Published on *The National Law Review* https://natlawreview.com

FDA Delays Enforcement of Cosmetic Product Facility Registration and Listing Requirements

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On Nov. 8, 2023, the U.S. Food and Drug Administration (FDA) issued guidance detailing its intent to delay enforcement of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA)'s cosmetic product facility registration and cosmetic product listing requirements. The guidance postpones until July 1, 2024, enforcement of the new registration and listing requirements for cosmetic manufacturers, importers, and responsible persons.

As detailed in our August 2023 GT Alert, MoCRA, under the Federal Food, Drug, and Cosmetic Act (FD&C Act), imposes two significant new requirements for cosmetic facility registration and product listing:

(1) Facility Registration

Cosmetic product manufacturers and processors must register their facilities with the FDA, update content within 60 days of any changes, and renew such registration every two years.

Pursuant to the FDA's August 2023 draft guidance, "manufacturing and processing of a cosmetic product" means "engaging in one or more steps in the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the product." However, the term "facility" does not include the following establishments:

- Beauty shops and salons, unless manufacturing cosmetic products at the location;
- Cosmetic product retailers, including individual sales representatives, direct sellers, retail distribution facilities, and pharmacies, unless manufacturing cosmetic products at the location;

- Hospitals, physicians' offices, and health care clinics;

- Public health agencies and other nonprofit entities that provide cosmetic products directly to the consumer;

- Trade shows and other venues where cosmetic product samples are provided free of charge;

- Entities (such as hotels and airlines) that provide complimentary cosmetic products to customers incidental to other services;

- Establishments that manufacture or process cosmetic products solely for research or evaluation;

- Establishments that solely perform one or more of the following: labeling, relabeling, packaging, repackaging, holding, or distributing;

- Small businesses (i.e., establishments whose average gross annual U.S. sales of cosmetic products for the previous three-year period is less than $1,000,000); or

- Establishments that manufacture or process drugs or devices.

(2) Product Listing

Under MoCRA, a responsible person (e.g., manufacturer, packer, or distributor of a cosmetic product whose name appears on the product label) must list and update annually each marketed cosmetic product with the FDA. Required product information includes:

- The facility registration number of each facility where the cosmetic product is manufactured or processed;

- The name and contact number of the responsible person;

- The name of the cosmetic product as it appears on the product label;
- The applicable cosmetic category or categories for the cosmetic product (as listed in Appendix A of the August 2023 draft guidance);
- A list of product ingredients including fragrances, flavors, and colors using the common or usual name of the ingredient;
- The product listing number, if previously assigned; and
- The type of submission (e.g., initial, annual update to content, abbreviated renewal).

Additional information, including the applicable parent company name, type of business, and image of the label, is optional.

Fees, Information Disclosure, and Penalties

The FDA will not charge a fee to satisfy either requirement. Further, the FDA will not disclose information from a facility registration, including the product listing number, unless responding to a Freedom of Information Act request. Failure to fulfill these requirements may be considered a prohibited act under the FD&C Act and hence grounds for penalties.

The FDA's Structured Product Labeling Resources and the Pragmatic Structured Product Labeling Editor offer an idea of what the registration platform will look like and how it will function. They feature templates for other FDA-regulated products requiring similar formalities and provide more information about structured product labeling.

Caroline Abbott contributed to this article.

National Law Review, Volume XIII, Number 320

Source URL:https://natlawreview.com/article/fda-delays-enforcement-cosmetic-product-facility-registration-and-listing