MoCRA requires federal regulatory overhaul By Kelly Bonner

n December 23, 2022, Congress enacted the **Modernization of Cosmetics Regulation Act (MoCRA)**—the first major statutory change to the U.S. federal government's ability to regulate cosmetics since 1938. Passed with bipartisan and industry support, MoCRA expands the **Food and Drug Administration's** authority over cosmetics, and creates substantial new obligations for manufacturers, packers and distributors of cosmetics intended for sale in the United States. Here's what beauty companies need to know.

Prior to MoCRA, the United States regulated cosmetics under the **Federal Food, Drug and Cosmetic Act (1938),** which required finished cosmetic products to be safe when used in accordance with product labeling or customary usage, and to not be misbranded or adulterated. In 1966, Congress enacted the **Fair Packaging and Labeling Act,** which further required honest and informative labeling.

Kelly Bonner, an associate at Duane Morris LLP

Cosmetics also are regulated at the state level, and subject to certain ingredient listing requirements such as California's Prop 65, or prohibitions on the use of certain intentionally added ingredients, like formaldehyde, mercury and perfluoroalkyl and polyfluoroalkyl substances (PFAS).

Scope: It's important to remember that the regulatory definition of "cosmetics" is much broader than is typically understood. "Cosmetics" are defined by the FDCA as "articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness or altering the appearance."

This definition includes skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors and deodorants, as well as any substance intended for use as a component of a cosmetic product.

MoCRA defines cosmetic products as "a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product."

Unless specified, MoCRA applies to finished cosmetic products rather than ingredients.

Key provisions: MoCRA amends Chapter VI of the FDCA, and imposes significant new requirements on companies. Many of those obligations fall on what MoCRA calls "a responsible person," meaning the manufacturer, packer or distributor of a cosmetic product whose name appears on the label in accordance with Section 609(a) of MoCRA, 21 U.S.C. § 364, or Section 4(a) of the FPLA.

1. Facility registration and product listing: MoCRA requires that the owner or operator of any facility that manufactures or processes cosmetic products intended for sale in the United States—irrespective of whether the facility is located in the United States—to register with the FDA by December 29, 2023 for existing facilities, and for new facilities, the later of 60 days after commencement of manufacture or 60 days after the deadline for existing facilities.

This requirement excludes salons (unless they manufacture or process cosmetic products that are not sold directly to consumers at the location) or cosmetic product retailers, including individual sales representatives, direct sellers or retail distribution facilities.

Additionally, MoCRA requires manufacturers, packers and distributors of cosmetics intended for sale in the United States to submit lists of products and ingredient information, including location of manufacture and the ingredients of any fragrances or flavors by December 29, 2023, for existing products, and for new products within 120 days of marketing.

Prior to MoCRA, FDA permitted companies to register on a voluntary basis through the **Voluntary Cosmetic Registration Program.** Since March 27, 2023, the FDA has stopped accepting submissions to VCRP, and information previously submitted to VCRP will not transfer over for purposes of MoCRA. To accommodate the large number of expected facility registrations and product listings now mandated by MoCRA, the FDA is creating a new electronic portal to receive submissions.

On August 7, 2023, the FDA released draft guidance to assist persons submitting cosmetic product facility registrations and product listings. The new submission portal is expected to be available in October 2023, with the FDA encouraging electronic submissions well in advance of the December 29, 2023 deadline for facility registration and product listing. To that end, the FDA has announced a pilot program to test the portal's functionality.

The Draft Guidance also provides clarity regarding what information companies will be required to submit to register their facilities and list products with the FDA, as well as who, when and how in advance of the upcoming registration and listing deadlines.

2. Safety substantiation: MoCRA requires that companies maintain records "adequate[ly] substantiat[ing]" product safety" by December 29, 2023. MoCRA defines "adequate substantiation" as "tests or studies, research, analyses or other evidence or information that is considered, among experts qualified by scientific training and experience, to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe."

MoCRA further defines "safe" to mean "not injurious to users under the conditions of use prescribed in the labeling ..., or under such conditions of use as are customary or usual" and– "not injurious to users solely because it can cause minor and transient reactions in some users." The FDA will consider cosmetic products that do not have adequate safety substantiation to be adulterated under FDCA.

3. Recordkeeping and reporting: MoCRA imposes greater recordkeeping obligations

regarding health-related adverse events and requires companies to report to the FDA any "serious adverse events."

MoCRA also expands the definition of "serious adverse event" to include infections or "significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance), other than as intended, under conditions of use that are customary or usual." Products will not be considered "injurious" if they cause minor or transient reactions to certain users.

4. Product labeling: MoCRA imposes new labeling requirements, including a. providing contact information for adverse event reporting by December 29, 2024; b. identifying products intended for licensed professionals by December 29, 2024; and c. identifying fragrance allergens on product labels consistent with FDA's upcoming regulations, with a rulemaking deadline of June 29, 2024.

5. Expanded FDA enforcement authority: MoCRA grants FDA additional enforcement authority over cosmetics, including expanded records access, facility registration suspension authority and mandatory recall authority over cosmetics when the agency determines there is a "reasonable probability" that a cosmetic is adulterated or misbranded, and that exposure will cause serious adverse health consequences.

6. Expanded FDA rulemaking authority: Finally, MoCRA requires the FDA to propose new regulations regarding:

- Good manufacturing practice regulations consistent with national and international standards by December 29, 2024, with a final rule no later than December 29, 2025.
- Fragrance allergens that must be disclosed on cosmetics labels and the format for disclosure, in line with EU and other international requirements by June 29, 2024, with a final rule no later than 180 days after the close of the public comment period.
- Standardized testing methods for detecting and identifying asbestos in talc-containing products by December 29, 2023, with a final rule no later than 180 days after the close of the public comment period.

MoCRA further requires the FDA to publish a report no later than December 29, 2025, assessing the use of PFAS in cosmetics and safety risks associated with such use.

Once FDA enacts the regulations required by MoCRA, they will be the first federal regulations to mandate the implementation of GMP by cosmetics companies. Prior to MoCRA, FDA did not require cosmetics companies to abide by defined GMP, such as those set forth in ISO 22716:2007 (which the EU requires) or identified by voluntary certifying organizations like the National Sanitation Foundation. Instead, FDA promoted voluntary guidelines for self-inspection of manufacturing facilities and practices and maintained the right to inspect facilities and finished products to ensure non-adulteration.

Small business accommodations

MoCRA makes certain accommodations for small businesses, defined as owners and operators whose average gross annual domestic sales for the previous three years is less than $1 million (adjusted for inflation).

Under MoCRA, "small businesses" are exempt from the requirements pertaining to good manufacturing practices and establishment registration and product listing, with the exception of those that manufacture injectables; cosmetics intended for internal use; products that alter appearance for more than 24 hours under normal use; or products that regularly come into contact with the mucus membrane of the eye. Additionally, small businesses must maintain adverse event records associated with the use of a product for only 3 years, rather than 6 years, with the exception of businesses that manufacture the aforementioned products

Additional provisions

Finally, MoCRA preempts state and local requirements for cosmetics that differ from MoCRA, with limited exceptions for prohibitions or limitations on the amount of an ingredient that can be used in a cosmetic under state law, and existing reporting requirements, such as California's Prop 65.

What doesn't MoCRA change?

Although MoCRA represents the most significant change in how the federal government regulates cosmetics in decades, it is not as far-reaching as earlier legislative proposals. MoCRA does not prohibit ingredients like PFAS or so-called endocrine disruptors, or change regulations for products containing CBD or other hemp-derived products. Nor does MoCRA prohibit or restrict the use of animal testing for cosmetics. MoCRA does state, "It is the sense of the Congress that animal testing should not be used for the purposes of safety testing on cosmetic products and should be phased out with the exception of appropriate allowances."

Cosmetics containing active pharmaceutical ingredients, or that make drug claims (such as claiming to affect bodily structure or function) will still be deemed "drugs" rather than cosmetics, and subject to heavier regulatory requirements under Chapter V of the FDCA.

Finally, MoCRA does not address existing regulatory framework for labeling & marketing, such as defining terms like natural, clean, nontoxic or safe. Nor does it address so-called "greenwashing" claims, which have been the focus of legislative action in the U.K. and EU, and litigation in the U.S. Instead, companies must look to guidance from enforcement actions by the FTC, state regulators and the FTC's updated Green Guides, which provide guidance on the environmental marketing claims companies can make.

What's next?

MoCRA represents a fundamental shift in how cosmetics are regulated in the United States, expanding FDA's rulemaking and enforcement authority, and creating substantial new obligations for cosmetics companies. The implementation will be a years-long process, and likely to evolve, based on industry input and the need for further guidance. It is important for companies to remain current with evolving regulations, to provide feedback through FDA's comment process on the practicalities of compliance with MoCRA, and to involve counsel and compliance expertise.

Kelly Bonner, an associate at Duane Morris LLP, focuses on litigation risk and regulatory issues affecting businesses in the cosmetics and personal care industries, as well as cross-jurisdictional and complex commercial disputes involving FDA-regulated and consumer-branded products.