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# Modernization of Cosmetics Regulation Act of 2022: What You Need to Know

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On December 29, 2022, President Biden signed into law the Consolidated Appropriations Act, 2023, which includes the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). MoCRA significantly changes the current regulatory framework for cosmetics in place since the enactment of the Federal Food, Drug, and Cosmetic Act (FD&C Act) in 1938.

Under MoCRA, cosmetic companies will be subject to facility registration and product listing requirements, good manufacturing practices (GMPs), serious adverse event reporting and recordkeeping, and safety substantiation. Furthermore, MoCRA grants the U.S. Food & Drug Administration (FDA or Agency) the authority to order a mandatory recall of a cosmetic product and to suspend a facility registration if FDA determines there are serious adverse health concerns.

MOCRA's key provisions are outlined below.

## Facility Registration and Product Listing

Each facility (domestic and foreign) that engages in the manufacturing or processing of a cosmetic product for U.S. distribution must register with the FDA no later than one year after the enactment of MoCRA, which is December 29, 2023. After the one-year registration deadline, new facilities must register with FDA within 60 days of initiating manufacturing or processing operations. Establishments that solely perform labeling, relabeling, packaging or repackaging of cosmetic products are not required to register with the FDA. Furthermore, facility registrations must be renewed biennially, and FDA must be notified within 60 days of any changes to information that is required to be submitted as part of registration. Note that foreign facilities must have a U.S. Agent.

A "responsible person" also must list each cosmetic product, including its ingredients, with FDA no later than December 29, 2023. "Responsible person" is defined as the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label. For products marketed after the enactment of MoCRA, a responsible person must submit the product listing within 120 days of

marketing. Additionally, the responsible person must update product listing information annually.

## Good Manufacturing Practices

Under MoCRA, FDA is required to promulgate GMP regulations for cosmetic manufacturing and processing facilities. The regulations must be consistent with national and international standards. The regulations must also be intended to protect the public health and ensure that the cosmetic products are not adulterated. Furthermore, FDA may promulgate regulations that would allow the Agency to inspect records necessary to demonstrate compliance with GMP.

In establishing GMP regulations, FDA must take into account the size and scope of the businesses engaged in the manufacture of cosmetics and the risks to public health posed by such cosmetics. Additionally, FDA must provide sufficient flexibility to be practicable for all sizes and types of facilities to which such regulations will apply. These regulations must also include simplified GMP requirements for smaller businesses and should not impose undue economic hardship for these businesses.

FDA is required to issue a proposed rule within two years after enactment of MoCRA, and a final rule no later than three years after such date of enactment.

### Serious Adverse Event Reporting and Recordkeeping

A responsible person must report to FDA any “serious adverse event” associated with the use, in the United States, of a cosmetic product manufactured, packed or distributed by the responsible person within 15 business days after it is received. Additionally, for one year after the initial submission, the responsible person must submit to FDA within 15 business days of receipt any new and material medical information related to the initial report. A “serious adverse event” is defined as an adverse health-related event associated with the use of a cosmetic product that 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.

The responsible person is required to include on the label of the cosmetic product the domestic address, domestic telephone number, or electronic contact information in order to receive reports of adverse events.

The responsible person must maintain records related to each report of an adverse event associated with the domestic use of a cosmetic product manufactured, packed or distributed by the responsible person for six years. Certain small businesses only have to maintain such records for a period of three years.

### Safety Substantiation

A responsible person must ensure and maintain records supporting that there is adequate substantiation of safety of the cosmetic product. “Adequate substantiation of safety” is defined as tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe. Under MoCRA, “safe” means that the cosmetic product is not injurious to users under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual. Additionally, the

law specifies that a cosmetic ingredient or cosmetic product is not injurious to users solely because it can cause minor and transient reactions or minor and transient skin irritations in some users.

In determining whether a product is safe, the FDA can consider the cumulative or other relevant exposure to the cosmetic product including any ingredient.

## Mandatory Recall and Facility Suspension Authorities

MoCRA grants FDA the authority to request a voluntary recall of a cosmetic product if the Agency determines that there is a reasonable probability that the product is adulterated or misbranded, and the use of or exposure to the product will cause serious adverse health consequences or death. If the responsible person does not comply with FDA's request, FDA can order a mandatory recall after providing the responsible person an opportunity for an informal hearing. For any recalls issued under this provision, FDA must ensure that a press release is published regarding the recall and the image of the cosmetic product that is the subject of the press release is available on FDA's website.

FDA is also authorized to suspend a facility registration if the Agency determines that a cosmetic product manufactured by that facility has a reasonable probability of causing serious adverse health consequences and believes other products may be similarly affected. If FDA suspends a facility registration, the facility is not permitted to introduce any cosmetic products into commerce until its registration is reinstated. Before suspending the facility registration, FDA is required to provide notice and an opportunity for an informal hearing to the facility registrant.

## Fragrance Allergens Disclosure, Talc Regulation, and PFAS Report

FDA is required to promulgate regulations to identify fragrance allergens that must be disclosed on the label of a cosmetic product. In establishing these regulations, FDA must consider international, state, and local requirements for allergen disclosure, including the European Union's substance and format for these requirements. Additionally, Congress has authorized FDA to establish threshold levels of amounts of substances subject to disclosure. FDA is required to issue a proposed rule within 18 months after the enactment of MoCRA, and a final rule no later than 180 days after the close of the public comment period for the proposed rule.

MoCRA also directs FDA to issue regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. FDA must issue a proposed rule within one year after the enactment of MoCRA, and a final rule no later than after the close of the public comment period for the proposed rule.

Furthermore, MoCRA requires FDA to issue a public report no later than three years after the enactment of MoCRA to assess the use of perfluoralkyl and polyfluoralky substances (PFAS) in cosmetic products, and the scientific evidence regarding the safety of such use in these products.

## Preemption

MoCRA contains an express preemption provision that prohibits states from establishing any laws, regulations, or orders pertaining to cosmetics that differs from federal law with respect to registration and product listing, GMP, records, recalls, adverse event reporting, or safety substantiation. States are permitted to prohibit the use or limit the amount of an ingredient in a cosmetic product.

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