FDA Signals Increased Cosmetics Oversight through MoCRA Implementation and Other Regulatory Efforts

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Last week, FDA touted its achievements in connection with implementing the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) – noting that the agency had "worked tirelessly, mostly using existing resources, to implement the provisions added or required by MoCRA." Enacted on December 29, 2022, MoCRA marks the most significant reform of U.S. cosmetic regulation in over 80 years and significantly expands FDA's authority and imposes substantial new obligations on cosmetic manufacturers, processors, and brand owners. Key changes include:

- Mandatory facility registration and product listing, including ingredient disclosure;
- Serious adverse event reporting requirements;
- Recordkeeping obligations to substantiate product safety;
- Mandatory recall authority for adulterated or misbranded cosmetics;
- FDA rulemaking mandates for cosmetic Good Manufacturing Practices (GMPs), fragrance allergen labeling, and asbestos testing methods for cosmetic products containing talc; and
- Mandatory assessment of the use and safety of perfluoroalkyl and polyfluoroalkyl substances (PFAS) in cosmetic products.

The law provides for limited exemptions for certain small businesses from the facility registration, product listing and GMP requirements.

While new shakeups in leadership at FDA with the departure of Commissioner Marty Makary and the appointment of Kyle Diamantas as acting Commissioner may change other priorities and policy positions, we do not expect a significant shift in FDA's implementation of MoCRA.

FDA's Ongoing MoCRA Implementation Efforts

Since MoCRA was passed, FDA has issued industry guidance addressing cosmetic product facility registration, product listing requirements and its mandatory recall and records access authority. FDA has also engaged stakeholders through listening sessions to inform forthcoming cosmetic GMP regulations, which are expected to establish mandatory minimum standards for how cosmetics are manufactured, processed, packed, and stored. In addition, the agency has launched Cosmetics Direct and ESG NextGen portals for electronic submissions for registration and listing of cosmetic product facilities and products, and enhanced adverse event reporting tools.

FDA also highlighted its focus on PFAS in cosmetic products. Relying on the new—and now mandatory—cosmetic product listings, FDA identified and published its report on the 25 most used PFAS in cosmetics. Although FDA did not reach definitive safety conclusions, the report underscores continued regulatory and public scrutiny around PFAS.

MoCRA has materially increased FDA visibility into the cosmetics marketplace. Through mandatory facility registrations and product listings, FDA now has significantly greater insight into which entities are manufacturing and processing cosmetic products, where products are being manufactured, what cosmetic products are being marketed in the U.S., and the ingredients used in those products. FDA reports that there are more than 15,000 active cosmetic product facility registrations and over 1 million cosmetic product listings—a dramatic increase compared to the 5,176 cosmetic facility registrations and 35,102 cosmetic product listings received through FDA's prior Voluntary Cosmetic Registration Program.

While FDA did not highlight an increase in the number of warning letters or other enforcement for cosmetic products, it is reasonable to expect that the expanded authority and increased visibility may lead to new enforcement, litigation, and reputational risk for cosmetic companies. Indeed, FDA's Adverse Event Reporting System (FAERS) Public Dashboard for Cosmetic Products gives the public access to cosmetic product safety issues in real-time, including plaintiffs' attorneys, consumer advocacy organizations, and competitors that may use the information to scrutinize cosmetic products and marketing practices. As MoCRA implementation advances, cosmetic companies should evaluate compliance programs, including safety substantiation and adverse event reporting, amid heightened regulatory and litigation risk.

FDA Continues Regulatory and Compliance Efforts under the FD&C and Fair Packaging and Labeling Acts

In addition to its MoCRA implementation efforts, FDA has continued enforcement under the broader FD&C Act and the Fair Packaging and Labeling Act. Recent actions—including guidance on microbial contamination in tattoo inks and a consumer alert regarding gel nail polish removers containing prohibited methylene chloride—underscore FDA's ongoing focus on cosmetic safety and ingredient compliance. Companies should continue monitoring FDA scrutiny of potentially unsafe ingredients and assess whether existing formulations remain compliant.

Key Takeaways

MoCRA marked a fundamental shift in FDA's regulation of cosmetics, and implementation efforts will likely continue throughout the next few years. We expect that these efforts will continue for years to come under FDA leadership. As FDA issues additional guidance and regulations, proactive compliance planning will be critical to managing regulatory, litigation, reputational, and business risk.