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FDA Publishes Draft Guidance For Submitting Cosmetic Product Facility Registrations and Product Listings Under MoCRA



The U.S. Food and Drug Administration (FDA) issued draft [guidance](#) on August 7, 2023, clarifying new requirements for cosmetic facility registrations and product listings under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).

The draft guidance sets out a tight compliance timeline: a comment deadline of September 7, 2023, a submission opening date in October 2023, and a compliance deadline in December 2023.

What's MoCRA?

As we previously [reported](#), President Biden dramatically expanded the federal oversight of cosmetics under the Federal Food, Drug, and Cosmetic Act's (FD&C Act) cosmetics provisions last December by signing MoCRA into law. MoCRA establishes several new requirements for cosmetic manufacturers, packers, and distributors, which will go into effect over time. Among other things, MoCRA's requirements include mandatory cosmetic product facility registration and product listing as set forth in Section 607 of the FD&C Act. Specifically, Section 607(a) requires that 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" is required to register each facility with the FDA. Further, under Section 607(c), for each cosmetic product distributed in the United States, a responsible person must submit to the FDA "a cosmetic product listing." Note that there are exemptions to these requirements, including for certain small businesses and for products that are regulated under the FD&C Act as drugs or medical devices.

What Are the New Registration Requirements?

Pursuant to MoCRA, the FDA has worked toward establishing a new system, including a submission portal for the cosmetic product facility registrations and product listings mandated by the new law. The agency intends that the new electronic submission system will be available in October 2023.

- For facility registrations, each 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 December 29, 2023. Registrations must be renewed biennially (i.e., every two years).
- For product listings, cosmetic companies must submit a cosmetic product listing no later than December 29, 2023. Any updates to product listings must be made annually. This includes 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. According to the draft guidance, there are no fees for submission for facility registration or product listing.

Interested stakeholders are encouraged to submit comments on or before September 7, 2023, in order to be considered before the final version of the guidance is published.

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