

MoCRA: Modernization of Cosmetics Regulation Act of 2022

In December 2022, the **Modernization of Cosmetics Regulation Act (MoCRA)** was signed into law, the most significant update to U.S. cosmetic regulation since 1938. It expands the **FDA's authority** to ensure cosmetic safety and impacts formulators, manufacturers, and brand owners.

Key Requirements

- **Facility Registration** – Manufacturers/processors must register with FDA and renew every 2 years. (see small business exemption)
- **Adverse Event Reporting** – Serious reactions must be reported within 15 days.
- **FDA Records Access** – FDA may inspect company records and facilities.
- **Ingredient Listing** – Submit and update annually with FDA.
- **Recalls** – FDA can mandate recalls if a product is unsafe.
- **VCRP Discontinued** – New FDA registration system pending.

Labeling Essentials

- Must include responsible party's **legal business name and contact info** (no P.O. boxes).
- Acceptable consumer contact: phone, email, or website.
- **FTC enforces truth in advertising**—claims must be accurate and non-misleading.
- **Principal Display Panel (PDP)**: Follow font size and placement rules.
- **Safety Substantiation**: Back product safety with data, COAs, IFRA certificates, and stability/microbial testing.
- **Ingredient Declaration**: List ingredients in proper order, use INCI names, disclose blends, fragrance, botanicals, and net weight.

GMP & Recordkeeping

- Ingredient tracking, lot numbers, and batch records required.
- FDA will establish mandatory **Good Manufacturing Practices (GMPs)**

Small Business Exemption

Exemption applies if sales are under \$1M (3 consecutive years), except for:

- Injectables
- Ingestible cosmetics
- Long-lasting cosmetics (e.g., lashes, nails)
- Products contacting the eye's mucous membrane

Upcoming FDA Actions (2025+)

- **PFAS Report** – Safety assessment due Dec. 29, 2025.
- **GMP Standards** – FDA will issue detailed regulations.
- **Asbestos in Talc** – Standardized testing methods coming.

Why MoCRA Matters

MoCRA ushers in **greater safety, transparency, and accountability** in cosmetics. To stay compliant:

- Maintain safety data and traceability
- Follow labeling and claim rules
- Stay updated with FDA guidance