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

Revamping Cosmetics Safety and Regulation: Updates from FDA on Regulatory Changes under MOCRA.

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On December 29, 2022, President Biden signed into law the "Consolidated Appropriations Act, 2023." The Act includes the Modernization of Cosmetics Regulation Act of 2022 ("MOCRA"), which increased the authority of the United States Food and Drug Administration (FDA) to regulate cosmetics products and provide enhanced cosmetics protections for consumers. For insight, please see our prior blog post, *Revamping of Cosmetics Regulation and Safety* (January 23, 2023).

FDA previously announced that it will no longer accept facility registration and product listing submissions to the Voluntary Cosmetic Registration Program (VCRP) beginning March 27, 2023. Formerly, cosmetic companies had the option of participating in the Voluntary Cosmetic Registration Program ("VCRP") for products sold in domestic commerce. The purpose of VCRP was to help FDA gather information on cosmetics, including ingredients, frequency of use, etc.

Most recently, in August 2023, the FDA released draft guidance, entitled *Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry*, on upcoming regulatory changes pursuant to MOCRA, including guidance on cosmetic product facility registrations and product listings. Importantly, because MOCRA imposes requirements that are different from those required under the VCRP, the FDA emphasizes in this guidance that it will not consider previous submissions to the VCRP as satisfying the facility reporting and product listing requirements under MOCRA. Comments on the draft guidance were due by September 7, 2023 and can be viewed on Docket No. FDA-2023-D-1716-002.

Several commenters, including multiple industry associations, requested that the FDA keep cosmetic facility registration and product listing information protected from public disclosure under the Freedom of Information Act (FOIA) and refrain from publicizing FDA's database of facility registrations and product listings. For example, industry groups requested that FDA (1) define the information within public facility registrations and product listings that would be considered "relevant information" under FOIA and therefore disclosable, and (2) provide clear confirmation that the identity of responsible parties remain confidential.

Some groups requested FDA to continue to use the same product listing categories that were used under the VCRP until the initial registration and listing period ends. This would allow industries to have more time to update their internal categorization systems to match with FDA's final guidance. Other groups have requested FDA go back to using the VCRP's categories permanently, explaining that the new list of categories could place several products in more than one category.

Additionally, a few foreign-based cosmetics companies provided comments seeking FDA clarification on whether a “Responsible Person” under MoCRA may be a foreign entity.

Product Categories

FDA developed a draft list of categories and codes for cosmetic products for facilities to use when registering a facility or listing a cosmetic product. This list is available in Appendix A of the draft guidance. Categories include (01) baby products, (02) bath preparations, (03) eye makeup preparations (other than children’s eye makeup preparations), (04) children’s eye makeup preparations, (05) fragrance preparations, (06) hair preparations (non-coloring), (07) hair coloring preparations, (08) makeup preparations (not eye)(other than makeup preparations for children), (09) makeup preparations for children (not eye), (10) manicuring preparations, (11) oral products, (12) personal cleanliness, (13) shaving preparations, (14) skin care preparations (creams, lotions, powder and sprays), (15) suntan preparations, (16) tattoo preparations, and (17) other preparations.

Each of these categories are assigned their own codes and subcategories. For example, (01) baby products are further broken down into (a) baby shampoos, (b) lotions, oils, powders, and creams, (c) baby wipes, and (d) other baby products – (i) leave-on and (ii) rinse-off.

New Submissions Portal

To replace the VCRP, the FDA has developed and plans to implement an online submission portal called “Cosmetics Direct” for facility registrations and product listings beginning October 2023. The FDA is now accepting public comments on this new

portal system. Comments can be submitted and viewed on docket No. FDA-2023-N-1029. The comment period ends on October 18, 2023.

The online portal system should function to streamline the process for submitting and receiving registrations and listings. The portal will use a "structured product labeling (SPL) format." This document format will allow facilities to register and to list products in bulk under one registration ID. Additionally, this format should allow manufacturers and facilities to enter information more easily at biannual renewal because the portal system retains submission information submitted in previous years.

Within this new submission portal, facilities will be able to create new product facility registrations or may upload registrations from an existing file. Facilities will also be able to view all of their previous submissions within the portal.

Applicability

Facilities regulated under MOCRA encompass any establishment that manufactures or processes cosmetics products. Under FDA regulations, a cosmetic product is defined as "a finished cosmetic the manufacture of which has been completed" and can include cosmetics that are also drugs, devices, or components. As a result, under MOCRA, entities that manufacture raw material inputs into cosmetics – but not final products – would not be subject to the heightened requirements. ,

Exemptions:

- **Downstream Establishments:** MOCRA explicitly exempts establishments downstream from the manufacturing and

processing of cosmetics including beauty shops, product retailers, health care entities, public health agencies, hotels and airlines that provide complimentary cosmetics, and establishments that are only involved with tasks such as labeling, packaging, or distributing.

- **Small Businesses:** MOCRA exempts small businesses from compliance with the GMPs and registration and listing requirements. Additionally, it provides for preemption of certain State laws with respect to registration and product listing, GMPs, records, recalls, adverse event reporting, and safety substantiation.
- **Dual Products:** Although dual products (*i.e.,* a product that is both a drug and a cosmetic) fits within the definition of cosmetic product, facilities that manufacture or produce a product that is both a drug and cosmetic are exempt from the registration and listing requirements of section 607 of the Food, Drug & Cosmetic Act. However, under MOCRA, facilities that manufacture or produce these dual products ***and*** also produce products which are solely cosmetics **must still register their facility and list their cosmetics with the FDA**.

Timing:

- **Facility Registration:**
  - Existing facilities must register within one year of the enactment date (on or before December 29, 2023).
  - Any new facilities, those established after the enactment date of MOCRA, must register within (a) 60 days of one year of the enactment date (February 27, 2023) or (b) 60 days of engaging in regulated activity, whichever is later.
  - Any facility that needs to update their registration must do so within 60 days of the change that requires the update.
- **Cosmetic Product Listing:**

- A listing for cosmetic products that existed on or before the enactment date must be submitted within one year of the enactment date (on or before December 29, 2023).
- Listings for new cosmetic products on the market after the enactment date (after December 29, 2022) must be submitted within 120 days of marketing the product in interstate commerce.
- Thereafter, listings must be updated annually.

Cosmetics facilities and manufacturers should review the new portal system and submit comments by October 18, 2023. Additionally, facilities and manufacturers should prepare to register their facilities and list cosmetics in advance of the December 23, 2023 deadline under MOCRA. Please contact our SPB team with any questions regarding the above-described updates.

National Law Review, Volume XIII, Number 290