Navigating MoCRA: Recent Updates and Key Strategies for Compliance

THE MODERNIZATION OF COSMETICS REGULATIONS ACT REACHES MANY MILESTONES IN THE COMING MONTHS. ARNOLD & PORTER ATTORNEYS EXPLAIN HOW TO STAY ON TOP OF THEM.

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More than a year has passed since President Biden signed the Modernization of Cosmetics Regulations Act of 2022 (MoCRA) into law, substantially increasing the federal government's oversight of the cosmetics industry. As a brief reminder, MoCRA imposes various new requirements on the cosmetics industry and provides FDA with additional authority to inspect, evaluate and take enforcement actions relating to cosmetics products. Specifically, MoCRA requires "responsible persons;" i.e., companies who manufacture, pack, or distribute cosmetic products and whose name appears on the label, to:

- Report serious adverse events to FDA;
- Register cosmetics manufacturing facilities and submit a product listing for each cosmetic product;
- Maintain adequate substantiation regarding the safety of cosmetic products; and,
- Update cosmetic product labeling to include (1) contact information to facilitate the reporting of adverse events, (2) fragrance allergens and (3) professional use designation.

Further, MoCRA also provides various new powers and responsibilities for FDA including:

- Authorizing FDA to suspend registration of cosmetic manufacturing facilities and order recalls of cosmetic ingredients deemed to be unsafe;
- Authorizing FDA to access and copy records relating to cosmetic products that the agency reasonably believes are likely adulterated or unsafe;
- Requiring FDA to issue regulations on cosmetic good manufacturing practices;
- Requiring FDA to issue rulemaking implementing MoCRA's fragrance allergen labeling requirement; and,
- Requiring FDA to issue regulations to establish and require standardized testing methods for detecting asbestos in talc-

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containing cosmetics and evaluate the use of PFAS in cosmetic products.

Under MoCRA, FDA will take a closer look at asbestos in talc.In an effort to facilitate the implementation of MoCRA, FDA has issued guidance documents and updates for industry throughout the past year. Most notably, the agency announced in November that it would delay enforcement of the requirements for cosmetic product facility registration and cosmetic product listing by six months, or until July 1, 2024, to allow industry sufficient time to comply with the new requirements.[1] However, personal care companies should note that while there is some breathing room to complete facility registration and product listing, other requirements, such as serious adverse event reporting, have been in effect since December 29, 2023 and therefore subject to enforcement by FDA. Companies should also expect FDA to engage in extensive rulemaking over the coming months and years as the agency continues to implement its obligations under MoCRA.

This article outlines key MoCRA-related FDA guidance and developments to date and what we can likely expect from the agency going forward and concludes with key steps personal care companies can take to stay apprised of and compliant with their MoCRA obligations.

RECENT FDA GUIDANCE AND DEVELOPMENTS

In the past year, FDA has taken multiple steps to update and inform the cosmetics industry and the public regarding how it intends to implement the various requirements set forth in MoCRA. Personal care companies that manufacture or sell cosmetics products should particularly note the following updates:

- FDA Published Final Guidance on Facility Registration and Product Listing—Pursuant to MoCRA, all persons who own or operate a facility that manufactures or processes cosmetics for distribution in the US are required to register each facility with FDA. In addition, responsible persons must also submit a product listing to FDA for each cosmetic product sold in the US. Beginning in the summer of last year, FDA has—at least publicly—focused much of its attention on implementing these two requirements when it comes to MoCRA requirements. The agency first issued a draft guidance for industry on August 7, 2023, which it finalized on December 18, 2023, a week before the statutory deadline to comply with the requirements.[2] The guidance offers recommendations and instructions to assist stakeholders with product facility registration and product listing submissions by describing which parties are responsible for making the submissions, the information to be included in the submissions, how to submit and when to submit, as well as relevant exemptions. Along with the guidance, FDA unveiled its newly developed electronic submission portal, Cosmetics Direct, through which companies can submit their facility registration and product listings.[3] While FDA will also make paper forms available, the agency strongly encourages companies to use electronic submissions to help facilitate efficiency and timeliness of data submission and management.
- FDA Delayed Enforcement of Facility Registration and Product Listing Requirements—As noted above, FDA announced last November that it does not intend to enforce the above requirements related to cosmetic product facility registration and cosmetic product listing for an additional six months after the December 29, 2023 statutory deadline, or until July 1, 2024. The announcement is likely a welcome development for industry given FDA's final guidance and electronic submission portal for registration and product listing only became available about a week before the statutory deadline. Notably, FDA indicated in its compliance update that it was initiating the delay in response to industry's concerns that additional time was needed to gather relevant information required for the submissions.
- FDA Issued Instructions for Serious Adverse Event Reporting—Unlike facility registration and product listing, the requirement to report serious adverse events went into effect on December 29, 2023 and is currently enforceable by FDA. Under MoCRA, responsible persons are required to submit to FDA, within 15 business days, any reports of serious adverse events associated with their cosmetic products used in the US. To help facilitate these submissions, FDA is developing a process for electronic submissions of man-

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datory adverse event reports. In the meantime, the agency provided guidance advising responsible persons to submit serious adverse event reports using the current MedWatch Form 3500A—the form used to submit reports involving drugs, medical devices and dietary supplements.[3] To assist the cosmetics industry, FDA announced in December that it had updated the instructions for the MedWatch Form 3500A to make it easier for industry to complete the form and report a serious adverse event for a cosmetic product. While the requirement is not set to go into effect until December 29, 2024, companies should remember that in addition to reporting serious adverse events, they are also required to update their cosmetic labeling to include contact information through which consumers can report adverse events.

While FDA has yet to provide additional guidance or updates relating to MoCRA's new safety substantiation requirements, industry should also keep in mind that this requirement is currently in effect and fully enforceable by FDA. In particular, responsible persons must ensure and maintain records supporting adequate safety substantiation of their cosmetic products. FDA has indicated on its website that responsible persons "can use relevant safety data that is already available to support the safety of their products" and reminds them that all such data must be "derived from scientifically robust methods."[4]

WHAT'S NEXT FOR MoCRA?

Now that FDA has completed its development of the submission process for facility registration and product listing, personal care companies can expect the agency to begin turning its attention to the many other requirements set forth in MoCRA. Notably, FDA has been tasked with promulgating several new regulations on which it will be seeking public comment. Based on the Biden Administration's most recent Unified Agenda of Regulatory and Deregulatory Actions, FDA is likely to start with the new rule establishing and requiring standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products.[5] In the coming months and years, companies should also anticipate new regulations establishing current good manufacturing practices for cosmetics and identifying fragrance allergens that must be disclosed on all cosmetic labeling.

Increased scrutiny of cosmetic safety and product claims should also be expected as the plaintiffs' bar monitors FDA action and data to inform civil litigation strategies (including allegations of product liability or consumer fraud).

KEY STEPS TO STAY ON TOP OF MoCRA OBLIGATIONS

With MoCRA requirements now largely in effect, it's crucial for personal care companies to take proactive steps to ensure they remain informed and compliant with their obligations. To navigate the evolving regulatory landscape effectively, companies should consider implementing the following key strategies:

- Stay Updated on FDA Guidance and Announcements – Companies should regularly monitor FDA announcements and updates related to MoCRA. In addition to checking FDA's website regularly, engaging with industry associations and legal counsel can also help provide insights and timely updates on regulatory changes. Importantly, companies should consider participating in FDA public meetings and comment periods to stay informed on forthcoming regulations and ensure the agency is taking their perspectives into account.
- Implement Robust Compliance Programs—If companies

Cosmetic companies must maintain comprehensive record-keeping protocols.

have not already done so, now is the time to develop comprehensive compliance programs that address the specific requirements of MoCRA, including facility registration, product listing, serious adverse event reporting and safety substantiation. These programs should include clear standard operating procedures, employee training, and periodic internal audits to ensure ongoing compliance.

- Maintain Comprehensive Record-Keeping Protocols—MoCRA sets forth extensive recordkeeping obligations including requiring companies to maintain records related to safety substantiation and adverse event reports. With these requirements now in effect, companies should ensure that all relevant data is accurately documented, easily retrievable, and securely stored. Moreover, companies should regularly audit their record-keeping practices to verify compliance and address any gaps promptly. This will not only mitigate the risk of being found non-compliant but also helps ensure companies are easily able to respond to questions and documentation requests in the event of an FDA inspection.

With these steps, personal care companies can not only ensure compliance with current MoCRA requirements but also position themselves to adapt swiftly to future regulatory developments as they come into effect. ■

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