

## With Launch of New Cosmetic Safety Reporting Dashboard, FDA's MoCRA Implementation Inches Forward

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On September 12, 2025, the US Food and Drug Administration (FDA) announced the launch of the FDA Adverse Event Reporting System (FAERS) Public Dashboard for Cosmetic Products, an online tool that provides access to adverse event data on cosmetic products. This dashboard allows the public to search, filter and download mandatory reports related to serious adverse events submitted under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) by "responsible persons" (defined by MoCRA as the manufacturer, packer or distributor whose name appears on the product label) in accordance with 21 USC § 364a, as well as voluntary reports submitted to FDA by healthcare professionals, consumers, salon professionals, cosmetologists and others.

For cosmetics companies and industry professionals, the dashboard can be a helpful tool for compliance and risk management. Specifically, the dashboard gives companies a way to keep track of publicly reported safety issues – not just for their own products, but also for others on the market with similar ingredients or uses. While the reports aren't verified by FDA, monitoring this data regularly can better position companies to spot and respond to emerging safety trends.

## Tracking MoCRA's implementation

These reporting obligations are part of the broader regulatory framework established by MoCRA, which expanded FDA's authority over cosmetics. In addition to adverse event reporting, companies are now subject to a range of requirements, such as facility registration and product listing, both of which FDA has begun enforcing in accordance with 21 USC § 364c. FDA <u>issued final guidance</u> to assist industry with the process for submitting cosmetic product facility registrations and product listings to the agency. MoCRA also gave FDA authority to establish regulations for Good Manufacturing Practices (GMPs) for cosmetics in accordance with 21 USC § 364b. However, FDA has not yet proposed or finalized any cosmetics GMP regulations, despite a statutory requirement to publish a proposed rule by the end of 2024 and a final rule by the end of 2025. The only cosmetics GMP (cGMP) guidance currently available is a <u>nonbinding draft guidance</u> published by FDA in 2013, which predates MoCRA. In the absence of any additional information from the agency, however, cosmetic companies are well-served in relying on this draft guidance for now as they stand up their cGMP policies and procedures to mitigate risk.

In addition to cGMP, FDA is still actively developing several other key regulations under MoCRA. These include a <u>proposed rule</u> issued in December 2024 that establishes testing methods for detecting asbestos in talc-containing cosmetics, as well as a planned rule that would require the disclosure of fragrance allergens on cosmetic product labels as required by 21 USC § 364e(b). For fragrance allergen labeling, MoCRA required FDA to issue a proposed rule within 18 months of the law's enactment. That deadline has passed, and no proposed rule has been published.

## Industry still awaits regulatory certainty

Overall, the implementation of MoCRA is moving much slower than the law's drafters likely anticipated, with the agency missing several deadlines for issuing rules. With the FDA's current focus on increasing transparency, perhaps the agency will turn to these yet-to-be defined regulations and guidance, so that the cosmetics industry can better understand the requirements they'll be expected to meet – and allow them to begin making informed adjustments to their operations.

The Cooley team, led by former FDA enforcement attorneys, is here to help. If you have any questions regarding your company's cosmetic products, please reach out to one of us.

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