Blogs
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Food & Consumer Packaged Goods Litigation

Congress Passes Major Update to Federal Cosmetics Regulation

Buried within the thousands of pages of the Consolidated Appropriations Act of 2023 is the most significant statutory expansion to the U.S. Food and Drug Administration's (FDA) authority over cosmetics since 1938. On December 29, 2022, President Biden signed the bill into law. Among the spending bill's many provisions is the Modernization of Cosmetics Regulation Act of 2022 (MOCRA), which will have lasting effects on the cosmetics industry as the FDA will have expanded authority to regulate cosmetic products.

MOCRA

Specifically, MOCRA makes several important changes to federal oversight of cosmetics, including:

- **Mandatory recall authority over cosmetics.** For the first time, the FDA will have mandatory recall authority over cosmetic products when the agency determines with a reasonable probability that (1) the cosmetic product is adulterated or misbranded, (2) the use of or exposure to the cosmetic will cause serious adverse health consequences or death, and (3) the responsible entity has refused to voluntarily cease distribution and/or recall the violative cosmetic product.
- **Adverse event reporting and recordkeeping.** MOCRA requires the reporting of serious adverse events associated with the use of cosmetic products in the United States. A "serious adverse event" includes, among other things, inpatient hospitalization or death. Responsible parties required to report adverse events include those who manufactured, packed, or distributed such products whose name appears on the cosmetic product's label. Responsible parties are required to keep records on adverse events associated with the use of the cosmetic for three years (for small businesses) to six years (for other businesses).
- **Good manufacturing practices for cosmetic facilities.** MOCRA provides the FDA the authority to promulgate good manufacturing practices (GMPs) regulations for facilities manufacturing or processing cosmetic products. GMPs are regulatory requirements regarding hygiene practices, process controls, and sanitation, among other matters. The FDA already has GMPs in place for many other product categories, such as drugs, food, and dietary supplements. The FDA last issued revised nonbinding cosmetic GMP guidance in 2013, but the agency has not previously promulgated GMP regulations for cosmetics. Failure to meet these new cosmetic GMPs could result in a finding that the cosmetic is adulterated. The regulations may provide the FDA the authority to inspect records to demonstrate compliance with GMPs. The bill requires the FDA to also promulgate simplified GMPs for smaller businesses. Before issuing the implementing regulations governing GMPs, the bill requires the FDA to consult with cosmetics manufacturers and consumer organizations. The bill requires the FDA to promulgate these GMP regulations within two years of the bill's enactment and requires final regulations within three years of enactment.
- **Identification of fragrance allergens on product labels.** MOCRA requires cosmetic labels to identify each fragrance allergen in a product once the FDA issues its forthcoming fragrance allergen rule, which will consider European Union (EU) and other international requirements. If a cosmetic product label does not include required fragrance disclosures, it will be considered misbranded under section 602(b) of the Food, Drug, and Cosmetic Act (FDCA).
- **Asbestos and perfluoroalkyl and polyfluoroalkyl substances (PFAS) in cosmetics.** MOCRA requires the FDA to issue proposed regulations to establish and require standardized testing methods for detecting

and identifying asbestos in talc-containing cosmetic products. In addition, MOCRA mandates that the FDA issue a report regarding the use of PFAS in cosmetic products and the scientific evidence regarding the safety and risks associated with the use of PFAS in cosmetics.
- **Preemption**. MOCRA expressly preempts state and local requirements that differ from MOCRA's standards related to registration and product listing, GMPs, records, recalls, adverse event reporting, or safety substantiation. MOCRA also contains a savings clause and certain limitations regarding the law's preemptive effect.

MOCRA and the larger Consolidated Appropriations Act of 2023 were signed into law on December 29, 2022. Many of MOCRA's provisions will go into effect over time, with some becoming effective a year after the bill's enactment and others awaiting finalized regulations. The cosmetic industry will have opportunities to provide notice and comment on proposed regulations.

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