



FEBRUARY 20, 2024

FDA Make-Over of Cosmetics Regulations is Not Limited to Cosmetics Businesses

The Food and Drug Administration (“FDA”) will begin enforcement of the Modernization of Cosmetics Regulation Act of 2022 (“MoCRA”) on July 1, 2024. [MoCRA](#) represents the biggest regulatory overhaul for the cosmetics industry in over a decade. However, cosmetics can include anything you apply to the body to beautify, cleanse, or alter the appearance, like moisturizer, lipstick, deodorant, perfume, or shampoo. The new regulations increase the FDA’s power to regulate cosmetics and narrow the gap between how the FDA regulates cosmetics and drugs. Businesses that manufacture these products should start reviewing the requirements of the Act and preparing to meet the upcoming deadlines.

HOW WILL MOCRA AFFECT YOUR BUSINESS?

Facilities Registration: If you manufacture or process cosmetics, **you must register your facility with the FDA by July 1, 2024.**

- This is a one-time requirement
- Some exceptions exist for small businesses
- You can register now through FDA’s [online portal](#)

Product Listing: Beginning on July 1, 2024, cosmetics companies will need to **list each product and each of the product’s component ingredients.**

- You can begin submitting your product listing information now using FDA’s [online portal](#)

Adverse Event Reporting: Cosmetics companies must record adverse events from use of their products and report them directly to the FDA in some cases. **The FDA is currently enforcing this provision.**

- Cosmetics companies must keep records of minor events, like allergic reactions
- The time period to maintain records will vary depending on the size of the entity in question
- Cosmetics companies must report serious adverse events directly to the FDA

Recalls: The FDA now has authority to **order a company to recall a cosmetic product to avoid injury to consumers, even over the company's objection.**

New Labeling Requirements:

- Cosmetic products intended exclusively for use by professionals will require specific labeling
- Beginning in early 2025, labels on cosmetics must disclose any fragrance allergens

Safety Substantiation: Companies must maintain records which substantiate their claims of product safety and, if requested, provide them to the FDA.

Blank Rome can help you navigate your company's MoCRA compliance and answer registration and reporting questions. For more information or assistance, contact [Terry Henry](#), [Erica Graves](#), or another member of Blank Rome's [Labeling & Advertising](#) team.

Terry M. Henry
215.569.5644 | terry.henry@blankrome.com

Erica R. Graves
424.239.3449 | erica.graves@blankrome.com