Modernization of Cosmetics Act of 2022 Overhauls FDA Regulation of the Cosmetics Industry

Mar 09, 2023

Categories:

Publications

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On December 29, 2022, President Joe Biden signed the Modernization of Cosmetics Act of 2022 (MoCRA) into law. MoCRA amends the Food, Drug, and Cosmetic Act (FDCA), extending the Food and Drug Administration's (FDA) authority over cosmetic companies and increasing the regulatory burden on cosmetics companies. Below is a summary of the major changes:

Adverse Event Reporting and Record Keeping Requirements (FDCA § 605)

Cosmetic Companies are now required to retain all reports of Adverse Events for six years. An Adverse Event is any health-related event that is associated with a cosmetics product. These reports can be inspected by the FDA and the FDA can request fragrance and ingredient information of the product if it is suspected that a certain ingredient caused the Adverse Event.

Additionally, cosmetic companies are now required to report all Serious Adverse Events[1] to the FDA within 15 business days of receiving the report. Cosmetic companies must also forward any new information about a Serious Adverse Event for one year following its initial report to the FDA.

Substantiation of Safety (FDCA § 608)

Cosmetic Companies must ensure and maintain records supporting that there is adequate substantiation of safety for a cosmetic product. These records can include:

- Tests or studies;
- Research;
- Analyses; Or

- Other evidence that is considered by experts qualified by scientific training and expertise to evaluate the safety of a cosmetic product and their ingredients, sufficient to support a reasonable certainty that the cosmetic product is safe.

Labeling Changes (FDCA § 609)

Cosmetic labels must include domestic address, phone number, and electronic contact information. Additionally, fragrance allergens must also be listed on the product label in compliance with forthcoming regulations mandated by MoCRA.

Registration and Listing (FDCA § 607)

A new requirement for the cosmetics industry, any person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States must register with the FDA. This includes foreign manufacturers.

Additionally, every cosmetic product introduced into interstate commerce must be listed with the FDA. The listing must include:

- The facility registration number for each facility where the cosmetic is manufactured or processed.
- Name and contact number of Responsible Person (i.e. the company name on product)
- Applicable cosmetic category
- A list of ingredients, including any fragrances/colors
- Can have a single listing for similar products if ingredients only differ in respect to colors, fragrances, flavors, or quantities.

This listing with the FDA is confidential. Even if a cosmetics company is not required to register with the FDA, if the company's name is on the product, then the company must still list all cosmetic products.

Facilities must initially register by December 29, 2023, thereafter new facilities must register within 60 days of starting operations. All products currently distributed in interstate commerce must be

listed by December, 29 2023. Under MoCRA, any new products distributed after December 29, 2022 must be listed within 120 days of marketing such product. However, to date the, FDA has not published any guidance nor provided any database for cosmetic companies to list their products to comply with MoCRA.

Good Manufacturing Practices (FDCA § 606)

No later than December 29, 2024, the FDA will publish notices of regulations regarding Good Manufacturing Practices for cosmetics. Final regulations will be published no later than December 29, 2025.

Forthcoming Regulations/Reports

By December 29, 2023, there will be proposed regulations for asbestos testing methods in talc products. Final regulations will take effect 180 days after the comment period closes.

No later than December 29, 2025, the FDA will publish a report regarding Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) in cosmetics.

MoCRA states that the FDA will phase out animal testing, although no timeline was provided.

Accommodations for Small Businesses

If a cosmetic company's average gross annual sales for the previous three-year period is less than $1 million, and the company does not engage in manufacturing or processing as defined under the Act, then the small business is exempt from Good Manufacturing Practices under FDCA §606 and the Registration and Listing Requirements under FDCA § 607.

New FDA Enforcement Powers

In addition to the new and forthcoming requirements, MoCRA also expands the enforcement powers of the FDA:

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- **Facility Suspension** (FDCA § 607)- A facility's registration can be revoked if the FDA concludes that the facility is non-compliant. No cosmetic products can be sold in interstate commerce until the registration is reinstated
- **Records Access** (FDCA § 610)- The FDA has authority to access records relating to cosmetic products if the FDA reasonably believes that the ingredients are adulterated and present a threat of adverse health consequences (does not include: formulas/recipes, financial information, pricing data, personnel data, research data, or sales data).
- **Recall Authority** (FDCA § 611)- If the FDA believes that a product is adulterated or misbranded and this violation has a reasonable likelihood of causing a serious health consequence or death, the FDA will provide the opportunity for a voluntary recall. If the cosmetics company does not institute the voluntary recall, then the FDA can force a recall.

Preemption (FDCA § 614)

MoCRA preempts any state laws that differ when concerning registration; product listing; good manufacturing practice; records; recalls; adverse event reporting; or safety substantiation. However, this **does not** impact state statutes concerning prohibiting use or limiting amount of cosmetic ingredients or any continuing requirements of state statutes in place at the time of MoCRA's passage for reporting an ingredient of a cosmetic product.

Cosmetic companies should institute new standard operating procedures and policies to comply with MoCRA and forthcoming FDA regulations.

If you have any questions about MoCRA or compliance with FDA regulations, please contact any attorney with Frost Brown Todd's Consumables industry team.

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[1] A Serious Adverse Event is a health related event that is associated with a cosmetics product that results in: death, life-threatening experience; inpatient hospitalization; a persistent or significant disability or incapacity; a congenital abnormality or birth

defect; an infection; or the significant disfigurement (including serious and persistent rashes, second or third degree burns, significant hair loss, or persistent or significant alteration of appearance), other than as intended, under conditions of use that are customary or usual; or requires medical or surgical intervention to avoid the consequences described above.

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