The Modernization of Cosmetics Regulation Act: A Breakdown

NPG gives the breakdown of FDA's MoCRA and Reviews its Impact on Cosmetics

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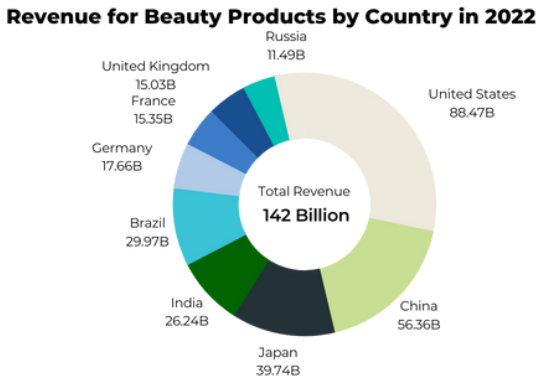
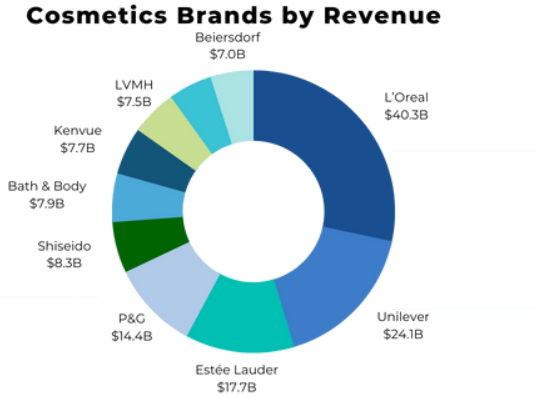


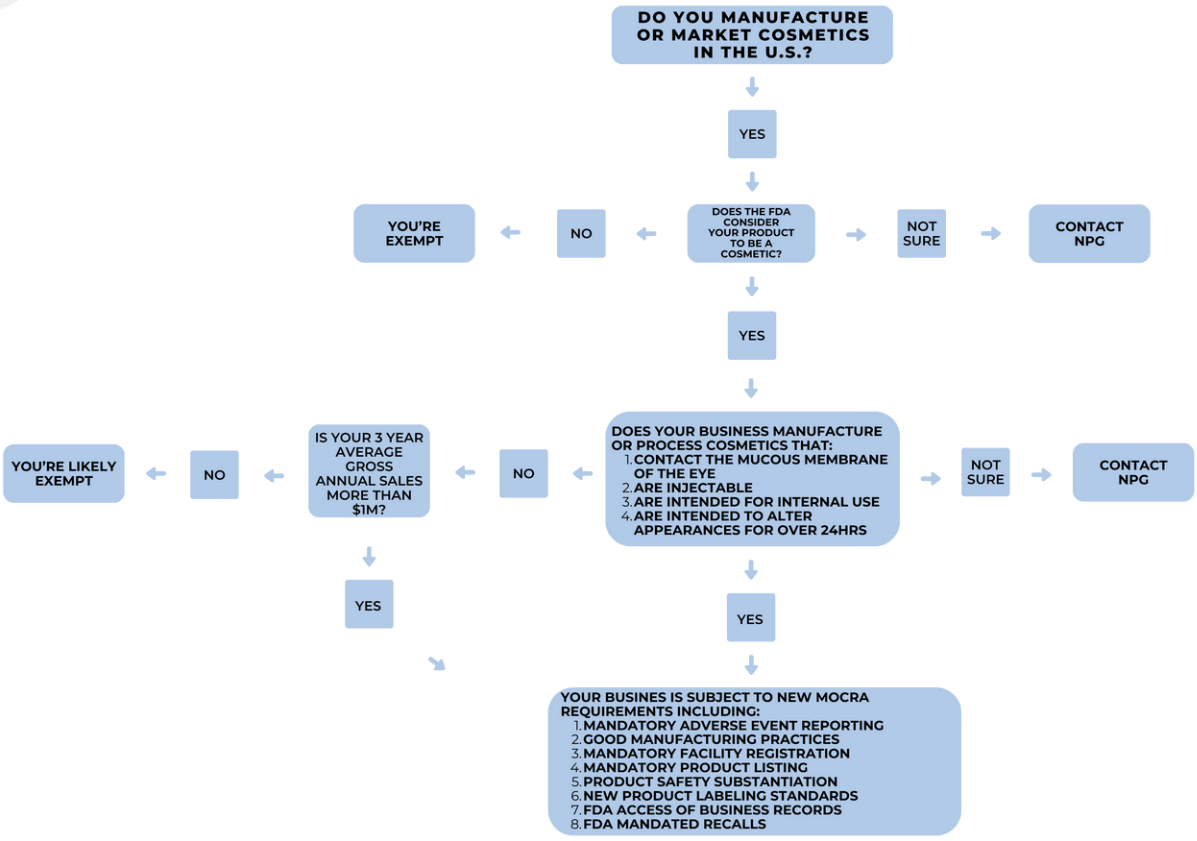


The Modernization of Cosmetics Regulation Act (MoCRA), enacted on December 29, 2022, marks the most significant expansion of the FDA's authority over cosmetics since 1938. More than just a law, MoCRA serves as an imperative call to action, urging cosmetic manufacturers to elevate their production standards to align them with global benchmarks and enhance the quality and safety of products for consumers.

In 2022, the US was a global frontrunner in the cosmetics market, valued at approximately $90 billion and home to over 4,250 cosmetic companies. With MoCRA's introduction, US manufacturers and those distributing to the US with annual revenues exceeding $1M USD over the past three years must quickly adapt to these new regulations. Given the US's status as the world's second-largest cosmetic product importer, MoCRA's ramifications may resonate globally.

By 2025, it will be mandatory for manufacturers to maintain categorically higher quality standards, transparency, credibility, and good manufacturing practices. Time is of the essence – act now to bring your company up to speed with MoCRA. The future of your business may depends on it!

Does MoCRA Apply to My Company?



What requirements must my company meet under MoCRA?

·Mandatory Adverse Event Reporting
·Facility Registration
·Ingredient Lists
·Updated Labeling Requirements
·Fragrance Allergens Disclosures
·Safety Substantiation
·Cosmetic Product Registration
·Cosmetic Good Manufacturing Practices (GMPs)
·Cosmetic Record Inspections

Timeline of MoCRA Enactment and Compliance Requirements

Frequently Asked Questions

What will be my company's obligation for Adverse Event Reporting?
Adverse events are defined by the FDA as any undesirable experience associated with the use of a product. Manufacturers will need to track, report and record these adverse events. Companies will also be required to report serious adverse events (SAEs) to the FDA within 15 business days. Any new medical information related to these events must also be reported within a year of the initial report. These records can be accessed by the FDA during inspections and can result in the suspension of a facility's registration if not found.

When must my facility register?
Manufacturers will need to register their facilities with the FDA by December 29th, 2023, and renew these registrations every two years. FDA intends to make the electronic registration and product listing submission portal (Cosmetics Direct) available in October, 2023.

What documentation must my company maintain?
Manufacturers must maintain a list of each ingredient that makes up their marketed products. Additionally, a detailed composition of fragrances, including allergens, which must be disclosed on product labels if used. Any product safety substantiation or tests you've conducted must also be maintained. These lists must be shared with FDA as part of product registration.

Can FDA require a recall of my company's products?
FDA has mandatory recall authority for a variety of products, including FDA-regulated cosmetics, drugs, devices, and food. FDA will use its mandatory recall authority when there is a serious public health risk and a firm has declined to initiate a voluntary recall. Because firms usually agree to an FDA request or recommendation for a recall, the agency infrequently uses its mandatory recall authority.

	What Happens if My Company Doesn't Comply
Adverse Event Reporting	• The FDA now has the authority to access your adverse event records. It can also access records related to each of your products if there is reason to believe that a product or an ingredient is adulterated or poses a threat to public health. • Failure to comply can lead to fines, product detainment, and suspension of facility registration.
Ingredient List	• Products may be categorized as Misbranded by the FDA. • MoCRA now grants the FDA Mandatory Recall Authority
Labeling Requirements	• Product will be categorized as Misbranded by the FDA. • The FDA can detain products. • Facility registration can be suspended, preventing facilities from manufacturing.
Mandatory Recall	• Prior to MoCRA, all product recalls for cosmetics were voluntary. MoCRA grants FDA the power to recall a product if there is a reasonable probability that it is adulterated, misbranded, or could cause serious health problems. • Based on information available to the FDA, such as consumer complaints, results from an inspection, or an outbreak investigation, the FDA may request that a firm initiate a voluntary recall. • If the firm refuses, the FDA has the authority to enforce a mandatory recall and may also initiate administrative, judicial or enforcement actions, such as seizing product, suspending a firm's registration, banning a firm's imports, requesting an injunction, or pursuing criminal prosecution.
Facility Registration	• If a manufacturing facility has not been properly registered with the FDA, it can face enforcement actions, including product seizures, import detentions, and issuance of warning letters.
Safety Substantiation	• Products may be categorized as Misbranded by the FDA.
Good Manufacturing Practices	• Cosmetics products that are manufactured or processed under conditions that fail to meet GMPs will be deemed adulterated, meaning they cannot be legally sold in the United States. Companies who introduce adulterated products into interstate commerce may be subjected to a civil money penalty.
How Much Will it Cost Me?	• The average direct cost of a recall is estimated at around $10M. • This can vary greatly depending on the scope of the recall and how many batches were affected. • Other factors at play not included in this estimate include reputational damage, litigation costs, or potential for government oversight post incident.

Do you have any other questions? Schedule a call with a consultant today!

Network Partners Group is your strategic partner for success in the food, drug, and cosmetic industries. Our team of expert consultants bring diverse experience to the table and are ready to deliver top-notch regulatory and quality strategies tailored to your needs. Count on us for seamless execution and support to meet MoCRA requirements efficiently and affordably. Let's drive your business forward together!