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New Cosmetic Regulations Dramatically Changing the Compliance Landscape

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Like drugs, dietary supplements, medical devices and foods, cosmetic products are regulated on the federal level by the United States Food and Drug Administration (FDA). Historically, cosmetic products, assuming they were properly marketed, have not required significant compliance obligations for manufacturers, as compared to, for example, dietary supplements. The compliance landscape for cosmetic products is now dramatically changing as a result of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), which imposes significant compliance obligations on the cosmetic industry in an effort to promote public safety and protect public health.

With significant portions taking effect on July 1, 2024, MoCRA is arguably the most significant expansion of the FDA's regulation of cosmetic products in decades. The law amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to include manufacturing facility registration, serious adverse event reporting, product listing, safety substantiation and enhancement of product labeling requirements for safety reporting. These requirements will apply to manufacturers and marketers (among other various parties in the cosmetic space), who will need to carefully consider their and their suppliers' compliance obligations under these new regulatory requirements.

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What Is a Cosmetic and Who Is Covered?

The key to determining if a product is a cosmetic (or something else) is its intended use. A product that is intended to affect the body's structure or function, even if related to beauty, or works subcutaneously, will not be considered by the FDA to be a cosmetic, and may otherwise be considered a drug (or both), even if it is labeled as a moisturizer, perfume or makeup application.

A long-standing definition of a cosmetic under the FD&C Act is an "article [other than soap] intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body … for cleansing, beautifying, promoting attractiveness, or altering the

appearance." MoCRA amends the FD&C Act to include the term "cosmetic product," which is "a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product." Because MoCRA applies to "cosmetic products", cosmetic ingredient suppliers may not be subject to certain requirements.

The Expanded MoCRA Requirements for Cosmetics and Cosmetic Products

MoCRA imposes a number of important and new requirements on those who manufacture and distribute cosmetics and cosmetic products.

Facility Registration: Owners or operators of facilities that manufacture or process cosmetic products for U.S. distribution (a "Cosmetic Product Facility") are required to register their facility with the FDA. MoCRA excludes certain entities from the definition of Cosmetic Product Facility, such as salons, retailers, and public health agencies and nonprofits, as well as (depending on the intended use of the cosmetic product) certain small businesses whose annual gross sales are under $1 million for the previous three years.

For existing Cosmetic Product Facilities as of the date of MoCRA's enactment, the initial registration was required to be submitted within one year after the date of enactment of MoCRA (or by Dec. 29, 2023), however the FDA announced that it would begin enforcing this requirement on July 1, 2024. New Cosmetic Product Facilities will need to be registered 60 days from engaging in the manufacturing or processing activities or 60 days after the existing facility deadline. Once Cosmetic Product Facilities are registered, the registrations will need to be renewed every two years and any changes to the registration information must be submitted within 60 days of such changes.

Product Listing: Responsible persons need to submit to the FDA a cosmetic product listing for each cosmetic product. For products existing at the time of MoCRA's enactment, the deadline for submission was July 1, 2024, extended from the original Dec. 29, 2023, deadline as was done for the facility registration. New cosmetic products will need to be listed within 120 days of marketing in interstate commerce. Like with facility registration, product listing is an ongoing obligation—responsible persons are required to submit annual updates to their listings. The listing must include contact information of the responsible person, facility registration numbers and a list of ingredients for the product, among other information. Since the product listing is tied to a product's formulation, a single submission for a product can include multiple brand names that have the same formulation, or multiple variations of a product if they differ only as to color, fragrance or flavor (for example, for a lipstick that has the same formulation but comes in various shades).

Serious Adverse Event Reporting: "Responsible persons," which means manufacturers, packers or distributors of cosmetic products whose name appears on the label of such cosmetic product in accordance with Section 609(a) of the FD&C Act or Section 4(a) of the Fair Packaging and Labeling Act, are required to submit to the FDA any report received of a "serious adverse event" within 15 business days, along with a copy of the applicable cosmetic product's label that was on or within the retail packaging. For purposes of MoCRA, a "serious adverse event" is a health-related event associated with the use of the 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 (including second- or third-degree burns or significant hair loss). A serious adverse event can also be an adverse event that requires medical or surgical intervention in order to prevent any of the aforementioned outcomes. In addition to the submission of the report, responsible persons will need to submit any "new and material medical information" related to the report that is received within one year of the filing of such report. Responsible persons will need to maintain records relating to serious adverse event reports for a period of

six years, or a shorter period of three years if the responsible person falls within MoCRA's small business exception.

Development and Maintenance of Safety Substantiation Records: Although the FDA's regulation of cosmetics is limited to products that are in the market and the FDA does not require specific testing to ensure that cosmetics are safe for consumers, a manufacturer or distributor of a cosmetic product must ensure that the product is safe for consumers when used as directed. MoCRA requires responsible persons to "ensure, and maintain records supporting, that there is adequate substantiation of safety of such cosmetic product." This means that responsible persons must rely on "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." The FDA has advised that responsible persons can rely on safety data that is already available for ingredients or similar formulations, but additional testing may be needed to fill any gaps when information is not otherwise available. Cosmetic manufacturers should work closely with management and their legal counsel to confirm they have robust compliance programs in place to ensure ongoing compliance with these requirements, in particular making sure that safety data (as well as adverse event data) is properly documented and stored.

Labeling: In addition to existing cosmetic labeling requirements, each cosmetic product needs to include on its label the contact information of the responsible person(s) for purposes of facilitating reporting of adverse events. Cosmetic products that are intended for use by professionals, meaning professionals licensed in cosmetology, nail care, barbering or esthetics, must include a label with a "clear and prominent statement" that the product is to be used or administered by licensed professionals and that it complies with FD&C Act labeling requirements as well as those of Section 4(a) of the Fair Packaging Labeling Act. While the labeling requirements for professional use are currently in effect, responsible persons will need to comply with the labeling requirements for responsible person contact information by Dec. 29, 2024.

In addition to the requirements outlined above, there is still more to come under MoCRA, as the FDA is required by the Act to promulgate new regulations on good manufacturing practices (GMPs), to implement the requirement to disclose fragrance allergens in cosmetic product labeling, and to establish and require standardized testing methods for detecting asbestos in talc-containing cosmetics, among other requirements. Given the substantial and expanding compliance obligations, parties in the cosmetic space will need to be mindful of the enhanced regulation requirements to maintain compliance moving forward.

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