U.S. Modernization of Cosmetics Regulation Act

Kim Norman, PhD, DABT, ERT
December 4, 2023
Modernization of Cosmetics Regulation Act of 2022 (MoCRA)

First significant amendment to Food, Drug & Cosmetic (FD&C) Act for cosmetics since 1938

President Biden signed into law Dec. 29, 2022
FDA Authority – Cosmetics/Color Additives

- 1938 Federal Food, Drug, and Cosmetic Act (FD&C Act)
- 1960 Color Additive Amendments to the Act
- 1966 Fair Packaging and Labeling Act (FPLA)
- 2022 Modernization of Cosmetics Regulation Act (MoCRA)
Prior to MoCRA

- Cosmetics must not be adulterated or misbranded
- FDA authority is post-market
- No requirements for FDA approval of cosmetic ingredients or finished products except color additives
- Manufacturer responsibility for ensuring cosmetic products are not harmful under intended conditions of use (may test or use available data for similar products for safety evaluation)
- FDA can take enforcement action on cosmetics products shown to be adulterated and/or misbranded
- Cosmetic Products should be labeled properly as per FD&C and FPLA
- Registration is voluntary
Overview of MoCRA

- Adverse Events
- Safety Substantiation
- Facility Registration & Product Listing (not approval process)
- Labeling
- Good Manufacturing Practices
- Records Access, Facility Suspension, Recalls
- Fragrance Allergen Disclosure
- National Uniformity
- Talc Rule & PFAS Report
Key MoCRA Timelines

- **Registration & Product Listing**
  (Enforcement discretion through Jul. 1, 2024)

- **Adverse Event Reporting**

- **Safety Substantiation**

- **Mandatory Recall Authority**

- **Labeling - Professional Use**

- **Testing Method for Asbestos Rule**
  (Final rule 180 days after comment period)

- **Labeling of Fragrance Allergen Rule**
  (Final rule 180 days after comment period)

- **Labeling - Contact Information**

- **Good Manufacturing Practice Rule**
  (Final rule Dec. 29, 2025)

- **PFAS in Cosmetics Report**
Key MoCRA Definitions

**Responsible Person**
“The term ‘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 [FD&C Act] or section 4(a) of the Fair Packaging and Labeling Act [FPLA].”

**Cosmetic Product**
The term ‘cosmetic product’ means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.

**Facility**
“The term ‘facility’ includes any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States.”
## Where Does MoCRA Place the New Responsibilities?

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Facility Registration & Product Listing

Owners or operators must register all their facilities that manufacture or process cosmetic products for distribution in the U.S.

Alternatively, any responsible person may register their contract manufacturers

Includes international facilities

Responsible persons must list all cosmetic products marketed in the U.S., or must ensure that such submissions are made

Certain very small businesses are exempt
Preparing for Registration and Listing

FDA has not begun accepting registrations & listings yet

- **COSMETICS DIRECT** expected to open soon
- FDA has extended compliance date through Jul. 1, 2024

While FDA continues to develop program:

- Companies can check FDA Establishment Identifier (FEI) status at FDA’s [FEI Search Portal](#)
  - If not previously assigned, follow [How can I request an FEI number instructions](#) (takes approx. 10-15 business days)
- Gather necessary information
Facility Registration

Registrations must contain:

- Facility’s name, physical address, email address, telephone number,
- FDA Establishment Identifier (FEI) number, and
- If the facility is located outside of the U.S., contact information for the U.S. agent of the facility and, if available, the agent’s electronic contact information

For each cosmetic product manufactured or processed at the facility, the registration must provide:

- Brand name under which the product is sold (to be withheld under FOIA),
- Product category or categories for the product, and
- Responsible person for the product
Product Listing

Required Information

Product listings must contain:

- FDA Establishment Identifier (FEI) number of each facility where the cosmetic product is manufactured or processed,
- Name and contact number of the responsible person and the name of the cosmetic product as it appears on the label,
- Applicable cosmetic category or categories of the cosmetic product,
- List of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by name, as required under 21 C.F.R. § 701.3, or by the common or usual name of the ingredient, and
- Product listing number, if any, previously assigned by FDA
Report serious adverse events (per use in U.S.) to FDA within 15 business days; plus “new and material” medical info within 1 year of report

Submit using FDA’s MedWatch 3500A Form (PDF); FDA developing electronic portal

Maintain records of all adverse events (per use in U.S.) for period of six years (except certain smalls businesses, three years); subject to inspection
Key MoCRA Definitions

Adverse Event

“The term ‘adverse event’ means any health-related event associated with the use of a cosmetic product that is adverse.”

Serious Adverse Event

“The term ‘serious adverse event’ means an adverse event that results in, or requires medical intervention to prevent:

(i) death;
(ii) a life-threatening experience;
(iii) inpatient hospitalization;
(iv) a persistent or significant disability or incapacity;
(v) a congenital anomaly or birth defect;
(vi) an infection; or*
(vii) significant disfigurement (including serious and persistent rashes or infections, 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.”*

*Added to existing serious adverse event definition, only for cosmetics
Additional Labeling Requirements

Builds on existing requirement to label a cosmetic product with the name & place of business of manufacturer, packager, or distributor (i.e., responsible person)

Domestic (U.S.) address or phone number, or electronic contact information (such as a website) for adverse event reporting

Professional products must comply with all FD&C Act & FPLA labeling requirements (e.g., ingredient disclosure, etc.)
“ensure, and maintain records supporting, adequate substantiation of safety”

Safety Substantiation

FD&C Act has prohibited adulterated cosmetics from U.S. interstate commerce since 1938; FDA’s regulations have required adequate substantiation of safety

New requirement to ensure/maintain records supporting adequate safety substantiation

Safe means a cosmetic product is not injurious to users under the conditions of use prescribed in the labeling thereof, or under customary or usual use (same as current standard)
Adequate Substantiation of Safety

- Under MoCRA, means “tests or studies, research, analyses, or other evidence or information that is considered among experts... sufficient to support reasonable certainty that a cosmetic product is safe.”

- FDA’s current regulations state that the safety of a product can be adequately substantiated through:
  
  (a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to the particular cosmetic,
  
  (b) performance of any additional toxicological and other tests that are appropriate in light of such existing data and information.
Safety Substantiation

- Not expecting additional guidance from FDA at this time
- Resources:
  - Cosmetic Ingredient Review (CIR)
  - Fragrance: IFRA/RIFM
  - Scientific Committee on Consumer Safety (SCCS)
  - EU Cosmetic Directive & Annexes
  - International Cooperation on Cosmetic Regulation (ICCR)
“identify on the label of a cosmetic product each fragrance allergen”

Fragrances

FDA to determine via rulemaking new label disclosure requirements for fragrance allergens

Must consider international, State, and local requirements, including EU

If reasonable evidence product or ingredient contributed to serious adverse event, FDA may request the list of fragrance/flavor ingredients

Responsible person must ensure that requested information is submitted to FDA within 30 days

FDA cannot disclose fragrance list (confidential)
Good Manufacturing Practices

“[FDA] shall by regulation establish good manufacturing practices for facilities”

GMPs established by regulation; shall be consistent if practicable and appropriate with national and international standards

Regulations must be focused only on requirements needed to protect public health and ensure that cosmetic products are not adulterated

FDA shall provide sufficient flexibility for all sizes and types of facilities and simplified requirements for small businesses; very small businesses fully exempt
MoCRA preempts any state or local laws that differ on registration, product listing, good manufacturing practice, records, recalls, adverse event reporting, or safety substantiation.

States may limit or ban use of cosmetic ingredients in cosmetic products, and may continue ingredient reporting requirements that predate MoCRA.

State laws “different from or in addition to, or otherwise not identical with” certain MoCRA provisions are preempted.
New FDA Tools

**Records Access**

- During routine inspections, records access limited to adverse events and GMPs
- If FDA has a reasonable belief that a cosmetic product or ingredient, and any other cosmetic product that the FDA reasonably believes is likely to be affected in a similar manner, is **likely to be adulterated such that the use or exposure to such product presents a threat of serious adverse health consequences or death to humans**, each responsible person and facility shall allow FDA to have access to other records including **safety substantiation** and **shipment data**
  - Does not extend to cosmetic formulas/recipes, or to financial, pricing, sales, personnel, or research data
New FDA Tools

Suspension of Facility Registration

- Facilities with suspended registrations may not distribute cosmetic products
- Detailed procedures for FDA in MoCRA; only FDA Commissioner can approve
- Standard: if the FDA determines that a cosmetic product manufactured or processed by a registered facility and distributed in the United States has
  - a reasonable probability of causing serious adverse health consequences or death to humans and
  - a reasonable belief that other products manufactured or processed by the facility may be similarly affected because of a failure that cannot be isolated to a product or products, or is sufficiently pervasive to raise concerns about other products manufactured in the facility
New FDA Tools

Mandatory Product Recall Authority

- FDA may issue mandatory recalls
- Detailed procedures for FDA in MoCRA; only FDA Commissioner can approve
- Standard: If the FDA determines that there is
  - a reasonable probability that a cosmetic is adulterated or misbranded and
  - the use of or exposure to such cosmetic will cause serious adverse health consequences or death.
FDA Resources on MoCRA

- Modernization of Cosmetics Regulation Act of 2022 (MoCRA) | FDA
- GMP Listening Session and Request for Comments (April 27, 2023)
- Draft Paperwork Reduction Act (PRA) Labeling, Registration, and Listing (May 1, 2023)
- Draft Guidance on Registration and Listing (August 8, 2023)
- Final PRA, Draft Forms & Screenshots Labeling, Registration, Listing, and Adverse Events (September 18, 2023)
- SPL Implementation Guide (October 13, 2023)
- Compliance Policy for Registration & Listing (November 9, 2023)