FDA’s Draft Guidance on Cosmetics Registration and Listing: A Good Reminder of End-of-Year Deadlines

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Earlier this month, in a step toward implementing the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), FDA issued a draft guidance document titled “Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry.” For those who may be new to MoCRA, this legislation significantly overhauled FDA oversight of the cosmetics industry by requiring manufacturers, packers, and distributors, to comply with a range of new standards, including mandatory product and facility registration, creation of safety substantiation information, and adverse event reporting subject to a December 2023 deadline (per the one-year timeframe set per statute). Additional compliance measures, including issuance of good manufacturing practices regulations, updated fragrance allergen disclosures, and domestic contact labeling are expected in 2024 and thereafter.

Regarding product and facility registration and listing, in question-and-answer format, the draft guidance addresses a range of topics, including:

- Definitions
- Who registers and submits product listings
- What information is submitted to register and list
- Will the information submitted be public
- How and when stakeholders register and list
- Treatment of cosmetic products that are also drugs
- Fees

The draft guidance is open for comment until September 7th. Previous voluntary facility registrations will not be considered adequate to comply with the mandatory registration and listing requirement. FDA expects to have an electronic portal available in October 2023 along with a paper registration option.

Other December 2023 Deadlines

Stakeholders will recall that several provisions in MoCRA have one-year deadlines, making December 29, 2023 a key date. In addition to establishment registration and product listing (§607), these

include:

- Adverse event recordkeeping and reporting (§605) – Every responsible person must maintain records of all adverse events associated with any of its cosmetic products for six years. Serious adverse event reports must be submitted to FDA (along with retail packaging of the product at-issue) within 15 business days after receipt of same.
- Safety substantiation (§608) – Responsible persons must ensure, and maintain documentation of, "adequate substantiation of safety" for each cosmetic product it distributes/manufactures.

Additional information regarding MoCRA's requirements is available here.