



Modernization of Cosmetics Regulation Act of 2022 (MoCRA)

Home / US FDA

/ Modernization of Cosmetics Regulation Act...



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- 1. Background:** The average American uses 6 to 12 cosmetic products daily, including makeup, nail polishes, shaving creams, perfumes, cleansers, haircare products, moisturizers, and more. MoCRA addresses the need for more robust regulatory oversight of these widely used products.
- 2. Key Definitions:** MoCRA introduces specific terms such as “adverse event,” “facility,” “responsible person,” and “serious adverse event.” These terms define the entities and circumstances under which regulatory measures apply.
- 3. New Authorities for the FDA:** The act grants the FDA powers to access records related to cosmetic products and the authority to order mandatory recalls under certain conditions.

- 4. Industry Requirements:** The act imposes new obligations on the industry, including the need for adverse event reporting, facility registration, and annual updates of product listings.
- 5. Safety Substantiation and Good Manufacturing Practices (GMP):** Companies are required to ensure and maintain records supporting the safety of their products. The FDA is mandated to promulgate GMP regulations for cosmetic manufacturing and processing facilities, which must align with national and international standards and be adaptable for businesses of different sizes and types.
- 6. Mandatory Recall and Facility Suspension Authorities:** MoCRA empowers the FDA to request voluntary recalls of products and suspend facility registrations if certain products are found to pose serious health risks.
- 7. Fragrance Allergens, Talc Regulation, and PFAS Report:** The act requires the FDA to establish regulations for the disclosure of fragrance allergens and standardized testing methods for detecting asbestos in talc-containing products. It also mandates a report on the safety of using PFAS in cosmetic products.
- 8. Preemption Clause:** MoCRA includes a preemption provision, restricting states from enacting cosmetic regulations that differ from federal law in specific areas.

MoCRA represents a comprehensive overhaul of cosmetic product regulation, emphasizing consumer safety and industry accountability. For businesses in the cosmetics industry, understanding and complying with these new regulations is crucial to ensure product safety and regulatory compliance

For more detailed information on MoCRA and Cosmetic Regulations

- [1. Top Questions on FDA New Cosmetic Regulations \(MoCRA\)](#)
- [2. FDA Overview](#)
- [3. Cosmetic Registration India](#)
- [4. US FDA Agent Services](#)

How Can we Help?

Preparing your business for compliance with MOCRA requires an understanding of both existing laws as well as any changes introduced through this act. Our team at FDApals can provide tailored guidance throughout every step of this process – from initial label review through registration assistance – so you can rest assured knowing that your business remains compliant with ease and confidence! [Contact us Now to learn more!](#)

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