American Shipping Company

"News Flash"

March 26, 2024

Modernization of Cosmetics Regulation Act of 2022 (MoCRA)

MoCRA is legislation which will help facilitate the updating and enhancing of cosmetic regulations in the U.S. The ACT addresses the need for more regulatory framework to ensure the safety of cosmetic products. It will also help to strengthen ingredient safety, improve labelling requirements and promote greater transparency between manufacturers and consumers. The deadline to comply with the Act is July 1, 2024.

The new regulation requires cosmetic manufacturers that ship cosmetics to the U.S. to register with FDA and renew their registration every two years. A responsible person in the U.S, defined as the manufacturer, packer or distributor of a cosmetic product also needs to be registered. FDA strongly encourages electronic submissions to facilitate efficiency and timeliness of data submission and management for the agency.

In addition to the above, the responsible person must also list each marketed cosmetic product with FDA, including product ingredients, and provide any updates annually.

Following is an FDA electronic submission portal for registration and submission, where both forms of registrations can be completed.

- **Cosmetics Direct**: You can submit your facility registrations using the Cosmetics Direct electronic submission portal at: https://direct.fda.gov.

Companies and individuals who manufacture or market cosmetics have a responsibility to ensure the safety of their products. Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients.

- A responsible person is required to ensure and maintain records supporting adequate safety substantiation of their cosmetic products. Manufacturers can use relevant safety data that is already available to support the safety of their products. Animal testing is not a requirement for marketing a cosmetic product. It's important, however, that all data used to support the safety are derived from scientifically robust methods.
- For more resources on cosmetics safety substantiation, please visit Product Testing of Cosmetics.

MoCRA also requires that industry comply with regulations that FDA will establish for:

- Good Manufacturing Practice (GMP) requirements for facilities that manufacture cosmetic products. For more information, please visit:

  - Public Meeting: Good Manufacturing Practices for Cosmetic Products Listening Session
  - Draft Guidance for Industry: Cosmetic Good Manufacturing Practices
- Fragrance allergen labeling requirements.
- Standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products

- A responsible person is required to report serious adverse events associated with the use of cosmetic products in the United States to FDA within 15 business days. The responsible person must include a copy of the label on or within the retail packaging of such cosmetic product. If the responsible person receives medical or other information about the adverse event within 1 year of the initial report to FDA, they must submit this new information to FDA within 15 business days. FDA will also have access to adverse event reports during an inspection.
- FDA recommends that industry responsible persons submit serious adverse event reports for cosmetics by using the current Form 3500A that is downloadable and fillable at MedWatch: The FDA Safety Information and Adverse Event Reporting Program - Mandatory (PDF). Please submit the completed form along with information to support the report, such as scans of labels and images of the serious adverse event to FDA via email at: CosmeticAERS@fda.hhs.govor by mail to:
- FDA CDER Mail Center
  Attn: Cosmetics MedWatch reports
  White Oak Campus, Building 22, G0207
  10903 New Hampshire Ave.
  Silver Spring, MD 20993

MoCRA exempts certain small businesses from GMP, registration, and product listing requirements.
However, such exemptions do not apply to manufacturers or facilities that manufacture or process the following cosmetic products:

- Products that regularly come into contact with 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.
For additional information regarding MoCRA and the Final Guidance issued by the FDA, you can access the following link:
https://www.fda.gov/cosmetics/cosmetics-news-events/fda-issues-final-guidance-registration-and-listing-cosmetic-product-facilities-and-products

OFFICE LOCATIONS

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