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Baby Steps as FDA Issues First Draft Guidance Under MoCRA

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On August 7, 2023, the US Food and Drug Administration (FDA) released its first draft guidance on the new regulatory requirements under the Modernization of Cosmetics Regulation Act (MoCRA). As we explained in a January 2023 client alert, MoCRA overhauls the regulatory framework for cosmetics in the United States, placing new obligations on manufacturers and granting the FDA additional authority over cosmetics. The FDA's first guidance document related to the new MoCRA requirements, Draft Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products, outlines the key components of these requirements: who must register, what information is required, when registration must be submitted, and how the FDA intends to accept registration and listing information.

Who must register?

Pursuant to Section 607(c) of the Federal Food, Drug, and Cosmetic Act (FDCA), every person who owns or operates a facility engaged in the manufacturing or processing of a "cosmetic product" – a defined term under MoCRA that means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product – for distribution in the United States must register the facility, with two exceptions:

1. Small businesses, defined as responsible persons, owners, and operators of facilities with average gross annual sales of less than $1 million across the previous three-year period, are exempt from the registration and listing requirements unless they engage in manufacturing or processing of cosmetics that regularly come into contact with the mucus membrane of the eye, are injected, are intended for internal use, or are intended to alter appearance for more than 24 hours.
2. Facilities subject to the requirements for drugs and devices are also exempt from registering separately as a cosmetic facility, unless they manufacture or process cosmetics that are not subject to drug and device requirements under the FDCA.

What information is required?

The registration requirements for facilities are specified under Section 607(a) and 607(b)(2) of the FDCA, and product listing requirements are specified under Section 607(c). Notably, registration as a cosmetics facility requires submission of the facility registration number, if one was assigned. The FDA's guidance indicates that to facilitate registration, owners or operators of a cosmetic facility should obtain an FDA Establishment Identifier (FEI) number prior to submitting the cosmetic facility registration.

When must registration be submitted?

Facilities that were engaged in manufacturing or processing of cosmetic products on December 29, 2022, must register no later than December 29, 2023. Facilities that first engaged in manufacturing or processing of cosmetics after December 29, 2022, must register within 60 days of first engaging in the activity or by February 27, 2024, whichever is later. Any amendments, including

cancellations, of registrations must be submitted within 60 days of the change.

How will registration and listing information be submitted?

The FDA intends to make a new electronic submission portal available in October 2023 and also is developing a paper submission form. The FDA has specified that the new electronic submission portal is intended to be efficient for subsequent submissions, as information from prior submissions can be reused without needing to be reentered. Additionally, because the cosmetic registration and product listing will use the same process as drug registration and listing, the FDA anticipates this will streamline the process for facilities that manufacture both drug products and cosmetics.

Because the registration requirements under MoCRA differ from those of the FDA's prior voluntary cosmetics registration program, manufacturers that have previously registered under the voluntary program should be aware that the FDA does not consider prior voluntary registration to fulfill the MoCRA requirements. Moreover, any information provided to the FDA under the voluntary program will not be transferred into the new system. Manufacturers previously registered under the voluntary program should be prepared to submit all the information required under MoCRA through the new electronic portal.

Future FDA guidance anticipated

As many provisions of MoCRA are set to take effect at the end of 2023, there are still several areas where we anticipate future guidance from the FDA, such as establishing good manufacturing practices (GMPs) consistent with national and international standards, as well as a system for adverse event reporting for cosmetics. In addition, we hope to gain some insight into how the FDA intends to approach inspections and enforce these new regulatory requirements, particularly given the agency's plans to restructure its Office of Regulatory Affairs.

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