The Future of Cosmetics Regulation is MoCRA – The Modernization of Cosmetics Regulation Act of 2022

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Overview

- Cosmetics Regulations Background
- What to Change in 2023
- Ways to Participate
- Looking Beyond
- Enforcement and Risk Mitigation

Background of Cosmetic Regulation

Who?

- The U.S. Food and Drug Administration (FDA) regulates cosmetics, drugs, medical devices, foods, tobacco products, and electronic products that emit radiation.
- The FDA regulates cosmetics, primarily under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA).
- With the passing of MoCRA, FDA will also regulate under MoCRA.

Background of Cosmetic Regulation

What?

- **Cosmetics**: "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."
  - Includes wide range of skin moisturizers, perfumes, lipsticks, fingernail polishes, shampoos, hair colors, deodorants, etc.

- Combo products
  - **Drugs** are "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and articles (other than food) intended to affect the structure or any function of the body
  - For example, an antidandruff treatment shampoo is a drug and a cosmetic.

What's new under MoCRA – what to change in 2023

Designation of a Responsible Person

- A 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.
- What must be on the label?: Must have a domestic address, Domestic telephone number, or electronic contact information

What's new under MoCRA – what to change in 2023

Facility Registration – Manufacturers and Processors

- Registration will include the following:
  - facility's name, address, email address, and telephone number
  - if the facility is a foreign facility, the contact information for the U.S. agent
  - any previously assigned facility registration number
  - all brand names under which cosmetic products are sold
  - the product category or categories
  - Responsible Person for each product manufactured or processed at the facility

Registration Deadline:
December 29, 2023

Renew every **2 years**

What's new under MoCRA – what to change in 2023

Facility Registration – Manufacturers and Processors

Exemptions:

- A facility that manufactures or processes cosmetics for multiple responsible persons only needs a single facility registration.
- Certain small businesses are exempt from facility registration.
- Beauty shops and salons, retailers, retail distribution facilities, pharmacies, hospitals, physicians' offices, and health care clinics that do not manufacture or process cosmetic products
- Establishments that solely perform one or more: labeling, relabeling, packaging and repackaging (but not filling containers with product), holding, and distributing cosmetic products

What's new under MoCRA – what to change in 2023

Product Listing

- A Responsible Person must list each marketed cosmetic product with the FDA, including product ingredients, and provide any updates annually.
- Listing will include the following:
  - the facility registration number
  - name and contact number of the Responsible Person
  - name for the product
  - applicable cosmetic category or categories for the product
  - list of ingredients, including any fragrances, flavors, or colors
  - product listing number, if any was previously assigned
- *Exemptions*
  - If cosmetic products have identical formulations (but for colors, fragrances or flavors, or quantity of contents) then only 1 product listing is needed.
  - Certain small businesses are exempt from product listing

Products that were marketed by 12/29/2022 must be listed by **December 2023.**

Products that are first marketed after 12/29/2022 must be listed **within 120 days of marketing** such product.

What's new under MoCRA – what to change in 2023

Safety Substantiation

- A responsible person is required to ensure and maintain records supporting adequate safety substantiation for their products.
- **"Adequate substantiation of safety"** means tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe.
- **"Safe"** means that the product, including *any* ingredient thereof, is not injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

What's new under MoCRA – what to change in 2023

Adverse Event Reporting

- A Responsible Person is required to report serious adverse events associated with the use of cosmetic products in the U.S. to the FDA within fifteen business days after receiving the report.
- A **"serious adverse event"** means an adverse event that results in death, life-threatening experience, inpatient hospitalization, persistent or significant disability or incapacity, a congenital anomaly or birth defect, an infection, or significant disfigurement, or an event that requires a medical or surgical intervention to prevent the previously described outcomes.
- Any records related to an adverse event report must be maintained for 6 years.

Labeling

Adverse events contact information – include domestic address, domestic phone number, or electronic contact information, which may include a website, through which your Responsible Person can receive adverse event reports.

What's new under MoCRA – Opportunities to Participate in 2023

Good Manufacturing Practice (GMP) requirements

- **May 18, 2023 (6:00 pm EDT):** Deadline to register if you wish to speak at the meeting. Each *speaker* will be limited to approximately 3 minutes.
- **May 22, 2023:** Deadline to submit all presentation materials, in PDF format, to MoCRAGMPMeeting@fda.hhs.gov.
- **June 1, 2023:** Deadline to register to attend the listening session; registration may be performed at any time before or during the listening session.

Public Meeting
June 1, 2023
10 a.m. to 1 p.m. EDT

What's new under MoCRA – Opportunities to Participate in 2023

Good Manufacturing Practice (GMP) requirements

The FDA is soliciting comments on the following topics:

- Identify any national or international standard and the extent to which it would be practicable for good manufacturing practice regulations for cosmetics. Would specific standards be too burdensome?
- What constitutes sufficient flexibility within GMP for cosmetics to ensure regulations are practicable for all sizes and types of facilities?
- What constitutes simplified GMP for small businesses?
- What are appropriate compliance times for GMP regulations?
- What is the economic impact of implementing GMP?
- How would implementing GMP impact the likelihood of recall of cosmetics or the likelihood of consumers experiencing adverse events?

July 3, 2023: Deadline to submit comments to Docket No. FDA-2023-N-1 466.

Summary

Actions You Can Take in 2023

- Designate a Responsible Person
- Register your facility
- List your products
- Review your records to ensure they show proper safety substantiation
- Review your records-keeping procedures for compliance with MoCRA
- Review your adverse event reporting procedures
- Start updating your labeling with contact information for your Responsible Person
- Start moving away from animal testing
- Assess whether your products contain PFAS and keep updated on the development and safety of PFAS

What's Next Before the FDA – Looking Beyond

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Looking Beyond

New Regulations

- *Good Manufacturing Practice* – after the rules are promulgated, you must ensure your facilities follow the GMPs
- *Fragrance Allergen Labeling Requirements* - The FDA will identify fragrance allergens that must be disclosed on cosmetics labels. You must include in your labeling by December 2024 the fragrance allergens present in your products.
- *Standardized Testing Methods for detecting and identifying asbestos in talc-containing cosmetic products* – you must comply with the promulgated testing methods

Looking Beyond

Labeling Changes under MoCRA

- In addition to all other labeling requirements, cosmetics labels must also include
  1. A list of each fragrance allergen included in the product
  2. Contact information for Adverse Event Reporting (by December 2024)
  3. Clear and prominent statement that explains that a "professional use only" product must be administered or used only by a licensed professional (by December 2023)

Enforcement Powers under MoCRA and Risk Mitigation

1. **Records access** - the FDA can access and copy records related to a cosmetic product, including safety records if FDA reasonably believes a product is likely to be adulterated and poses a serious adverse health consequence or death to humans.
2. **Mandatory recall authority –** The FDA will provide the Responsible Person with an opportunity to voluntarily cease distribution and recall the product. If the Responsible Person refuses, the FDA may order the person to immediately cease distribution and/or recall.
3. **Facility Suspension_-** The FDA can suspend registration if a product has a reasonable probability of causing serious adverse health consequences or death and other products manufactured/processed at the facility may be similarly affected

Risk Mitigation

Per and Polyfluoroalkyl Substances (PFAS) in Cosmetics

- **Examples PFAS**: in cosmetics include PTFE (polytetrafluoroethylene), perfluorooctyl triethoxysilane, perfluorononyl dimethicone, perfluorodecalin, and perfluorohexane
- **MoCRA:** FDA to release a report within 3 years. In particular, the FDA will monitor for relevant toxicity studies and dermal absorption information.
- **A New Wave of Litigation:** PFAS in cosmetics, especially when the products make claims that they are free of harmful chemicals.
- **State Level**: California, Maryland, Maine, and Colorado banned products with PFAS intentionally added. Additional 32 states are considering PFAS restrictions, including for use in cosmetics.

Conclusion

Checklist (this is NOT an all-inclusive list)

- Designate a Responsible Person
- Involve counsel before marketing "safety" claims
- Review all product composition, safety, and toxicity to ensure that your records show proper safety substantiation
- Review your records-keeping procedures for compliance with MoCRA and the upcoming GMPs
- Review your adverse event reporting procedures
- Register your facility
- List your products
- Update your labeling to comply with new MoCRA labeling requirements
- Start moving away from animal testing
- Assess whether your products or packaging contain PFAS and keep updated on the development of the safety of PFAS.

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