FDA now has the budget to take a closer look at cosmetics.

Prepare for The Modernization Of Cosmetics Regulation Act

MoCRA DRAMATICALLY EXPANDS FDA'S AUTHORITY WITH RESPECT TO COSMETICS, INCLUDING, AMONG OTHER THINGS, ALLOWING FOR MANDATORY RECALLS, INSPECTION OF RECORDS, SUSPENSION OF FACILITY REGISTRATIONS, AND PROMULGATION OF REGULATIONS TO ESTABLISH COSMETIC GOOD MANUFACTURING PRACTICES.

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On December 29, 2022, President Joe Biden signed the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) into law heralding a new era of cosmetics regulation with significantly expanded authority for FDA and new requirements for personal care companies.[1] MoCRA is the culmination of years-long efforts to increase FDA's oversight of personal care products (cosmetics, specifically), including prior bills like the Personal Care Products Safety Act,[2] first introduced by Senators Dianne Feinstein and Susan Collins in 2015, which sought to implement many of the same measures contained in MoCRA. The prior legislative efforts and ultimate passage of MoCRA largely stem from growing concerns regarding the safety of cosmetic products, as evidenced by recent allegations of asbestos contamination and per- and polyfluoroalkyl substances (PFAS) in certain cosmetics.[3]

Notably, MoCRA's long-awaited updates to US cosmetics regulations have been welcomed by the personal care products industry. The Personal Care Products Council, for instance, applauded Congress for passing the legislation stating in a press release that "[t]he long-awaited legislation advances product safety and innovation for the science-driven beauty and personal care industry and reinforces consumer confidence."[4] While the new legislation will likely provide the consistent and modernized regulations desired by industry, MoCRA will also usher in a new regulatory landscape in which the personal care product industry will not only be subject to more requirements but also greater scrutiny from FDA—changes that companies should prepare for as soon as possible. In fact, as a sign that FDA is already gearing up to implement the new cosmetics requirements, FDA recently announced that it is moving cosmetic regulation and color certification out of the Center for Food Safety and Applied Nutrition (CFSAN) and into the Office of the Chief Scientist—a move that, according to the agency, "will leverage the FDA's areas of expertise across the agency as it works to implement [MoCRA]."[5]

MoCRA dramatically expands FDA's authority with respect to cosmetics, including, among other things, allowing for mandatory recalls, inspection of records, suspension of facil-

ity registrations and promulgation of regulations to establish cosmetic good manufacturing practices. Importantly, the legislation also significantly expands the legal obligations of cosmetic companies. This article highlights key new regulatory requirements impacting personal care product companies and then closes with steps companies can take to prepare for the brave new world of MoCRA.

REGULATORY OBLIGATIONS

MoCRA establishes notable reporting, listing and recordkeeping obligations related to cosmetic products. In particular, key new requirements companies should prepare for include obligations to:

- **Report Serious Adverse Events**—Under MoCRA, "responsible persons;" i.e., companies which manufacture, pack or distribute cosmetic products and whose name appears on the label, will be required to submit to FDA reports of any serious adverse events involving the use of their cosmetic products within 15 days of receiving any such report. Companies should particularly be aware that the definition of "serious adverse event" in MoCRA is broader than existing definitions of "serious adverse event" applied in the context of over-the-counter drugs and dietary supplements. Specifically, the new definition adds infections and significant disfigurement (including "serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance") to the list of events that would need to be reported to FDA. MoCRA will also require companies to maintain records related to each adverse event report for a period of six years and to permit FDA access to such records. Notably, the new law allows FDA to request a list of ingredients or categories of ingredients in a fragrance or flavor if FDA has reasonable grounds to believe they caused or contributed to a serious adverse event. Like most provisions in MoCRA, this requirement will go into effect in December 2023, one year from enactment of the bill.
- **Register Cosmetics Facilities and Submit Product Listings**—Before passage of MoCRA, cosmetics were the only FDA-regulated products without some sort of registration and product listing requirement. MoCRA changes this by requiring all persons who own or operate a facility that manufactures or processes cosmetics products for distribution in the US to register each facility with FDA. Responsible persons are also required to submit a product listing for each cosmetic product, which includes a list of ingredients in the cosmetic product, including fragrances, flavors or colors, with each ingredient identified by name. Personal care companies that already operate facilities will be required to register by December 2023 and to renew their registration biennially. New facilities will need to register within 60 days of beginning their manufacturing or processing operations. Likewise, the requirement to submit product listings will also go into effect by December 2023 and companies will need to submit updates to their product listings on an annual basis. For new cosmetics, companies must submit their product listing within 120 days of marketing the product.
- **Maintain Adequate Safety Substantiation**—Under current law, personal care companies already have a legal responsibility to ensure the safety of their cosmetic products; however, the law does not explicitly require that they substantiate the safety of their products.[6] Rather, if a company has not substantiated the safety of its product, it is required to include a warning on the product's label, stating "Warning—The safety of this product has not been determined."[7] Starting in December 2023, MoCRA will require that companies ensure, and maintain records supporting, there is adequate substantiation of safety for each cosmetic product sold in the US. The new law defines "adequate substantiation of safety" 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."
- **Adhere to New Labeling Requirements**—MoCRA also introduces three new cosmetic labeling requirements. Under the new law, cosmetics product labels must:

1. Include contact information through which the "responsible person" for the product can receive adverse event reports;
2. Disclose each fragrance allergen included in the cosmetic product; and
3. For products intended to be used by a licensed professional, bear a clear and prominent statement that the product may only be administered or used by licensed professionals and include all information currently required for cosmetics intended to be sold to consumers.

While professional use labeling requirements go into effect in December 2023, companies have two years from MoCRA's enactment; i.e., until December 2024, to add the required contact information for adverse event reporting. Companies will also have more time before they need to disclose fragrance allergens, as FDA has to first publish regulations identifying which substances count as fragrance allergens.