



Allison Stevenson of Hill Ward Henderson. Courtesy photo

COMMENTARY

New Federal Regulations on Cosmetics Industry Will Impact Fla.-Based Businesses

MoCRA's requirements are sure to present challenges to Florida beauty businesses, and it mandates that both the brand owner and the manufacturer of a cosmetics product are responsible for compliance.

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By Allison M. Stevenson | December 07, 2023 at 09:00 AM

For decades, cosmetics manufacturers and distributors based in the Sunshine State have largely had to look no further than Florida's statutes governing the drug and cosmetics industry as their guidebook for business operation and compliance. This is because the only federal regulation governing cosmetics was enacted in 1938, left the cosmetics industry largely unregulated, and was untouched—until now.

The Modernization of Cosmetics Regulation Act of 2022, or MoCRA as it has become coined, is the first major federal legislation governing cosmetics in nearly a century. MoCRA was signed into law at the end of 2022, as part of a more than 1,600-page omnibus bill, with provisions going into effect on a phase-in basis beginning in 2024. Notably, the act mandates wide-sweeping requirements for manufacturers and distributors of cosmetics products, and because the act will supersede Florida statutory authority it is imperative that Florida-based beauty businesses ensure that they: fall, or do not fall, within the scope of MoCRA; and comply with MoCRA's provisions should they in fact fall within its parameters.

Evaluating and determining if a Florida-based business triggers the provisions of MoCRA is paramount, and time is of the essence. If a Florida business does fall within MoCRA's scope, there are several federal provisions now in play that were not on the table under the state law alone.

For instance, current Florida law requires permitting and compliance for cosmetics manufacturers except those with less than \$25,000 per year in gross sales. MoCRA has no such exemption; rather, it applies to “any establishment ... that manufactures or processes cosmetic products distributed in the United States” Section 604(3)(A), although some small businesses may be exempt from certain sections of the act (but not exempt in entirety). Section 612. MoCRA issued its own definition for cosmetics products, identifying them as “a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product, Section 604(2), and more fully defined by the Federal Drug & Cosmetic Act 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.” And while MoCRA carves out exemptions for certain businesses such as health care clinics and beauty salons, any business in Florida dealing in cosmetics products should be diligent in assessing whether or not they now fall within new or different regulation guidelines due to MoCRA’s definitions—even if they are excluded under Florida’s cosmetics regulation authority. By way of example, a beauty spa that manufactures its own line of facial moisturizer for retail sale to the public and grosses less than \$25,000 in annual product sales may be surprised to find that, although it does not trigger Florida’s cosmetics permitting requirements (unless under other bases), they likely do trigger at least some of the provisions of MoCRA.

MoCRA’s requirements are sure to present challenges to Florida beauty businesses, and it mandates that both the brand owner and the manufacturer of a cosmetics product are responsible for compliance. The act directs facilities to register with the FDA no later than July 1, 2024,

and biennially renew their registration. Ingredient lists for each product must be provided, and updated annually. In addition to establishing registration and listing requirements, MoCRA prescribes several rules regarding good manufacturing processes (with mandatory regulations to be issued in 2025), adverse event reporting and tracking, safety substantiation, recalls, and FDA inspection guidelines. These are just some of the new federal regulations issued upon the cosmetics industry with the enactment of MoCRA, and failure to comply could result in mandatory recalls and revocation of registration.

The requirements are fulsome, and non-compliance could interrupt the ability to conduct business, potentially permanently. Even when an affected business is fully compliant, the new requirements could open the door to increased litigation from product users, as there will be opportunities for product users and their attorneys to claim that manufacturing fell below the newly imposed threshold requirements, thereby supporting claims for substandard product manufacturing.

For Florida businesses that fall within the scope of MoCRA, now is the time to establish a plan of action for ensuring compliance. FDA guidance is continuously being released, so at a minimum the monitoring of that guidance should be happening so that the business's knowledge is current with respect to requirements, as there have already been shifts in target dates since MoCRA was signed into law last year. Also vital at this juncture is the establishment of business practices designed to sufficiently maintain adverse event reporting and record keeping, registration, and ingredient listing. Businesses should also prepare for potential future facility and record inspections, and establish internal

best practices to put into play in the face of a mandatory recall and anticipated litigation, among other things.

MoCRA's requirements are undoubtedly a large undertaking for any business, but smaller-scale manufacturers and distributors may find that the requirements are especially daunting. All Florida-based businesses that are involved in cosmetics manufacturing or distribution should engage legal counsel to assist in evaluating MoCRA's application and requirements as to that business, and to assist in establishing compliance with each and every provision of the act. Preparing for full compliance early and often will help protect the business from greater risk of recalls, business interruption, and potential litigation impacts.

Allison M. Stevenson *is an attorney at Hill Ward Henderson in Tampa, Florida. She devotes her practice to working with product manufacturers and retailers to ensure they are protected against claims for personal injury, wrongful death, false or unfair marketing, and trade libel. She has successfully defended a diverse array of claims in state and federal courts, including in the cosmetics litigation, tobacco litigation, and home product litigation arenas.*