FDA Regulatory & Compliance Alert

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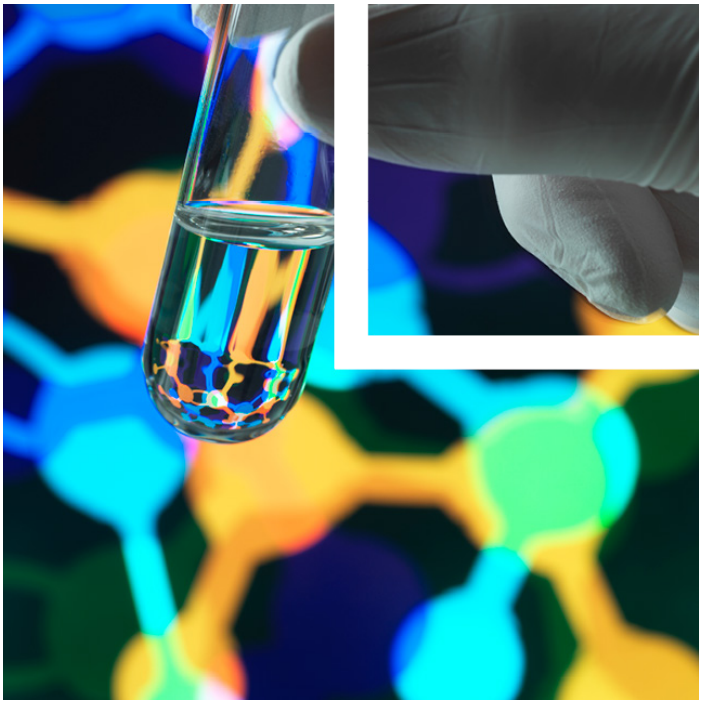
MoCRA Increases FDA Oversight of the Cosmetics Industry



For the first time in 80 years, sweeping new legislation has been enacted to update the U.S. Food and Drug Administration's (FDA) regulatory oversight of the cosmetic products industry. Signed into law on Dec. 29, 2022, the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) creates a comprehensive regulatory framework that imposes new FDA registration and listing requirements, labeling rules, enforcement authority, and good manufacturing practices (GMP) requirements, among other regulatory obligations, on cosmetic manufacturers. MoCRA represents the first substantial cosmetics-related amendments to the Food, Drug, and Cosmetic Act (FDCA) since its enactment in 1938.

The legislation, which is included at Section 3501 of the Food and Drug Omnibus Reform Act of 2022 (FDORA) as part of the Consolidated Appropriations Act, 2023, brings the FDA's authority over the beauty and personal care sector more in line with other categories, including drugs, devices and foods, the agency oversees. It does so largely by requiring cosmetic manufacturers to register their facilities and list their products, thereby putting such entities and products on the FDA's radar. The FDA also increases its oversight of cosmetic safety by requiring adverse event reporting, GMP and recordkeeping requirements.

As explained below, cosmetic manufacturers should not delay considering compliance with MoCRA, as the act takes effect on Dec. 29, 2023, and will require facility registration and product listing by this date.

Registration and Listing Requirements

The FDA, for the first time, will impose facility registration and product listing requirements on the cosmetic industry.

Compliance with registration and listing requirements is required by Dec. 29, 2023—one year after the enactment of the law:

- **Facility registration**. MoCRA requires registration of each facility (domestic or foreign) that "manufactures or processes" cosmetic products for distribution in the U.S. Retailers, salons and private label distributors, among others that do not engage in such activities, do not need to register their facility. Compliance by existing facilities is required by Dec. 29, 2023. New facilities that begin manufacturing cosmetic products after the law takes effect will have 60 days to register after commencing operations. Registration must be renewed biennially thereafter.
- **Product Listing**. MoCRA requires that the responsible person for each cosmetic product offered for distribution in the U.S. provides the FDA with listing information for the product, including an ingredient list and the name/place of business of manufacture. Under the law, a "responsible person" means the manufacturer, packer or distributor of a cosmetic product whose name appears on the label of the product. Compliance for existing cosmetic products is

required by Dec. 29, 2023. For new products marketed after the law's effective date, manufacturers have 120 days after marketing has commenced in interstate commerce. Listings must be updated annually.

Adverse Events—Recordkeeping and Reporting

MoCRA outlines recordkeeping and reporting requirements related to adverse events for cosmetic product manufacturers. Manufacturers must maintain records of all health-related "adverse events" (defined as "any health-related event associated with the use of a cosmetic product that is adverse") for six years, or three years for small businesses. Additionally, manufacturers must report to the FDA any serious adverse event within 15 business days after receiving information concerning such event. Notably, the MoCRA adds to the FDA's current definition of a "serious adverse event" to include any event resulting in "significant disfigurement, including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance."

In addition, a cosmetic product manufacturer must give the FDA access to records relating to a product when the agency "reasonably believes the product presents a threat of serious adverse health consequences."

Labeling, Safety and GMP

- **Cosmetics product safety substantiation**. Manufacturers must maintain records demonstrating that adequate substantiation of U.S. safety standards has been met. Under MoCRA "adequate substantiation" of safety standards is defined as tests, studies, research, analyses or other evidence considered by qualified scientific experts that support the reasonable certainty a cosmetic product is safe.
- **Fragrance allergens disclosures**. Labels for cosmetics products used by both consumers and professionals must list each fragrance allergen included in the product. Professionals are defined as individuals licensed by the state to practice cosmetology, nail care, barbering or esthetics. The FDA will implement a regulation that determines the substances considered fragrance allergens under MoCRA. The agency will issue a notice of proposed rule-making within 18 months after the date of MoCRA's enactment.
- **GMP**. While the cosmetic industry has historically relied on nonbinding guidance from the FDA related to GMP, MoCRA directs the FDA to issue binding regulations governing GMP for cosmetic manufacturers by Dec. 29, 2025—within two years of the law's enactment date. As with other regulated product categories, the GMP requirements will permit the FDA to inspect cosmetic manufacturing facilities for GMP compliance. MoCRA also allows more simplified GMP regulations governing small businesses, as defined below.

Enforcement of MoCRA

MoCRA supersedes state and local laws governing cosmetic product safety. The FDA has the authority to recall potentially harmful cosmetic products and suspend a manufacturing facility's distribution of the product.

- **Preemption**. MoCRA preempts all state and local laws that differ from it regarding cosmetic product registration, listing, GMP, records, recalls, adverse event reporting and safety substantiation. However, MoCRA does not prevent states from prohibiting the use or limiting the amount of a cosmetic product ingredient or from continuing a requirement that was in effect at the time MoCRA was enacted for reporting to the state an ingredient in a cosmetic product.
- **Mandatory recall authority**. The FDA may recall a cosmetic product if it determines that the product either
  - Is adulterated
  - Is misbranded
  - Will cause serious adverse health consequences or death
- If the FDA determines a cosmetic product must be recalled, the agency must first give the manufacturer the opportunity to voluntarily cease distribution and recall the product itself. If the manufacturer refuses to so or refuses to do so within the time frame set by the FDA, the agency may order the manufacturer to immediately cease distribution of the cosmetic product at issue. In conducting a recall, the FDA will notify the public through press releases and public notices, as appropriate.

- Facility suspension. The FDA may suspend a manufacturer's registration of a cosmetics product if the agency reasonably believes the product could cause serious adverse health consequences.

Additional MoCRA Provisions

MoCRA also provides guidance in additional areas:

- Small businesses. MoCRA defines small businesses as having average gross annual sales of certain cosmetic products in the United States for the previous three-year period of less than $1 million. These small businesses are not subject to the requirements of Section 606 – Good Manufacturing Practice and Section 607 – Registration and Product Listing.
- Trade secrets. The FDA will ensure that effective procedures are in place to prevent the unauthorized disclosure of any trade secret or confidential commercial information that is obtained during the enforcement of MoCRA's provisions.
- Animal testing. MoCRA notes that Congress believes that the safety of cosmetics products should not be tested on animals and that animal testing, "with the exception of appropriate allowances," should be phased out.
- Funding. For fiscal year 2023, $14.2 million is allotted to conduct activities specified by MoCRA, including hiring personnel. For fiscal year 2024, $25.96 million is allotted, with $41.89 million allotted for each of fiscal years 2025 through 2027.

Related Professional

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