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FDA Regulatory Framework for Cosmetics Gets Major Overhaul

January 6, 2023

Enacted on December 29, 2022, as part of the 2023 omnibus bill, the Modernization of Cosmetics Regulation Act (MoCRA) is a major overhaul of the Food and Drug Administration's current regulatory framework for cosmetics. MoCRA amends Chapter VI of the Federal Food, Drug, and Cosmetic Act (FDCA) to include new provisions for cosmetic products. These provisions create significant new authorities for the FDA and, for the first time since the FDCA was enacted in 1938, enhance the FDA's regulatory oversight of cosmetics. While MoCRA does not include a premarket approval requirement for cosmetics, it does create new obligations for the cosmetics industry. Some of the key provisions are outlined below.

Facility registration

Owners and operators of facilities that manufacture or process cosmetic products must now register with the FDA and renew such registration biennially. Notably, unlike food and dietary supplement facility requirements, facilities that only perform activities related to the labeling, relabeling, packaging, repackaging, holding and/or distributing of cosmetic products will not be required to register.

Product listing

"Responsible persons" (i.e., manufacturers, packers or distributors of a cosmetic product whose name appears on the label, as set forth under the Fair Packaging and Labeling Act) are required to list with the FDA each cosmetic product, including its ingredients and information about where the cosmetic product is manufactured, and update cosmetic product labels to include contact information through which the responsible person can receive adverse event reports.

Mandatory adverse event reporting

Responsible persons are obligated to submit reports of serious adverse events to the FDA no later than 15 days after receiving the report and maintain all records related to serious adverse events for a minimum of six years, similar to adverse event reporting requirements for dietary supplements and nonprescription drugs. Unlike the FDA's other regulated products, for cosmetics, MoCRA provides specific details on what constitutes a reportable event to include infections or "significant disfigurement," such as "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."[1] Currently, the FDA uses MedWatch for voluntary cosmetics adverse event reporting and presumably will continue to do so for mandatory serious adverse event reporting.

Safety substantiation

Responsible persons will be required to maintain records supporting "adequate substantiation" that the cosmetic product is safe. Cosmetic products that do not have adequate safety substantiation will be considered adulterated under a newly created adulteration provision within the FDCA.

Current good manufacturing practice for cosmetics

For the first time, the FDA must issue mandatory current good manufacturing practice (GMP) regulations for cosmetics that are consistent with national and international standards. As the FDA's current draft guidance for cosmetic GMP leverages elements from ISO 22716, we anticipate that the FDA's future cosmetic GMP regulations will do the same.

Mandatory allergen labeling

MoCRA requires the FDA to determine by regulation fragrance allergens that must be disclosed on a cosmetic's label. This labeling requirement applies regardless of whether a cosmetic product is subject to drug or device regulations.

Mandatory recall

MoCRA grants the FDA the authority to order a mandatory recall of a cosmetic product if it determines that the cosmetic product is likely to cause serious adverse health consequences or death.[2]

In addition to the mandatory recall authority, MoCRA creates attendant adulteration and misbranding provisions to facilitate the FDA's enforcement of these new authorities under existing FDCA prohibited acts.[3] For example, products that fail to comply with the new GMP and safety substantiation regulations will be deemed adulterated under newly created adulteration provisions within the FDCA, and if a cosmetic product's labeling fails to include the required allergens, a cosmetic product is deemed misbranded under a newly created misbranding provision within the FDCA.[4] The FDA's enforcement authority under MoCRA also allows the agency to suspend the registration of a cosmetic facility if there is a determination that a product manufactured or processed by the facility has a reasonable probability of causing serious adverse health consequences or death, and there is a reasonable belief that other products manufactured by the facility may be similarly affected.[5]

Overall, these provisions bring cosmetics regulation into greater alignment with other FDA-regulated products, particularly those such as dietary supplements and over-the-counter drugs that do not require premarket approval.

Notably, MoCRA gives certain exemptions to small businesses with gross sales of less than $1 million. For example, while small businesses still will be required to maintain records of adverse events, they only will be required to maintain these records for three years, rather than six.

MoCRA also preempts any state laws or regulations regarding registration and product listing, GMP, records, recalls, adverse event reporting, or safety substantiation for cosmetics that is different from MoCRA's requirements. Outside of these areas of express preemption, however, states are free to implement additional requirements for cosmetics, such as prohibiting the use or amount of specific ingredients.

Questions remain

Many of the key provisions, such as facility registration, product listing, and the new adulteration and misbranding definitions, take effect a year from the enactment date. With this deadline looming, many open questions remain. For example, to what extent will the new registration requirements conform with the regulations that set forth the current requirements for voluntary registration and voluntary filing of cosmetic product ingredients statements, respectively?[6] (How) will the FDA enforce the adulteration provisions regarding GMP at the end of this year, when regulations might remain in the rulemaking process until the end of 2025? Now that registration is mandatory, when will the FDA begin routine inspections of cosmetic establishments? Will the FDA create a new division within its Office of Regulatory Affairs to conduct these inspections, or will it group the inspections under the food program? Will cosmetic regulation remain within the Center for Food Safety and Applied Nutrition? While many questions are outstanding, what we do know is that this new regulatory framework is likely to have a significant impact on the cosmetics industry.

Senior regulatory analyst Kelly Marco and law clerk Madelon Bird also contributed to this alert.

Notes

1. Modernization of Cosmetics Regulation Act of 2022, House Resolution 2617 – 117th Congress (2021 – 2022): Consolidated Appropriations Act, 2023, HR2617, 117th Cong., §3502 (2022).
2. Unlike recall requirements for food and dietary supplements, the text of MoCRA does not extend mandatory recalls to serious adverse events in animals. While the omnibus bill does not contain express requirements that the FDA ban animal testing for cosmetic product safety, it contains the sense of the Congress that animal testing should be phased out with the exception of appropriate allowances.
3. *See* 21 USC §331.
4. HR2617 – 117th Congress (2021 – 2022): Consolidated Appropriations Act, 2023, HR2617, 117th Cong., §3503(a) (2022), amending 21 USC §331.

5. Modernization of Cosmetics Regulation Act of 2022, HR2617 – 117th Congress (2021 – 2022): Consolidated Appropriations Act, 2023, HR2617, 117th Cong., §3502 (2022).
6. *See* 21 CFR Parts 710 and 720.

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