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MoCRA: 6 Key Takeaways From The New Cosmetics Law

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(January 20, 2023, 5:49 PM EST)

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In its federal omnibus appropriations legislation passed at the end of 2022, Congress modernized the U.S. Food and Drug Administration's regulatory framework for cosmetics marketed in the U.S.

Titled the Modernization of Cosmetics Regulation Act, or MoCRA, these reforms represent the first major changes to the FDA's cosmetics authorities since President Franklin Roosevelt signed the Federal Food, Drug, and Cosmetic Act, or FDCA, into law in 1938.

While many federal bills have been introduced over the years to reform the FDA's regulatory framework for cosmetics, those bills have resulted in much debate and not a lot of legislative action — until now. The reforms in MoCRA are meaningful and significant.

A notably wide range of personal care and beauty products are defined as "cosmetics" under the FDCA, from makeup and shampoo to hair dye and hand soap. Any cosmetics company, or lawyer advising cosmetics companies, must be aware of MoCRA's key points, and should review the legislation closely. Here are six important takeaways.

1. MoCRA brings the FDA's regulation of cosmetics into closer alignment with other product categories regulated by the agency.

Across the many products it regulates, the FDA has available a suite of familiar regulatory tools — for example, current good manufacturing practice requirements, or CGMPs, serious adverse event reporting, facility registration, product listing, and records access and inspections.

MoCRA generally seeks to put these familiar tools in place for the FDA's regulation of cosmetics — better aligning the agency's cosmetics program with the frameworks that it already has in place to regulate other product categories.

Now, like dietary supplement and over-the-counter drug makers, cosmetic companies will have to report serious adverse events associated with the use of their products and comply with CGMPs, which

the FDA will establish through rulemaking. And like food, drug and device manufacturing facilities, cosmetic manufacturing facilities now will need to register with the FDA in order to lawfully market products produced at the relevant facility.

Additionally, each cosmetic product sold in the U.S. now must be listed with the agency, and include information about the product's ingredients and place of manufacture, among other data. MoCRA also makes it an explicit statutory requirement for cosmetic products and ingredients to be adequately substantiated for safety prior to marketing in the U.S.

Importantly, MoCRA accounts for differences of the cosmetics category. The definition of a reportable "serious adverse event" for cosmetics goes beyond the current definition used for dietary supplements and OTC drugs to include infections and "significant disfigurement … other than as intended, under conditions of use that are customary or usual."

And, unlike the statutory provisions directing the FDA to issue CGMP regulations and imposing facility registration requirements for dietary supplements, and unlike CGMP regulations for OTC drugs, MoCRA requires the agency to provide small business exemptions for certain requirements, as discussed further below.

2. There is time to comply, but companies should get started soon.

MoCRA delayed the effective date of its key enforcement provisions to Dec. 29 of this year — one year after its enactment. That said, cosmetic companies marketing products in the U.S. should start taking steps now to ensure they have compliance programs in place in advance of that date.

Companies should be aware that even though the enforcement provisions of MoCRA do not take immediate effect, some of the FDA's new authorities arguably could be used by the agency earlier than Dec. 29 — such as the agency's authority to inspect cosmetic records or mandate cosmetic recalls, if the relevant statutory standards of MoCRA are met.

That said, the FDA will need time to implement the new law internally, likely resulting in updates to the agency's processes and procedures. But starting in 2024, the FDA will want to show Congress, other stakeholders and the cosmetics industry that it is utilizing its new tools — and this will manifest itself in a variety of ways.

Notably, MoCRA's preemption provision takes effect immediately to preempt state and local laws that differ from the federal framework on the subjects of registration, product listing, good manufacturing practice, records, recalls, adverse event reporting and safety substantiation. The preemption provision does have some carveouts, such as around a state's ability to ban ingredients in cosmetic products.

Stakeholders should closely watch how the preemption provision is interpreted by the FDA, the states and courts, particularly given that different federal administrations tend to have differing views on federal preemption.

Regardless, the industry anticipates that state legislatures will recognize the comprehensive nature of this federal overhaul, and appropriately curtail efforts to create a patchwork of state regulatory regimes in these categories.

3. The FDA has meaningful new enforcement tools.

In the event of a public health issue involving a cosmetic, MoCRA provides the FDA with a suite of new tools to take prompt action to protect consumers.

Similar to the Food Safety Modernization Act, passed in 2011, MoCRA allows the agency to suspend the registration of a cosmetic manufacturing facility — which would effectively prevent the facility from operating — access a host of records, and mandate that a cosmetic company recall its product or products.

For all of these actions, Congress put in place standards and procedures that must be followed by the FDA. The agency will need time to implement these new tools and update internal procedures to ensure they are used appropriately and consistently.

4. The FDA is required to issue rules and reports, and will likely issue guidance.

MoCRA sets in motion several opportunities for the public to help shape the FDA's implementation of the new framework. The agency will be soliciting public comments on topics ranging from CGMP requirements to assessments of the safety of per- and poly-fluoralkyl substances in cosmetic products, with opportunities for input starting in 2024.

For starters, the FDA must issue three new rules that will go through notice-and-comment rulemaking:

- The CGMP rule will require cosmetic manufacturers to meet cosmetic manufacturing and processing standards.

- The fragrance allergen rule will require cosmetic product labels to indicate when the product contains certain fragrance allergens.

- The talc rule will require industry to use standardized testing methods to detect asbestos in talc-containing cosmetics.

The FDA will issue a proposed CGMP rule within two years after MoCRA's enactment, and a final rule within three years after enactment. By contrast, the agency must issue the proposed fragrance allergen and talc rules within 18 months after MoCRA's enactment, and final rules no later than 180 days after the close of each rule's public comment period.

In addition to commenting on the new proposed rules, stakeholders will also likely have opportunities to provide feedback on the FDA's forthcoming report on the use and safety of PFAS in cosmetic products, as well as on expected FDA guidance documents related to MoCRA's other requirements.

5. Small businesses have various accommodations under MoCRA.

In recognition of the many smaller entities in the cosmetics space, MoCRA offers a number of exceptions and accommodations to small cosmetics companies. As previewed above, the FDA's CGMP rule must offer small businesses flexibility, simplified requirements and a longer compliance period.

Certain small businesses with average gross annual sales for the prior three years of less than $1 million dollars are exempt from CGMP, facility registration and product listing requirements. With respect to adverse event records retention, some small businesses must maintain records for three years rather than six.

These exemptions are intended to help ensure that small businesses can continue to grow in the U.S. and navigate regulations more nimbly, as the cosmetics sector is known for many small business success stories.

6. The cosmetics industry, NGOs and the FDA all supported MoCRA's passage.

MoCRA's requirements were imposed with significant input from many stakeholders, including key champions in Congress, FDA leadership, consumer and environmental groups, and notably, companies in the beauty and personal care industry, large and small. This broad group of stakeholders worked in their own ways to advance cosmetics reform and supported MoCRA's enactment.

Considered a "super-rider" for the underlying FDA user fee reauthorization package, MoCRA initially did not advance when Congress enacted the user fee legislation in late September 2022.

But during the final weeks of 2022, Senate Committee on Health, Education, Labor and Pensions Chair Sen. Patty Murray, D-Wash., and ranking member Sen. Richard Burr, R-N.C., worked with House Energy and Commerce Committee Chairman Rep. Frank Pallone, D-N.J., and ranking member Rep. Cathy McMorris Rodgers, R-Wash., to settle on a suite of FDA reforms to attach to the year-end omnibus appropriations package, which included MoCRA.

While an end-of-session deal on FDA reforms is unusual, it has happened previously — for example, the 21st Century Cures Act, passed in 2016, which overhauled some of the FDA's drug and device authorities. Those who advocated for MoCRA seem pleased to see the passage of a strong, bipartisan, national framework for cosmetics regulation.

MoCRA's statutory language can only provide so much information. The ultimate effect of the legislation will become clearer based on how the FDA implements its new authorities over cosmetics.

Given that many of the new tools are already familiar to the agency from other product categories, cosmetics companies and practitioners should be mindful of how the FDA has implemented similar regulatory authorities in the past, as that will be instructive.

The FDA likely will adopt similar interpretations and tactics for MoCRA, so long as those approaches make sense for the cosmetics sector. It will be critical for industry stakeholders to engage with the agency throughout the implementation process.

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Disclosure: The authors represented the Personal Care Products Council, a national trade association representing cosmetics and personal care products companies, before Congress during the development of MoCRA.