

The Consolidated Appropriations Act of 2023, signed into law by President Biden on Dec. 29, 2022, includes the Modernization of Cosmetics Regulation Act (MoCRA) of 2022. MoCRA modernizes federal regulatory oversight of cosmetics and personal care products and creates a comprehensive and uniform national framework for cosmetics regulation.



MoCRA Requirements

Adverse Event Recordkeeping and Serious Adverse Event Reporting. Product manufacturers must maintain records of any health-related adverse events for six years (three years for some small businesses) and report to the FDA any serious adverse events no later than 15 days after learning about the issue.

Mandatory Facility Registration and Product and Ingredient Listing. Facilities that manufacture or process cosmetics products for distribution in the U.S. must register with the FDA. In addition, cosmetics manufacturers must list each product with the FDA, including its ingredients and where it is manufactured.

Cosmetics Safety Substantiation. Manufacturers must ensure a cosmetics product is “safe” and maintain records demonstrating “adequate substantiation” of safety standards that products must meet to be marketed in the U.S.

Cosmetics Labeling and Fragrance Allergen Transparency. Cosmetics product labels for consumers and for professionals must include contact information to report potential adverse events and identify each fragrance allergen in the product. Professional product labels must state that only licensed professionals may use the product.

Note: Not all requirements are effective immediately; the legislation outlines a timetable for compliance.

MoCRA

For more than a decade, the Personal Care Products Council (PCPC) and its 600 member companies – representing some of the most beloved and trusted brands in beauty and personal care – have worked diligently with a bipartisan group of congressional leaders and a diverse group of stakeholders to enhance the effectiveness of the U.S. Food and Drug Administration’s (FDA) regulatory authority and to provide the safety reassurances that consumers expect and deserve.

The long-awaited law adds significant new authorities to the Federal Food, Drug, and Cosmetic Act (FDCA), advances product safety and innovation for the science-driven beauty and personal care industry and reinforces consumer confidence. As a result, the FDA will have new tools to regulate cosmetics and personal care products consistently.

Enforcement

Facility Suspension. The FDA has the authority to suspend a facility's registration if a cosmetics product manufactured by that facility has reasonable probability of causing serious adverse health consequences. Records Access. The FDA has the authority to access product manufacturers' records relating to a cosmetics product if the Agency reasonably believes the product presents a threat of serious adverse health consequences.

Recall Authority. The FDA has mandatory recall authority if the Agency determines a cosmetic product is adulterated or misbranded and that exposure to the product will cause serious adverse health consequences or death.

Preemption. MoCRA preempts state and local laws that differ from the federal law on registration, product listing, good manufacturing practice, records, recalls, adverse event reporting or safety substantiation. MoCRA does not prevent states from prohibiting or limiting the use of ingredients in cosmetics products or continuing in effect existing laws that require reporting of certain ingredients to states.

Over-the-Counter Drug-Cosmetic Clarity. For products classified as a drug and as a cosmetic under the FDCA, the drug requirements of the FDCA take precedence over the cosmetic requirements.

Other Notable Provisions

Small Business Accommodations. The Current Good Manufacturing Practices Rule (CGMP) regulations issued by the FDA must offer flexibility, simplified requirements and a more extended compliance period for small businesses. They need to maintain health-related adverse event reports for three years rather than six years. Very small businesses (as defined by MoCRA) are generally exempt from compliance with the GMP and facility/product registration requirements.

Animal Testing. MoCRA did not include any specific provisions related to animal testing but notes that Congress believes manufacturers should not use animal testing for cosmetics products. PCPC and its member companies have worked closely with key stakeholders, including Cruelty-Free International (CFI) and the Humane Society of the United States (HSUS), to advocate for the passage of the Humane Cosmetics Act.

Looking to the Future

MoCRA's passage was a truly bipartisan effort that brought together members of Congress from both sides of the aisle and a diverse group of stakeholders who gathered in the spirit of collaboration and compromise to advance science-based federal regulatory reforms. PCPC is meeting this historic moment by providing the FDA with industry's perspective as the Agency develops implementing regulations. PCPC remains firmly committed to supporting the FDA in its public health mission as the Agency works to implement this new law.