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FDA ISSUES DRAFT GUIDANCE ON COMPLYING WITH MOCRA

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The U.S. Food and Drug Administration has issued a draft guidance to assist companies submitting cosmetic product facility registrations and cosmetic product listings to the FDA in compliance with the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). The deadline for facility registration and product listings is December 29, 2023. The FDA states that it intends to make a new electronic submission portal available in October 2023 for submitting registration and product listing information.

MoCRA is the most significant expansion of FDA's authority to regulate cosmetics since the Federal Food, Drug, and Cosmetic (FD&C) Act was passed in 1938. This is the first in a series of posts on complying with MoCRA.

MoCRA creates a number of new regulatory obligations for cosmetics companies, including the following:

- **Facility registration:** Cosmetic manufacturing facilities must register with the FDA by December 29, 2023 and update their facility registration every two years. The FDA will have the authority to withdraw a facility's registration where there is a reasonable probability that a cosmetic product poses serious adverse health consequences or death.
- **Cosmetic product listing:** Also by December 29, 2023, a "responsible person" whose name appears on the cosmetic product label must provide FDA with a listing of their cosmetic products, including ingredients and fragrance allergens.

The FDA's draft guidance, "Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry," provides definitions and clarification on who needs to register as a facility, who needs to list their cosmetic products and what information needs to be provided. In our three-part series on MoCRA, part 2 focuses on the FDA's facility registration requirements, and part 3 provides more detail on submitting product listings to the FDA.

MoCRA also creates a number of additional requirements, including:

- **Safety substantiation:** By December 29, 2023, the responsible person whose name appears on a cosmetic product label must have and maintain documentation of safety substantiation for the cosmetic product. FDA will consider products without adequate safety substantiation to be adulterated.

- **Adverse event reporting and record keeping:** Also by December 29, 2023, the responsible person must start keeping records of all adverse events associated with use of a cosmetic product, and maintain those records for six years (three years for small businesses). Adverse events do not include minor and transient reactions in users. Serious adverse events must be reported to FDA within 15 days, and include any incidents involving death, hospitalization, persistent disability or incapacity, a congenital anomaly or birth defect, infection, or significant disfigurement.

- **Product labeling:** By December 29, 2024, cosmetic product labels must include the responsible person's domestic address, phone number, or electronic contact information (such as a website portal) in order to facilitate adverse event reporting. (Note that this requirement takes effect *after* the adverse event record keeping and recording requirement.) Labels also must list whether cosmetic products are for professional use only, and any fragrance allergens (which FDA has until June 29, 2024 to define).

- **Good manufacturing practices:** By December 29, 2024, FDA is to issue draft good manufacturing practices (GMPs) for cosmetic products, to be finalized by December 29, 2025. The FDA will have authority to inspect records necessary to demonstrate compliance with the GMPs.

In tomorrow's post, we'll discuss FDA's guidance for registering as a cosmetic facility. In Thursdays' post, we'll discuss providing cosmetic product listings to FDA.

For questions or information, or to schedule a free webinar on complying with MoCRA, contact one of the authors listed.

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