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MoCRA Update for Starting the Year Off Right

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Key Takeaways

- What Happened: The Food and Drug Administration (FDA) released four updates regarding MoCRA in December.
- Who's Impacted: Cosmetic product manufacturers.
- What Should You Do: Companies should stay up to date with ongoing updates, ensure they report serious adverse events, and register their facilities and list products by July 1, 2024.

The Modernization of Cosmetics Regulation Act of 2022 (MoCRA), passed in December 2022, added new cosmetics provisions to the Federal Food, Drug, and Cosmetic Act. For more details on MoCRA, see our previous alert. In December 2023, the Food and Drug Administration (FDA) made significant progress in achieving the goals outlined in MoCRA through several updates and guides.

Serious Adverse Event Reporting

On December 14, FDA issued updated instructions for Serious Adverse Event Reporting for cosmetic products. MoCRA added the requirement to report serious adverse events involving cosmetic products. The announcement of the updated instructions details who is responsible for the reporting and what constitutes a serious adverse event. FDA recommends that reporting be done through the MedWatch program using Form 3500A. While the form and instructions are online, FDA currently does not have an electronic system in place for submissions, so responsible parties must either send the information via email or by mail, with email being FDA's preferred delivery method. FDA says it is working on an electronic submission process. The December 14 announcement noted the updated instructions for the adverse event reporting form to make it easier for cosmetic reports.

Cosmetics Direct

On December 15, FDA announced a Structured Product Labeling (SPL) Implementation Guide with Validation Procedures. SPL is an established document sanctioned by health level seven for the exchange of product and facility-related information. The guide discusses updates to the cosmetics product facility registrations and product listings included within the SPL framework.

Second, on December 18, FDA launched Cosmetics Direct, the electronic submission portal for the registration and listing of cosmetic product facilities and products. MoCRA originally mandated that cosmetic product facilities and cosmetic products be registered by December 29, 2023. As noted in our previous alert, this requirement was pushed back to July 1, 2024 following a delay in the roll out of FDA's registration system. Cosmetics Direct is an SPL authoring tool that is meant to ease the registration process. FDA also noted in the announcement of this tool that registrations can be submitted via SPL-formatted submissions through the Electronic Submissions Gateway (ESG) or via paper forms that are still under development. FDA encouraged electronic submission and emphasized that the new tool should be more user-friendly than submitting through the ESG, which may be more time-consuming for new users given the wait time for creating an account.

Cosmetic Product Facility Regulations & Product Listings

Finally, on December 18, FDA issued its final guidance on cosmetic product facility registrations and product listings. This guidance was initially discussed in our August 10, 2023 alert when FDA initially proposed the guidance. In addition to what the draft guidance originally included, the final guidance includes information about Cosmetics Direct and a FAQ section that answers common questions on cosmetic product facility registrations and product listing submissions.

Cosmetic product manufacturers should ensure they report serious adverse events and register their facilities and products by the July 1, 2024 deadline.

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