

Locke Lord QuickStudy: Amendments to Section VI of the Federal Food and Drug and Cosmetic Act in the Omnibus Bill

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On December 30th, 2022, President Biden signed into law the Food and Drug Omnibus Reform Act of 2022 (“FDORA”), which included an Act now signed into law entitled the Modernization of Cosmetic Regulations Act of 2022 (“MoCRA”). The Act significantly expands FDA’s oversight authority over cosmetics and provides new funding to the Cosmetic Program which will support far more Agency oversight over the regulation of cosmetic products and their manufacturers and marketers. Perhaps the most accurate characterization of MoCRA came from the Wall Street Journal, which characterized it as “giving your mascara a headache.”

The broad provisions of MoCRA make sweeping changes to how cosmetic products and the companies that manufacture and market them will be regulated in the U.S. Of particular import, is FDA’s enhanced record’s access on inspection. Prior to MoCRA, FDA could only access this information by instituting enforcement actions which procedurally required a level of evidence to commence. Under FDA’s new enhanced enforcement tools, FDA will be able not only to access this information but also utilize it to support its new mandatory recall authority with a reduced evidentiary threshold and little to no due process. In addition to mandatory recall, FDA will now be empowered to cancel a facilities registration or product listing, essentially shutting down a facility and stopping product distribution based only on a showing of a “reasonable belief of harm by FDA.” Some of the greatest impacts MoCRA will have on the current cosmetics industry are summarized below.

Safety and Adverse Events – While existing federal laws have always required responsible parties to insure that their products and ingredients are safe for their intended use, MoCRA introduces a far heavier burden than previous regulation. MoCRA requires responsible parties—the parties whose name appears on the product label—to substantiate a product’s safety at a level sufficient to satisfy an expert in the field that their products and its ingredients are safe for their intended use. MoCRA further requires responsible parties to take into consideration cumulative exposures from other products that a consumer may use when establishing the safety of their own products. Industry toxicologists would agree that such substantiation efforts amount to more than a trivial exercise and will require investment by all industry stakeholders for each marketed product.

MoCRA requires the reporting of “serious adverse events” to FDA within 15 days of receiving a report of such an occurrence. This provision mirrors regulations governing the reporting requirement of adverse events for dietary

supplements and OTC drugs that have been in place for years, but sets forth a more expansive and burdensome definition for “serious adverse events” than required for those products, *i.e.*, death or serious hospitalization. MoCRA defines a “serious adverse event” as an adverse event that results in (or requires, based on reasonable medical judgment, a medical or surgical intervention to prevent):

- death;
- a life-threatening experience;
- inpatient hospitalization;
- significant hair loss and rashes;
- a persistent or significant disability or incapacity;
- a congenital anomaly or birth defect;
- an infection; or
- severe disfigurement (including severe 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.

Since several of these “serious adverse events” are comorbid with many other conditions such as infection, hair loss and rashes, every responsible party is now at risk of under or over reporting, and potentially ending up crosswise to FDA.

MoCRA also requires manufacturers and marketers retain records of adverse health events, defined as “any health related event associated with a cosmetic,” for a period of six years for large companies and three years for smaller companies that must be made available for inspection by FDA personnel upon any inspection or request. What constitutes a health event is not defined, which again puts companies at risk for under or over reporting.

Thus, under MoCRA all sellers, marketers, and manufacturers will need to set up proper systems for the recording, submission, and maintenance of all serious and non-serious adverse event reports. And common mistakes in attempting to discern what a health effect is could result in significant consequences.

Facility Registration and Good Manufacturing Practices – While FDA has had a voluntary facility registration program for over forty years under the Federal Food, Drug, and Cosmetic Act (“FDCA”), MoCRA mandates that all facilities that manufacture or process cosmetic products register with FDA within a year of MoCRA’s enactment. The format for registration will follow that of the current voluntary system, including a list of all cosmetic products manufactured or processed within the facility that will need to be updated frequently to avoid suspension of the facility’s registration.

MoCRA requires FDA to propose regulations or rules providing requirements for Good Manufacturing Practices (“GMPs”) within two years of enactment. The proposed GMPs will be finalized through notice and comment rulemaking procedures and must comply with national and international standards for the production of cosmetics and other regulated products. FDA will be permitted to monitor GMP compliance through its new facility inspection and record access powers. MoCRA also allows for modified GMPs for small businesses (businesses that gross less than one million dollars a year) to avoid undue economic hardship if the product categories permit modified GMPs.

Given FDA’s past experiences with pharmaceuticals and dietary supplements, it appears unlikely GMPs will be

finalized for several years, though it can be expected that FDA will review current manufacturing processes through facility inspections and records access long before official GMPs are issued.

Product Listing and Labeling – MoCRA institutes a new requirement that not later than one year after enactment, the responsible seller, manufacturer, or marketer of every cosmetic product sold in the U.S. file a product listing identifying the manufacturing facility, responsible party, brand name, and cosmetic category, as well as a list of all ingredients, including flavors, fragrances, and colors. These product listings must be updated annually.

In addition, MoCRA provides that FDA may obtain a list of ingredients separate and apart from the product listing to identify potential fragrances or flavors if FDA believes the fragrances or flavors may have contributed to a serious adverse event.

MoCRA also includes new requirements that the labeling for every cosmetic product include a domestic address, domestic phone number, or electronic contact information, including a website, through which adverse events may be reported to the seller, marketer, or manufacturer. MoCRA amends the FDCA to make the failure to include such labeling information a misbranding violation, which may subject the responsible party to criminal or civil fines or sanctions. MoCRA also alters the standard for cosmetics labeling by requiring identification of any fragrance allergen present in the product, a list of which will be assembled by FDA based in part upon state and international regulations on the subject.

Records Retention and Access – MoCRA requires that responsible parties, including manufacturers, marketers, and sellers, retain all records related to adverse events, product registration, facility registration, safety substantiation, labeling, and GMPs. These requirements will greatly increase the recordkeeping and storage burdens on the industry.

In a significant change from current practice, MoCRA dictates that any designated FDA officer or employee may access or copy all records related to any cosmetic product or ingredient the Secretary reasonably believes is likely to be adulterated such that its use presents a threat of serious adverse health consequences or death, upon presentation of appropriate credentials and written notice. MoCRA also provides for similar records access in the event of the report of a serious adverse event. Such records access may include product ingredient lists and safety information.

Separately, MoCRA permits FDA to access all records maintained or stored in accordance with the Act during inspection of a manufacturing facility. In effect, this provision will require that companies file all required records, including their safety data and adverse event reports with their manufacturer so that the records are available, along with their formula data during any visit.

New Enforcement Tools – Under MoCRA, FDA will have significant teeth to enforce the new statute. As noted above, FDA's ability to deem cosmetic products misbranded or adulterated under MoCRA provides the possibility of legal action that could result in civil or criminal penalties. Yet, these penalties pale in comparison to MoCRA's mandatory recall provision that permits FDA to order that a cosmetic product be removed from the U.S. market immediately and require a mandatory product recall with basically no due process other than a hearing where FDA officials will serve as both the prosecutor and the judge. In such an administrative proceeding, FDA will only need

to set forth evidence not of actual harm from the product's use, but rather a reasonable probability of harm should the responsible party fail to cease marketing or recall the cosmetic product voluntarily. Voluntary recalls will have their own downside as publication of the deficiency cited by FDA in their request will have to be made public.

Similarly, MoCRA as noted above permits FDA to cancel a facility registration or a formula registration thereby stopping further product production of the product in question at the facility and stopping further distribution of the product-at-issue based on only a minimal showing of possible serious harm. In other words, FDA, with little to no due process, could significantly damage a company's business without showing its product causes actual harm.

These new enforcement procedures represent a significant deviation from FDA's previous enforcement tools which required the establishment of a violation of law and the institution of enforcement proceedings through judicial proceedings that provide full due process.

The industry should not take these potential risks lightly. While FDA had previously reduced resources dedicated to monitoring cosmetic products over the last fifteen years based on determinations that cosmetics were generally safe for their intended use, MoCRA provides for a significant increase in funding which will surely result in increased enforcement activity.

Timeline for compliance – MoCRA has several different implementation deadlines, though most of the new provisions went into effect upon the bill's passage. Some dates to be wary of: (1) registration for facilities and cosmetic products will be required one year from the passage of MoCRA; (2) compliance dates for issuing regulations on fragrances and finalizing guidance on testing for asbestos in talc products set forth in the statute; and (3) FDA's later-to-be implemented dates for issuing and finalizing GMPs.

Preemption – MoCRA does not change the status quo in terms of state regulatory activity related to cosmetics ingredients. Cosmetic sellers, marketers, and manufacturers must still comply with all state regulatory obligations with respect to ingredients in addition to the new obligations created by MoCRA.

Conclusion

The cosmetics industry cannot ignore the sweeping changes required by MoCRA, but can act quickly to get its practices in compliance. Locke Lord's FDA Regulatory and Cosmetics teams are available to assist in these efforts based on their significant experience with the industry and similar practices with other FDA-regulated products such as pharmaceuticals and over the counter drugs, medical devices, and dietary supplements.

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