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ALERT

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# FDA Updates Requirements for Cosmetics Registration, Listing, and Serious Adverse Event Reporting

## Have You Met the July Deadline?

***By: Michael J. Schwab***

Two years ago, Congress greatly expanded the authority of the U.S. Food and Drug Administration (FDA) by enacting the Modernization of Cosmetics Regulation Act (MoCRA). This Act requires companies to register each facility with the FDA where they manufacture or process cosmetics and list those products with the FDA, too. Then, late last year, FDA issued two MoCRA-related guidances: one that delays MoCRA's enforcement dates for registering cosmetics manufacturing and processing facilities and listing cosmetic products, and a second that provides specific details on registration and listing amendments and renewals – including when a product is also a drug. This last item is one indication that MoCRA has narrowed the gap between how the FDA regulates cosmetics and drugs.

**MoCRA Changes, and How Cosmetic Companies Should Respond**

The first guidance, announced in November 2023, extended the deadline for compliance with registration and listing requirements by six months, to July 1, 2024. (For registration, this is a one-time requirement that has some exceptions for small businesses). The second guidance, published in December, requests information that the FDA would like companies to submit, but which MoCRA doesn't require, such as parent company name, type of company, DUNs number, image of the product label, Unique Ingredient Identifiers, and product webpage link. It also contains a list of product categories and a discussion about the responsible party(ies) for registration and listing purposes.

Separately last December, the FDA revised instructions to make it easier to submit serious adverse events for cosmetic products on its MedWatch Form 3500A, which is the document required for making these event reports. These submissions became mandatory as of December 29. The agency also launched a Cosmetics Direct electronic submission portal, where users can create separate accounts for drugs and cosmetics, or a joint account for both. (This is an expansion of the free, web-based product labeling authoring tool from the Center for Drug Evaluation and Research (CDER), known as CDER Direct.)

What's important to know about all this is that companies should familiarize themselves with the portal and – particularly if they carry extensive product lines – the information they need for registration and listing. And, if they haven't already done so, companies should develop a Standard Operating Procedure to fulfill MoCRA's requirement for serious adverse event reporting – and start SOP training for their employees.

Perhaps most importantly, the FDA now has the power to compel a company to recall a cosmetic product to prevent injury to consumers – even if the company that made or distributed the product objects to the recall.

**MoCRA Basics**

The persons responsible for meeting cosmetic product listing requirements are the cosmetic manufacturer, packer, or distributor whose name is on the product label. Again, as of July 1, 2024, the information required to be listed includes their own name and contact number; the product name on the label; the registration number of the facility where the product was made; the product's cosmetic category from the MoCRA list; all ingredients, including fragrances, flavors, or colors; and the product listing number, if the FDA provided one.

Another rule, specifying labeling requirements, is scheduled to take effect in early 2025. MoCRA requires that labels identify each fragrance allergen in the cosmetic; clearly and prominently state on professional-use-only products that only licensed professionals can administer or use them; and carry a domestic address, phone number, or electronic contact information so that the responsible person can obtain adverse event reports about the cosmetic.

The responsible persons also have mandatory tasks related to adverse event reporting and record-keeping. Within 15 days of receiving it, they must file with the FDA any report of a serious adverse event – defined as an event that results in death, life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, a congenital anomaly or birth defect, an infection, or significant disfigurement (such as serious and persistent rashes, second-or-third degree burns, significant hair loss, or persistent or significant alteration of appearance). And, they must maintain, for six years, all adverse (health-related) events associated with a cosmetic product that they manufacture or distribute.

That's not all. These persons must ensure and maintain safety records that adequately substantiate the safety of their product and its ingredients. This requires that qualified scientific experts can affirm that studies, tests, research, analyses, or other information

show with "reasonable certainty" that the product and its ingredients are safe, and that people can use the product according to conditions prescribed on the label without sustaining an injury from it.

If you have any questions regarding the matter raised in this Alert, please feel free to contact **Michael J. Schwab** at mschwab@moritthock.com or (212) 239-5527.

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