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ALERT

Time's Up! Cosmetic Facilities Must Comply With FDA's New Registration Requirements by July 1

June 17, 2024

The July 1, 2024 deadline is fast approaching for cosmetic product manufacturers to comply with new registration and listing requirements under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).

Passage of the 2022 law represented a historic event in the regulation of cosmetics in the United States and the most significant expansion of the U.S. Food and Drug Administration's (FDA) authority to regulate cosmetics since the Federal Food, Drug, and Cosmetic Act (FD&C Act) was passed in 1938. New FD&C Act sections added by MoCRA require cosmetic product companies to, among other things, register facilities, list products, report serious adverse events, develop and maintain safety substantiation records, and once promulgated, follow good manufacturing practice (GMP) regulations.

Many of the new requirements became effective on December 29, 2023, but FDA stated that it did not intend to enforce the following requirements for an additional six months, until **July 1, 2024**, to provide regulated industry additional time to comply:

- Cosmetic product facility registration and cosmetic product listing; and
- Registration for owners or operators of facilities that first engaged in manufacturing or processing a cosmetic product after December 29, 2022, or the listing requirement for cosmetic products first marketed after December 29, 2022.

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This (much-appreciated) extension for companies to register and list is rapidly nearing its end. We urge any entities that fall under FDA's regulatory authority to complete and submit the applicable registration and listing information. To that end, we provide some brief background, guidance, and resources, and are pleased to respond to any questions and provide more detailed guidance as needed.

Who must comply?

1. **Cosmetic Product Facilities** must register with FDA and renew their registration every two years.

   A **Cosmetic Product Facility** is defined as any establishment that manufactures or processes cosmetic products distributed in the United States.

   The terms **manufacturing** or **processing** of a cosmetic product mean 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.

   Cosmetic Product means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product. This definition is more narrow than the statutory definition of **cosmetics** which are "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body … for cleansing, beautifying, promoting attractiveness, or altering the appearance," and articles used as a component of any such article (FD&C Act Section 201 (i)). Thus, as a result of this more narrow definition under MoCRA, cosmetic ingredient manufacturers or suppliers are not subject to registration and listing requirements except to the extent they supply bulk finished cosmetic product in which the only additional processing steps are packaging and labeling.

   MoCRA excludes certain entities from the definition of Cosmetic Product Facility.

   - **NOT a Cosmetic Product Facility:**
     - Salons, retailers, healthcare-related facilities, entities that provide free cosmetics incidental to other services, public health agencies/nonprofits providing cosmetics directly to consumers, trade shows where cosmetics are provided for free, manufacturers of cosmetics solely for research purposes; and
     - Firms that solely perform the following activities: labeling, relabeling, packaging, repackaging, holding, or distributing (although the packaging exclusion does not extend to filling product containers).

   FDA has developed a **Decision Tool** to assist companies in determining whether they are required to register as a Cosmetic Product Facility. To use the tool, click through the series of questions provided on FDA's website.

2. A **Responsible Person** must list each marketed cosmetic product, including product ingredients, with FDA.

   Responsible person means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with Section 609(a) of the FD&C Act or

Section 4(a) of the Fair Packaging and Labeling Act.

Who is exempt?

MoCRA exempts certain small businesses from facility registration and product listing requirements.

Small Businesses are companies whose average gross annual sales of cosmetic products in the U.S. for the previous three years is less than $1 million.

However, such exemptions do not apply to facilities that manufacture or process, or responsible persons for, the following cosmetic products:

- Products that regularly come into contact with the mucus membrane of the eye under customary or usual conditions of use.
- Products that are injected.
- Products that are intended for internal use.
- Products that are intended to alter appearance for more than 24 hours under customary or usual conditions of use, and removal by the consumer is not part of such conditions of use.

Exemptions also exist for certain products and facilities that are subject to requirements for drugs and devices.

What are the requirements?

- **Facility Registration:** Manufacturers must register their Cosmetic Product Facilities with FDA by July 1, 2024, and renew their registration every two years thereafter (FD&C Act Section 607(a)).
- New facilities that first engaged in activities subjecting them to the registration requirement after December 29, 2022, must register their facilities. Please note that according to FDA, new facilities must be registered within 60 days of first engaging in cosmetic manufacturing or processing, or by July 1, 2024 – whichever is later.
- **Product Listing:** A responsible person must initially list each marketed cosmetic product with FDA according to the same timelines as initial registration, and provide any updates, including product discontinuation, annually (FD&C Act Section 607(c)).

More details can be found in FDA's December 2023 **Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products**. The guidance provides recommendations and instructions to assist persons submitting cosmetic product facility registrations and product listings to FDA.

How to comply?

FDA strongly encourages electronic submissions and has developed for that purpose **Cosmetics Direct**, an electronic submission portal designed to help streamline submission and receipt of registration and product listing information. Registration and listing data are submitted electronically using structured product labeling (SPL) format. More information on SPL is available on **FDA's website.**

As an alternative, companies may transmit SPL-formatted submissions through FDA's **Electronic Submissions Gateway (ESG)** or any SPL authoring software including **SPL Xforms**. The FDA ESG system requires users to apply for a free account before submitting data, a process that can take one to three weeks. Given the potential one-to-three-week processing period, it is possible that the account creation process will not be completed prior to the July 1 deadline, resulting in a late registration. The ESG process may be better suited for renewals for companies that have not yet established an ESG account.

FDA also developed and accepts paper forms as another alternative submission tool, despite FDA's clearly stated preference for electronic registrations. These forms are accessible below:

- **Form FDA 5066: Registration of Cosmetic Product Facility**
- **Form FDA 5067: Cosmetic Product Listing**

FDA intends to use the FDA Establishment Identifier (FEI) as the required facility registration number. To facilitate the registration process, the owner or operator of a facility will need to obtain an **FEI number** before submitting the facility registration.

Generally, a cosmetic product listing must include the facility registration number of each facility where the cosmetic product is manufactured or processed. Thus, it is important for facilities to register before the product listing is completed.

There is no fee to submit a registration or product listing to FDA.

Is the submitted information publicly disclosed?

The product listing number will not be available for public disclosure (FD&C Act Section 607(d)). Further, FDA will not disclose information from a facility registration on the brand names under which cosmetic products manufactured or processed in the facility are sold, or from a product listing on the facility registration number of the facility where the cosmetic product is manufactured or processed, in response to a request under the Freedom of Information Act (FOIA) (5 U.S.C. 552) (FD&C Act Section 607(e)).

Beyond that, FDA intends to make relevant information from cosmetic product facility registration and listing available to the public to the extent permitted by law. Therefore, all other information from cosmetic product facility registration and listing would be available for public disclosure consistent with the FOIA, FDA's disclosure regulations under 21 CFR Part 20, and other applicable federal laws.

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Please do not hesitate to reach out to the authors of this alert if you have any questions about these or other requirements under MoCRA.