MoCRA Enforcement Pushed Six Months

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Key Takeaways

What Happened: FDA announced delayed enforcement for MoCRA facility registration and product listing information. Who's Impacted: Cosmetic product manufacturers What Should You Do: Keep up to date with the ongoing updates and prepare to register your facilities and list your products by July 1, 2024.

As described in our previous aler, Congress enacted the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) in December 2022. MoCRA amended the Federal Food, Drug, and Cosmetic Act (FFDCA) to add several new provisions, including requiring manufacturers and processors of cosmetic

products to register their facilities with the Food and Drug Administration (FDA) and submit product lists to FDA. FFDCA § 607. Prior to the November 8, 2023 announcement, every person who owns or operates a facility that engages in manufacturing or processing a cosmetic product for distribution in the U.S. was required to register with FDA starting on December 29, 2023. FFDCA § 607(a)(1)(A). Additionally, the responsible person for each cosmetic product sold in the U.S. was required to submit a cosmetic product listing to the FDA starting on December 29, 2023. FFDCA § 607(c)(2). The FDA's announcement pushed back the enforcement of these requirements for six months to ensure that the industry had time to comply. The new deadline for both facility registration and product listing information is July 1, 2024.

The accompanying guidance document indicates that FDA still intends to be ready to accept registration and listing information by the statutory deadline of December 29, 2023. Companies will be able to submit their information then.

The delay was precipitated by industry comments to FDA indicating that companies needed more time to gather the

required information for facility registration and product listing. The commenters cited concern about the timeframe required to obtain facility registration numbers for cosmetic product listings, to access the electronic submissions database (which at the time of this alert, is not live), and to enter and submit accurate registration and listing information.

Cosmetic product manufacturers should ensure they are on track to meet the new July 1, 2024 deadline, and also note that the December 29, 2023 deadline remains in effect for other MoCRA requirements, including the requirement that FDA propose regulations for standardized testing methods for the detection and identification of asbestos in talc-containing cosmetic products, and the requirement that responsible persons ensure adequate safety substantiation.

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