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Practice Update

# New FDA Regulatory Framework for Cosmetics: The Modernization of Cosmetics Regulation Act of 2022 (MoCRA)

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The highly anticipated cosmetic regulatory overhaul, Modernization of Cosmetics Regulation Act (MoCRA), was signed into law on December 29, 2022, ushering heightened regulatory oversight of cosmetic products and facilities. MoCRA is the first major update to the Food and Drug Administration's (FDA) cosmetics authorities since 1938, and amends Chapter VI of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to include new provisions for cosmetic products. MoCRA enhances FDA's regulatory jurisdiction and enforcement of cosmetics. MoCRA covers a wide range of personal care and beauty products, including hair and hair removal products, makeup, nail products, soaps and lotions, and tanning products.

MoCRA now requires cosmetic manufacturing facility registration and product listing. It implements new labeling requirements, and imposes current good manufacturing requirements, adverse events reporting and record keeping compliance. To meet MoCRA's new requirements, cosmetic companies should start looking toward registration and listing, and implementing compliance programs in advance of MoCRA's December 29, 2023, effective date.

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Cosmetic companies may also want to participate in the FDA's solicitation of public comments on the Current Good Manufacturing Practice Requirements, fragrance allergens, and testing for talc-containing cosmetics. Cosmetic companies will also have opportunities to provide feedback on the use and safety of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in cosmetic products. In addition, because the FDA may leverage enforcement provisions before December 29th, such as the FDA's authority to inspect cosmetic records or mandate cosmetic recalls, companies should consider overall compliance early.

Overall, MoCRA brings cosmetics regulation into greater alignment with other FDA-regulated products. This practice update summarizes the key provisions of MoCRA.

## 1) Mandatory Facility Registration

Cosmetic manufacturing facilities, no matter where they are located in the world, that manufacture or process cosmetic products for U.S. distribution must register with the FDA to lawfully market cosmetic products. In registering, foreign facilities must identify a U.S. agent.

Note the exception that facilities that solely perform labeling, relabeling, packaging, repackaging, holding, and/or distributing cosmetic products need not register. However, facilities that perform "packaging" and "repackaging" by filling a product container with a cosmetic product must register. Other establishments excluded from the mandatory facility registration include establishments that manufacture or process cosmetic products that are solely for use in research or evaluation, including for production testing, and not offered for retail sale, and establishments that manufacture cosmetic ingredients but not cosmetic products.

Existing facilities must register within one year after MoCRA's date of enactment. Any new facility must

register within 60 days after beginning to manufacture cosmetics, or 60 days after the deadline for registering existing facilities, whichever is later. All registrations must be renewed biennially.

## 2) Product Listing

MoCRA does not include a premarket approval requirement for cosmetics. However, "responsible persons" (i.e. manufacturers, packers or distributors of a cosmetic product whose name appears on the label) are required to list each cosmetic product with the FDA. Each product listing must include information about the place of manufacture, the cosmetic category, the product's ingredients (including any fragrances, flavors, or colors), and the product listing number. Cosmetic products that are identical but for their color, fragrance, flavor, or quantity of contents may be listed under a single listing.

Responsible persons must submit existing product listings no later than one year after enactment. New products marketed after MoCRA's enactment must be listed within 120 days of marketing. Listings must be updated annually.

## 3) Current Good Manufacturing Practice Requirements (CGMPs)

MoCRA directs the FDA to establish good manufacturing practice regulations consistent with national and international standards. The FDA will issue a proposed rule within two years of the enactment, and a final rule within three years after the enactment. Cosmetic products manufactured or processed under conditions that do not meet the CGMPs will be deemed adulterated.

## 4) Adverse Event Reporting

Like other industries that the FDA regulates, cosmetic companies will have to maintain records of any health-related adverse events associated with the use of the product for six years. In addition,

cosmetic companies must report to the FDA any serious adverse events within 15 days of learning about the issue. MoCRA broadens the scope of what constitutes a serious adverse event to include 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." Records related to each report of an adverse event must be maintained for 6 years, unless a small business exception applies. Additionally, product labeling must identify a US point of contact for adverse event reporting.

## 5) Records Access and Inspections and Safety Substantiation

Cosmetic products and ingredients must be adequately substantiated for safety before marketing in the U.S. Adequate substantiation of safety includes tests or studies, research, analyses, or other information that is considered among experts to be sufficient to support a reasonable certainty that a cosmetic product is safe. Cosmetic products that do not have adequate safety substantiation will be considered adulterated.

The FDA now has the authority to access the required adverse event records during an inspection pursuant to section 704. If the FDA has reasonable grounds to believe that an ingredient or combination of ingredients in a fragrance or flavor has caused or contributed to a serious adverse event required to be reported under MoCRA, the FDA may request a list of such ingredients or categories of ingredients in the specific fragrances or flavors in the cosmetic product. The cosmetic company must provide the requested information within 30 days of such request.

## 6) Labeling

MoCRA requires cosmetic product labels to include the domestic address, domestic telephone number,

or electronic contact information through which the cosmetic company can receive adverse event reports. Professional cosmetics products must meet the same labeling requirements as cosmetic products intended for sale to consumers and must state that only licensed professionals may use the product. Lastly, after public comments and the FDA's issuance of a fragrance allergen rule, MoCRA will require cosmetic labels to identify each fragrance allergen in a product. Products that fail to include the fragrance allergen disclosure will be considered misbranded.

The labeling requirement will take effect at the end of 2024.

## 7) Enforcement

MoCRA provides three new enforcement powers to the FDA. First, if the FDA determines that a cosmetic product manufactured by a facility has a reasonable probability of causing serious adverse health consequences or death to humans, and other products manufactured by the facility may be similarly affected, the FDA may suspend that facility's registration. Suspension of the facility's registration prevents the facility from operating.

Second, the FDA now has the authority to access records relating to a cosmetic product if it reasonably believes that a product or its ingredients are adulterated and present a threat of serious adverse health consequences. The FDA may also request a list of ingredients in the fragrances or flavors in a product if it believes that a fragrance or flavor contributed to a serious adverse event.

Third, the FDA may mandate recalls if it determines there is a reasonable probability that cosmetic is adulterated or misbranded and exposure to the product will cause serious adverse health consequences or death.

## 8) Small Business Exemptions

The exemptions offer small businesses flexibility, simplified requirements, and a longer compliance period. For example, certain small businesses may be exempt from CGMP, facility registration, and product listing requirements. And as for the event records retention, some small businesses will need to maintain records for only three years rather than six years.

## 9) Preemption

Although MoCRA will not become effective until December 29, 2023, MoCRA's preemption provision will take effect immediately. Under the preemption provision, MoCRA will preempt any state or local laws that differ from the federal framework. The FDA, states and courts, and other federal administrations will interpret MoCRA's preemption provision.

## Cosmetic Companies' Take-Aways and Next Steps

Cosmetic manufacturing facilities and responsible persons should plan for facility registration and product listing before December of 2023. Moreover, cosmetic companies should also review MoCRA's requirements related to product safety substantiation, CGMP compliance, adverse events reporting, record keeping, and labeling. As the FDA is scheduled to initiate rule making on these key areas of compliance, cosmetic companies should expect more guidance and specific regulations in the coming years.

Cosmetic companies should take the time now to review their products, policies and procedures to ensure compliance with MoCRA and responsiveness to the additional regulations that the FDA will be implementing.

If you have questions on how MoCRA may affect your business, or are seeking guidance on the new cosmetic regulatory framework, contact your

Akerman Government Affairs and Public Policy FDA attorney.

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