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MoCRA Will Give Cosmetics Litigation A Makeover

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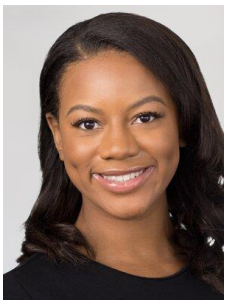
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Law360 (August 10, 2023, 3:50 PM EDT) -- Every day, consumers in the U.S. use a wide variety of cosmetic products. Yet the U.S. cosmetics industry long remained largely unregulated.

On Dec. 29, 2022, the Modernization of Cosmetics Regulation Act became law. MoCRA is the most significant expansion of the U.S. Food and Drug Administration's authority to regulate cosmetics in nearly 85 years.

Among other things, the FDA will now have the power to require facility registration and reporting of serious adverse events, impose certain record-keeping obligations, recall cosmetic products, and establish good manufacturing practices, or GMPs.

All of these new requirements and upcoming regulations present both added benefits and new challenges for cosmetic companies — especially with regard to litigation.

For many U.S. cosmetics companies, MoCRA is likely to mean big changes in the ways that they validate products prior to sale, substantiate the safety and efficacy of those products, track products through the distribution chain, and monitor consumer feedback.

Many of MoCRA's provisions go into effect at the end of 2023. It is important for all cosmetics companies to be aware of the potential litigation impacts of MoCRA's requirements — and the steps that they can, and should, take now to put themselves in the best possible position to deal with all that is to come.

Potential Litigation Impacts

Discovery of Adverse Event Reports, Safety Substantiation and Voluntary Recalls

Plaintiffs are prohibited from using adverse events, or serious adverse event reports, as evidence of an admission that a cosmetic product caused or contributed to an adverse event.[1] But this does not prevent discovery of this information.

The record-keeping, reporting and testing now required by MoCRA are fair game. With access to this information, plaintiffs, potential plaintiffs and their counsel may be better positioned to scrutinize —

and criticize — a company's safety substantiation data and risk assessment processes, and allege with more specificity the potential risks posed by a company's products.

Plaintiffs may also attempt to use the information in an adverse event report to show that a company knew of a problem with its product, or had a habit of dilatory reporting.

Companies should expect to see broad discovery requests seeking not only data from the adverse reports, but also information on the company's testing and compliance practices — which, prior to MoCRA, a company might have had a better chance of shielding as privileged or proprietary.

Violations of Good Manufacturing Practices and Per Se Liability

Once the FDA issues GMPs for cosmetics' manufacturers and processing facilities, there will be clearer guidance for companies on the standard of care in the cosmetics industry.

A manufacturer's or facility's failure to comply with these GMPs could face not just scrutiny from the FDA, but from discerning plaintiffs — who can argue that the violation is sufficient evidence to show that the company was negligent.

Under the law, this would be described as negligence per se: The company is presumed to have breached the duty of care, and rather than the plaintiff having the burden of proof, the company must demonstrate that it was not negligent in its conduct.

Unclear Guidance as a Defense

Although MoCRA's requirements provide guidance to cosmetics companies, much of this guidance is relatively vague and open-ended.

Given this ambiguity, companies might consider arguing that MoCRA and its requirements are not specific enough to put companies on notice as to what is prohibited and what is acceptable.

Primary Jurisdiction as a Defense

Companies may also be able to rely on the primary jurisdiction doctrine as a defense in product liability litigation. Under the primary jurisdiction doctrine, a court may dismiss or stay a case pending agency review when the case presents a novel or complex issue that implicates the specialized or technical expertise of a regulatory agency.

Pursuant to MoCRA, the FDA now has the authority to, among other things, investigate and propose rules regarding the use and safety of per- and polyfluoroalkyl substances, cosmetics labels, and the disclosure of fragrance allergens.

Once the FDA issues this guidance, cosmetics companies will be in a position to potentially defeat lawsuits early on in the proceedings, on the grounds that the FDA has made pronouncements on the same issues.

Prudential Mootness as a Defense

Another defense that may be available to cosmetics companies in litigation is prudential mootness.

Under this doctrine, courts may dismiss a case as moot where the alleged product defect has been properly remedied by the defendant while the litigation is pending — or even before it has started.

Particularly in recent months, federal district courts have increasingly exercised their discretion to dismiss cases where a government agency is overseeing the remedial actions — e.g., product recalls — that address and alleviate any potential injuries arising from the alleged product defect.

As a result of the FDA's newfound ability to mandate recalls of cosmetic products and suspend facility registration — and therefore, operation — of companies that manufacture and process those products, cosmetics companies who recall products or carry out other remedial actions in coordination with the FDA may have a strong defense against certain lawsuits involving their products.

Compliance as a Defense

Any ambiguity aside, MoCRA provides cosmetics manufacturers, packers and distributors with a better road map for how to, among other things, substantiate product safety, track customer feedback, respond to adverse events and guarantee the quality of their products.

Cosmetics companies that invest in educating their employees and creating internal systems aimed at achieving compliance with MoCRA's new requirements will be in the most defensible position in the event of a lawsuit involving one of their products.

Evidence of compliance may lead to inferences that the company acts diligently, and even that its products are safe and effective. And industry members who are making every effort to comply with MoCRA's various requirements may help set a baseline standard of care — i.e., what is considered sufficient compliance.

Recommended Next Steps

MoCRA may mean big changes — and big undertakings — for many U.S. cosmetics companies. And there is still time for the public to comment on many of the new regulations associated with MoCRA.

Affected companies may submit their own feedback, recommendations, or concerns, or solicit trade groups to advocate on their behalf.

Among other things, companies might want to consider which aspects of the 2022 GMP guidelines and inspection checklist for cosmetics might create unforeseen costs or other problems, and whether any critical exemptions are needed to MoCRA's mandatory reporting requirements.

Public comment periods are opportunities to be heard and to potentially influence the scope of forthcoming rules and regulations. Regardless, with the proper planning and the steps outlined below, companies will have the time and the tools to put together policies and procedures to ensure compliance with MoCRA and everything that is to follow.

Conducting a Gap Analysis

Before taking any action to comply with MoCRA's requirements, companies should engage in gap analysis to determine what systems, records and processes they already have in place — and how this differs from what is now required.

For example, companies may already have a way for consumers to provide product feedback and report a negative reaction. If so, those companies need to determine whether and how this process might be updated to enable reporting of serious adverse events within 15 days of receipt.

The outcome of a gap analysis is a list of items that may already comply with MoCRA, and a list of items that do not — allowing companies to direct their resources to tasks with the most imminent deadlines.

Creating Systems for Tracking, Reporting and Maintaining Records of Adverse Events

Following a gap analysis, the next key step is to create an online portal, system or telephone line to efficiently and effectively collect and store consumer feedback — particularly complaints involving adverse health-related events.[2]

At the same time, companies should also create a corresponding system for maintaining all records related to adverse events, and train employees on how to use these systems.

Preparing for Inspections, and Creating a System for Maintaining Safety Substantiation Records

Companies will also need to ensure that they have sufficient records demonstrating that all products and their ingredients are safe.[3] For some companies, this may be as simple as ensuring that all safety substantiation records are saved and maintained, and creating a system that enables the FDA to view these records upon inspection or request.

For other companies, sufficient safety substantiation may require new or additional testing, studies, research, and analysis. Given the FDA's new record inspection authority, companies should implement the same processes for all future products.

While the FDA works to establish new guidelines and regulations for safety substantiation, companies should familiarize themselves with existing FDA requirements for premarket food additives and tobacco product petitions, which offer insight into what FDA will likely expect from the cosmetics industry.

For premarket food additives, the FDA requires:

- A detailed description of the additive;
- Information on the method of manufacture and alternative methods of manufacture;
- Specifications for the identity and purity of the additive, including published specifications, and special attention to the proposed specification for lead;
- Data demonstrating the stability of the additive, considering whether it is sensitive to environmental conditions;
- An analysis of the intended use of the additive, including data that shows the amount required to achieve the intended effect;
- A method of quantifying how much of the additive is in food, if the assurance of safe use depends on a limitation; and

- An analysis of the estimated daily intake.[4]

For premarket tobacco product applications, the FDA requires:

- Full reports of all information published or known to the applicant concerning investigations which have been made into health risks of the product;
- A full statement of the components, ingredients, additives and properties of the product;
- A full description of the methods used in the manufacture, processing, packing and installation of the product; and
- Information demonstrating that the product complies with applicable tobacco product standards.

As for health risk investigations, applicants must include toxicological and pharmacological profiles of the product, a health risks comparison between products, and studies on the impacts of using the products.[5]

Putting Together a Plan for Facility Registration and Product Listing

MoCRA requires facility registration and product listing by Dec. 29 of this year, but the FDA is still developing its new systems.

To best prepare for accurate and timely filing during a tight turnaround, companies should start compiling current facility registration information, and preparing their product listing information — including the place of manufacture, category of product and a full list of ingredients.

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[1] 21 U.S.C. § 605(h)(4).

[2] Id. at § 605.

[3] See id. at § 608, 704.

[4] Guidance for Industry: Recommendations for Submission of Chemical and Technological Data for Direct Food Additive Petitions, FDA (Sept. 20, 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-recommendations-submission-chemical-and-technological-data-direct-food-additive.

[5] Premarket Tobacco Product Applications, FDA (April 11, 2023), https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications.