisions by the end of 2023, FDA has extended the deadline for registration and listing requirements. FDA also issued a guidance on Serious Adverse Event reporting with which companies must begin to comply by year's end. Here are some of the most recent end-of-year announcements to keep you up to date as we turn the calendar to 2024.

## Registration and Listing of Cosmetic Facilities and Products

- MoCRA requires certain companies that “engage[] in the manufacturing or processing of a cosmetic product for distribution in the United States” to register each facility with FDA and requires every cosmetic product to be listed with FDA; certain small business and other exemptions may apply. On November 8, 2023, FDA issued guidance for industry entitled “[Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing](#),” which stated that FDA does not intend to enforce the MoCRA registration and listing requirements until July 1, 2024, thus extending the deadline for industry to comply.
- On December 18, 2023, FDA issued [Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products](#). This guidance provides definitions and details for registering facilities and listing cosmetic products with FDA, with specifics on registration and listing amendments and renewals, including when a product is also a drug. It is worth noting that this guidance includes requests for information that FDA would like companies to submit but which is not required under MoCRA, such as parent company name, type of company, DUNS number, image of the product label, Unique Ingredient Identifiers, and product webpage link. It provides a list of product categories and a Q&A section with answers to some specific cosmetic product questions. There are also discussion points regarding the responsible party for purposes of registration and listing and further information for importers and testing laboratories.
- Finally, on December 18, 2023, FDA announced the launch of the [Cosmetics Direct](#) electronic submission portal. The portal is an expansion of the Center for Drug Evaluation and Research (CDER) web-based and free structured product labeling authoring tool, known as CDER Direct.

FDA states that users can create separate accounts for drugs versus cosmetics or a single account to include both.

- Takeaway: While registration and listing obligations will not be immediately enforced, it is important to become familiar with Cosmetics Direct and the information needed for registration and listing, particularly companies with extensive lines of product.

### **Serious Adverse Event Reporting for Cosmetics**

- MoCRA also requires the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of that product (per § 609(a) of the FDCA or § 4(a) of the Fair Packaging and Labeling Act) to report certain serious adverse events to FDA within 15 business days of becoming aware of the event. A serious adverse event is defined as an adverse event that
  - (A) results in
    - death;
    - a life-threatening experience;
    - inpatient hospitalization;
    - a persistent or significant disability or incapacity;
    - a congenital anomaly or birth defect;
    - an infection; or
    - significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance) other than as intended under conditions of use that are customary or usual; or
  - (B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in (A) above.
- The reporting requirement becomes effective beginning December 29, 2023.
- On December 14, 2023, FDA issued “[Updated Instructions for Serious Adverse Event Reporting for Cosmetic Products](#)” (SAE Update). As noted in the SAE Update, FDA revised the instructions for MedWatch Form 3500A to make it easier to submit serious adverse events for cosmetic products. The MedWatch Form 3500A is the current mechanism for industry to use for submission of these events. FDA is working on an electronic process for submitting serious adverse events, as required by MoCRA.
- MedWatch Form 3500A can be downloaded and completed at [MedWatch: The FDA Safety Information and Adverse Event Reporting Program — Mandatory \(PDF\)](#). The form, along with information to support the report, such as scans of labels and images of the serious adverse event, can be submitted to FDA through either email or regular mail.
- Takeaway: If not completed already, companies should develop a Standard Operating Procedure for implementing the MoCRA requirement for serious adverse reporting and begin training employees. The law applies to adverse events received from any source, so it is important for all

employees to understand their obligations to report information regarding adverse events internally through the proper channels.

## CONTACTS

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work, or

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