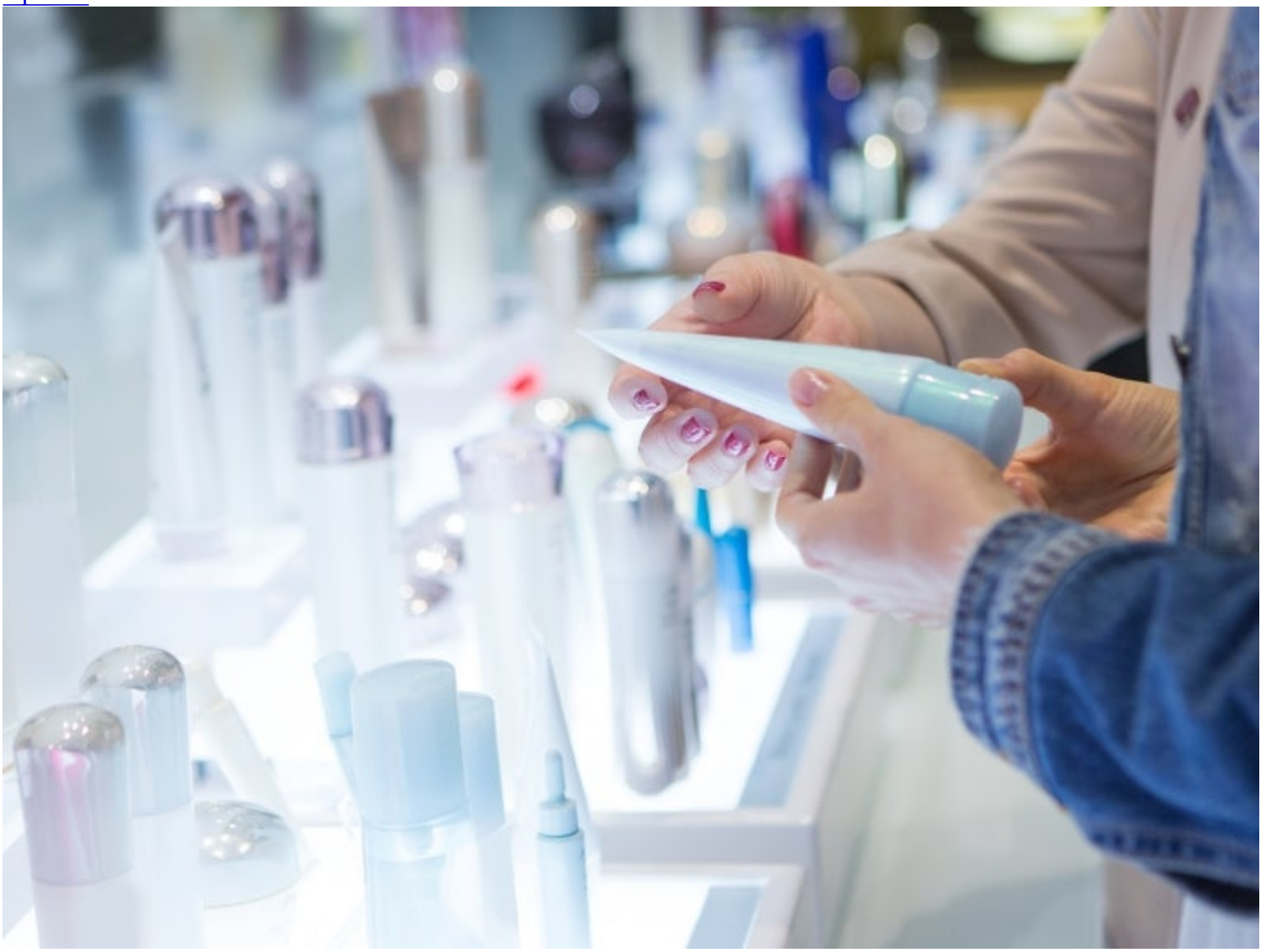
Updates



Update: FDA recently delayed MOCRA facility registration and product listing enforcement deadlines to **July 1, 2024** announcing here that the Agency "does not intend to enforce requirements related to cosmetic product facility registration and cosmetic product listing for an additional six months."

We've updated the summary and chart below to reflect the new FDA timeline for enforcement.

In the beauty, cosmetics, and personal care world, companies are preparing to comply with upcoming Modernization of Cosmetics Regulation Act (MoCRA) provisions of the Federal Food, Drug and Cosmetic Act (FD&C Act) going into effect on December 29, 2023.

In this Update, we discuss key requirements related to registering facilities and listing cosmetic products with FDA, substantiating the safety of cosmetic products, meeting new adverse reporting requirements, implementing new cosmetic labeling requirements for professional use products, and complying with FDA's new mandatory recall authority.

A summary of deadlines relevant to MoCRA can be found in a table at the end of this Update.

Mandatory Facility Registration and Product Listing

First, cosmetic facilities must be registered, and cosmetic products must be listed with FDA no later than July 1, 2024:

- **Facility registrations.** Every person who owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States must register each facility **no later than July 1, 2024**. This includes facilities that are located outside of the United States. Registrations must be renewed biennially (every two years). New facilities must register within 60 days after engaging in manufacturing or processing of cosmetic products for U.S. distribution. Note that facilities solely engaged in the labeling, relabeling, packaging, repackaging, holding, or distribution of cosmetics products need not be registered.
- **Product listings.** Cosmetic companies must submit a cosmetic product listing no later than July 1, 2024. Products already on the market as of the date of enactment must be listed no later than one year after that date. New products need to be listed within 120 days of entering the U.S. market. Thereafter, product listings must be updated annually, including an update that the product was discontinued.

Failure to register or submit listing information in accordance with Section 607 of the FD&C Act is a prohibited act under Section 301(hhh) of the FD&C Act (21 U.S.C. § 331(hhh)), prompting possible sanctions. There are no fees for submission for facility registration or product listing.

Safety Substantiation

By December 29, 2023, cosmetic companies must ensure adequate substantiation of the safety of each cosmetic product they offer and maintain records supporting adequate substantiation of the safety of their products. Section 608 of the FD&C Act clarifies that the term "adequate substantiation of safety" requires companies to acquire evidence that qualified experts agree is reasonably supportive of the fact that their cosmetic products are not injurious to people when used as instructed.

Here, FDA can review any other documentation related to a cosmetic product if they have a "reasonable belief" that the cosmetic product is likely to pose a threat of serious adverse health consequences or death. Companies should establish a safety substantiation policy to address these new requirements and should consider retaining a certified toxicologist to conduct a risk assessment on their products.

Adverse Event Reporting Requirements

As of December 29, 2023, cosmetic companies will be required to submit any report received of a serious adverse event associated with domestic use of a cosmetic product manufactured, packaged, or distributed by the company. A "serious adverse event" occurs when any of an enumerated list of health-related events—including death, inpatient hospitalization, infection, and disfigurement—requires medical intervention.

Serious adverse events must be reported within 15 business days of the receipt of the report, and companies must regularly update the FDA as new information is reported. Additionally, cosmetic companies are required to maintain records of any health-related adverse event for at least six years after the reporting of the event. MoCRA provides for inspection of any registered facility, during which FDA may request copies of all adverse event reports. Failure to provide such records renders a product or facility noncompliant. Companies should work to establish an adverse event reporting program and ensure that they meet the recordkeeping requirements of MoCRA.

Cosmetic Labeling for Professional-Use Products

Any cosmetic product introduced into the United States and intended to be used only by a professional shall bear a label that contains a clear and prominent statement that the product shall be administered or used only by licensed professionals. Additionally, these products must be in conformity with the requirements for cosmetics labeling under MoCRA and section 4(a) of the Fair Packaging and Labeling Act.

Mandatory Recall Authority

FDA will also have new mandatory recall authority as of December 29, 2023. If FDA determines that there is a reasonable probability that a cosmetic is adulterated or misbranded, and the use of or exposure to such cosmetic will cause serious adverse health consequences or death, FDA will provide the responsible person with an opportunity to voluntarily cease distribution and recall such article. If the responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic within the time and manner prescribed by FDA (if so prescribed), FDA may order that distribution of the product be immediately ceased.

Takeaways

Cosmetic companies should determine whether they need to register any facilities with FDA and have a list of products which need to be listed with FDA by July 1, 2024. Companies should implement reporting and compliance policies for updating FDA annually as to product listings, updating FDA as to product changes (within 60 days of the change), and updating FDA within 120 days of marketing new products.

Companies should also have updated policies in place for adverse event reporting procedures, recordkeeping, good manufacturing practices (GMP), and recall insurance coverage. Finally, companies need to ensure that the safety of their products is substantiated and keep records detailing such substantiation.

Key MoCRA Deadlines and Ongoing Requirements

Action	Deadline	Ongoing Requirements
Maintain safety substantiation documentation.	December 29, 2023	• Indefinitely.

Submit serious adverse event reports to FDA.	Within 15 business days of the receipt of the report	• Update FDA regularly with new information. • Maintain records for at least six years.
Register covered cosmetic manufacturing and processing facilities.	July 1, 2024	• Register new facilities within 60 days after covered activities. • Renew registrations biennially.
List covered cosmetic products.	July 1, 2024	• List new products within 120 days of product entering the U.S. market. • Update product listings annually.

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