Registrar Corp

EXECUTIVE BRIEF

Protect Revenue & Reputation by Complying with FDA's New Cosmetics MoCRA Regulations

Executive Summary:

The $500 billion global cosmetics industry is undergoing a profound regulatory and business shift with the implementation of **MoCRA (Modernization of Cosmetics Regulation Act)**. MoCRA is the biggest U.S. cosmetics regulation change in 85 years and sets tough new standards for brands, manufacturers, co-mans, testing labs, and packers. The U.S. FDA has new enforcement authority for ensuring MoCRA compliance that is patterned on the FDA's drug/medical device oversight.

Leaders should not naively assume that MoCRA only impacts the regulatory department. In reality, MoCRA impacts the entire organization including R&D, sales, marketing, product labeling, manufacturing, legal, quality, and safety teams. Cosmetics executives and managers need to understand the business implications of MoCRA and take quick action to ensure their organizations are prepared.

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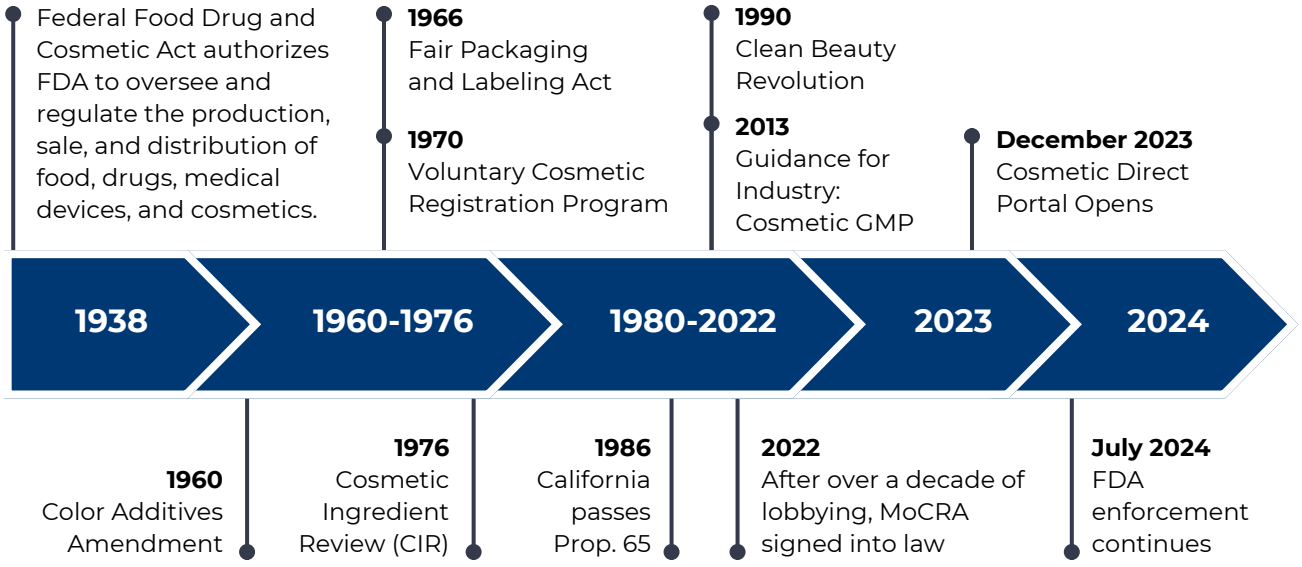
MoCRA: A New Era of Cosmetics Regulation

The U.S. Congress passed MoCRA in 2022 in response to rising consumer concerns over cosmetics safety. The bi-partisan legislation is the biggest change in cosmetics regulation since the original Food, Drug, and Cosmetic (FD&C) Act of 1938.

Evolution of Cosmetics Regulation: 1938-2024



As of July 1, 2024, FDA enforces the following 5 provisions of MoCRA:

1. Product & Ingredient Listings
2. Facility Registration and U.S. Agent
3. Adverse Event Management
4. Product Labeling
5. Safety Substantiation

Product & Ingredient Listings

Responsible Persons must list all cosmetic products sold in the U.S. and their ingredients annually alongside their company's facility registration. Each product shade or type must be listed separately, including seasonal resets and holiday kits. The Responsible Person must also renew product listings regularly with any updates.

Facility Registration & U.S. Agent

Cosmetics facilities that manufacture or process cosmetics under their own or another brand label must register with FDA. Facilities that manufacture or process non-drug cosmetics and manufacture or process drugs must register with FDA as both a cosmetic facility and a drug establishment.

All facilities required to register must complete and renew their registration every two years and update their information within 60 days of any changes.

Facilities based outside of the U.S. must designate a U.S. Agent to communicate with FDA on their behalf when completing or renewing their annual registration. U.S. Agents must be physically present in the USA to communicate with FDA for inspections, serious adverse events or public health concerns, and non-compliance on behalf of the facility.

Adverse Event Management

Adverse event management includes several requirements: **serious adverse event reporting**, **adverse event receiving**, and **recordkeeping**. Responsible Persons must report a "serious adverse event" to FDA within 15 business days.

FDA's updated "serious adverse event" definition is a health-related event that results in:

- Death or a life-threatening experience
- Inpatient hospitalization or an infection
- A persistent or significant disability or incapacity
- A congenital anomaly or birth defect
- Significant disfigurement (serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance not intended under conditions of use). This item was added specifically to reflect serious adverse events that may occur in cosmetics.

Reports must include patient information, details of the serious adverse event and outcome, suspect product information, and a copy of the product label. Any additional information submitted about the serious adverse event must be reported to FDA within 15 business days of receipt.

Responsible Persons are also responsible for receiving and recording all adverse events and storing records for 6 years (3 years for small businesses).

Product Labeling

FDA requires Responsible Persons to oversee new labeling requirements under MoCRA, in addition to general requirements in the Code of Federal Regulations (CFR) and FDA guidance documents. These requirements include:

Professional use labeling: Cosmetic products meant for professional use (salon, etc.) must indicate on the label that they are only to be used by licensed professionals.

Adverse event contact labeling: All cosmetic product labels must include Responsible Person's contact information (domestic address, phone number, and/or electronic contact information) for adverse events. Enforceable by FDA beginning December 29, 2024.

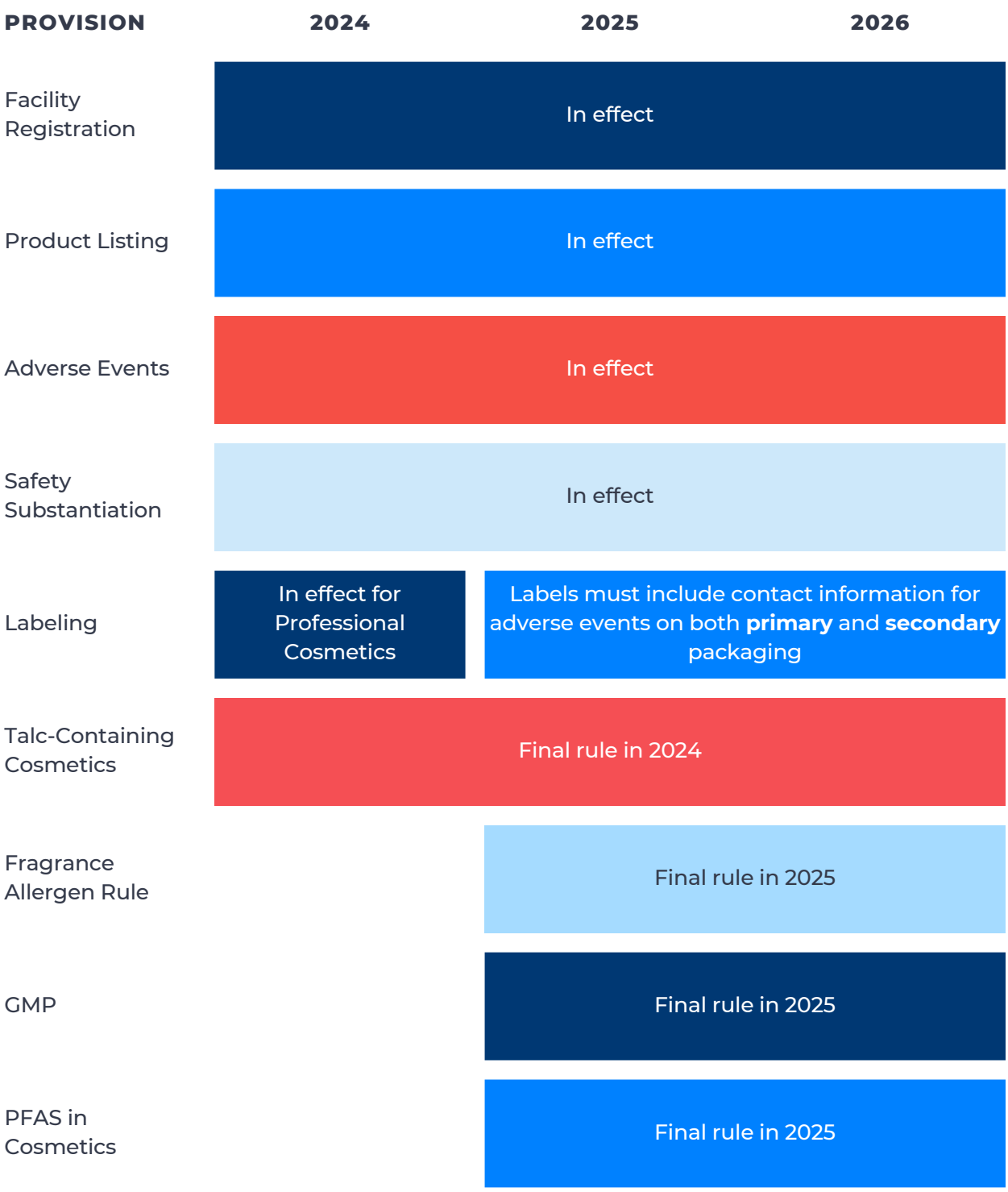
Fragrance allergen disclosure: Companies must disclose any potential fragrance allergens on product labels. FDA will be announcing proposed and final rules for this requirement in 2024 and 2025, respectively.

Safety Substantiation

Cosmetics companies must be able to provide documentation of tests or studies, research, analyses, or other evidence sufficient to support that a cosmetic product is safe.

FDA has no specific guidelines on the type of tests required but can request records from the Responsible Person in the case of potential violations.

Additional MoCRA Regulations in Coming Years

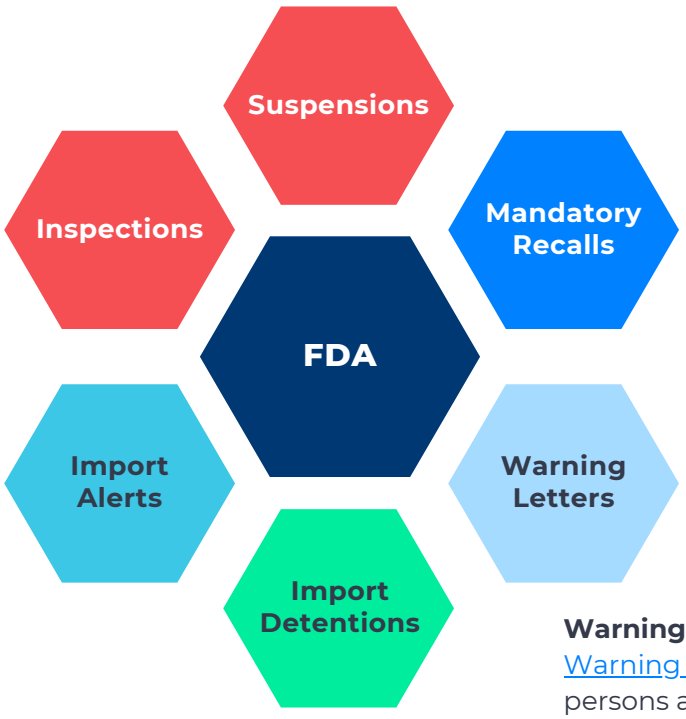


MoCRA Gives FDA Unprecedented Authority Over the Cosmetics Industry

MoCRA has also granted FDA expanded regulatory power over **all** cosmetics companies:

Suspensions: FDA can suspend a facility if there is a reasonable probability that a cosmetic product may cause a serious adverse health consequence or public health concern.

Inspections: FDA can inspect facilities and request access to records relating to a cosmetic product.



Mandatory Recalls: FDA may issue a mandatory recall if they determine that a cosmetic product is adulterated or misbranded, or the use and exposure will cause serious adverse health consequences or death.

Import Alerts: FDA has the ability to prevent potentially violative products from being distributed in the U.S. and places regulatory responsibility back on the importer. An Import Alert indicates that a country, company, and/or products are in potential violation and may be detained without a physical examination (DWPE).

Import Detentions: FDA may detain an imported product if FDA finds that the product appears to violate the Food, Drug, and Cosmetics Act (FD&C Act) during an import.

Warning Letters: FDA can issue Warning Letters to the responsible persons and manufacturers that violate FDA regulations around MoCRA requirements. Warning Letters notify the appropriate parties of potential concerns and require corrective action or an appeal of FDA's decision within a specific timeframe.

Key MoCRA Terms & Definitions

MoCRA has made critical updates to FDA terminology and introduced several new roles mandatory for cosmetics regulation. Knowing these terms will help you better understand how MoCRA affects your organization and how to comply efficiently and effectively.

Facility

Any establishment, including an establishment of an importer, that manufacturers or processes cosmetic products distributed in the United States.

Responsible Person

Manufacturer, packer, or distributor or a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of (FD&C) or section 4(a) of the Fair Packaging and Labeling Act (FPLA).

Cosmetic Product

Preparation of cosmetic ingredients with a qualitatively and quantitatively set compositions for use in a finished product.

Serious Adverse Event

Adverse event that results in:

- Death or a life-threatening experience
- Inpatient hospitalization or an infection
- A persistent or significant disability or incapacity
- A congenital anomaly or birth defect
- Significant disfigurement (serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance not intended under conditions of use)

Or requires reasonable medical judgment, a medical or surgical intervention to prevent a similar event.

MoCRA Requirements Across the Value Chain & Exemptions

Depending on their primary business activities, cosmetics companies might fall into one or several MoCRA regulation categories: cosmetic brand owner, manufacturer or contract manufacturer, filler, and processor.

MoCRA Compliance by Industry Role

Regulation	U.S. Contract Manu-facturer / Filler	Non-U.S. Contract Manu-facturer / Filler	U.S. Brand Owner	Non-U.S. Brand Owner	U.S. Brand Owner & Manu-facturer	Non-U.S. Brand Owner & Manu-facturer
Product & Ingredient Listings	N	N	Y	Y	Y	Y
Facility Registration	Y	Y	N	N	Y	Y
U.S. Agent	N	Y	N	N	N	Y
Adverse Event Management	Y	Y	Y	Y	Y	Y
Label & Ingredient Review	N	N	Y	Y	Y	Y
GMPs	Y	Y	Y	Y	Y	Y

Note: *Labs that perform cosmetic product batch release must also register with FDA.*

Exemptions to MoCRA Compliance

Small businesses with less than $1 million in average annual gross sales during the previous 3-year period are exempt from product listings and facility registration. The small business exemption does not apply to companies that manufacture the following products:

- Products that regularly come into contact with the 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

Importance of MoCRA Compliance Despite Small Business Exemption

Even if a company qualifies for the small business exemption, FDA and retailer/market realities make it challenging. For example, the FDA has no system to assess a company's revenue during the port inspection. In order to prove the exemption, a company would have to provide three years of financial data to the FDA. In addition, retailers selling the product will not risk their own reputation on a supplier not complying with FDA regulations.

Not sure which regulations apply to you?

Try the MoCRA Wizard.

Business Implications of MoCRA Non-Compliance

In addition to the regulatory impact of non-compliance covered earlier, companies face business impacts that may be far greater along three dimensions:

1. Retailer Actions
2. Supply Chain Disruptions
3. Legal Ramifications

1. Retailer Actions

U.S. retailers have tremendous power in the industry value chain. They do not want to risk their own reputation by selling non-compliant products. Nor do they want to manage product returns, destroy/return inventory, field negative media coverage, or face potential lawsuits.

That's why many top retailers are requiring suppliers to be MoCRA compliant. If a brand is not MoCRA compliant, there are serious business consequences including:

- Penalties paid to retailer for missed sales
- Jeopardized contracts
- Returned or destroyed products
- Reduced shelf space or brand removed from shelves entirely

Complying with MoCRA ensures brands meet their retailer partner's expectations.

2. Supply Chain Disruptions

For brands that use co-manufacturers or packagers, ensuring the entire supply chain is MoCRA compliant is critical. For example, if the FDA detains a product at the factory or in transit, it can impact the entire supply chain. This can be a disaster during critical seasonal/holiday resets.

3. Legal Ramifications

FDA violations can be the basis for class-action lawsuits along multiple fronts. For example, not reporting a serious adverse event (or following all the investigation and recordkeeping requirements) can create legal liability for the brand/manufacturer.

Protect Your Business with a Trusted Partner

As this executive brief shows, the entire cosmetics industry faces new and unfamiliar MoCRA compliance requirements. As the world's largest FDA compliance company with over 30,000 clients, we have the solutions, expertise, and data security to support all of your MoCRA compliance needs.

Complete MoCRA Solutions

Registrar provides over a thousand cosmetics companies with MoCRA services and software including:

- Product Listings
- Facility Registration & U.S. Agent
- Adverse Events Management
- Label Compliance Review
- Product Lifecycle Management (PLM) software
- Custom Consulting

Unmatched Expertise

Leading cosmetics brands, retailers, and manufacturers rely on Registrar's deep expertise with FDA processes and systems. We have hundreds of dedicated FDA experts with decades of experience to accurately and quickly execute all of your MoCRA compliance needs.

Industry-Leading Data & Privacy Protection

Protecting sensitive data like ingredients, formulations, and consumer adverse event medical information is critical. That's why Registrar is ISO 27001 certified – the gold standard for data security.

Registrar Corp

30,000+ Customers in **190+** Countries

20+ Years in Business

4.7/5 Customer Rating on Trustpilot

27 Services & Software

462+ Years of Regulatory Expertise

ISO 27001 Certified

Your MoCRA Experts

MoCRA is complicated. Let Registrar be your partner to get and stay compliant. Contact us to learn more about our complete compliance solutions for cosmetics.

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