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FDA Has Early Holiday Gift For Cosmetics Industry: More Time To Register Under MoCRA

by [Eileen Francis](#)

The US Food and Drug Administration will delay enforcement of the first registration deadline for cosmetic facility manufacturers and cosmetic product listings under the Modernization of Cosmetics Regulation Act until 1 July, 2024.

The US Food and Drug Administration, less than two months before cosmetic facilities and products must be registered under the Modernization of Cosmetics Regulation Act and with a registration portal yet to launch, is delaying its enforcement of the first registration deadline by six months.

In a final guidance on facility and product registration made public 8 November, a day before a [notice](#) on the guidance was published in the Federal Register, the agency announced that stakeholders facing the 29 December statutory deadline for registration now have until 1 July, 2024 to complete the process.

The delay in enforcement should “help ensure that owners or operators of cosmetic product facilities and responsible persons for cosmetic products have sufficient time to gather the relevant information required for facility registration and product listing, including obtaining facility registration numbers to associate with cosmetic product listings, obtaining access to the electronic submissions database and verifying accurate registration and listing information for submission,” the guidance states.

The initial deadline was in place for cosmetic facilities or operators that had engaged in manufacturing or processing a cosmetic product and for firms that marketed cosmetic products on or before 29 December 2022. Later deadlines were to be allowed for companies which began manufacturing or marketing products after 2022. However, the July date will also mark the

earliest the agency enforces on those stakeholders as well.

The FDA's flexibility on the deadline isn't entirely a surprise, given the agency is late in making the registration portal, Cosmetics Direct, available. In an August draft guidance on registering cosmetic product facilities and products, FDA announced it planned to open the portal in October after a two-week pilot in September (Also see "[US FDA Provides Guidance On MoCRA Facility Registration 17 Weeks Before Deadline To Register](#)" - HBW Insight, 7 Aug, 2023.)

FDA Shooting For Early December Cosmetics Direct Launch

For companies prepared to register, the FDA aims to make Cosmetics Direct available in early December, along with technical assistance documents and paper submission forms.

"FDA will be ready to accept registration and listing information by the statutory deadline of December 29, 2023, and we encourage companies to meet that deadline if they are able to do so," the agency says in the guidance.

Industry, noting the significant data many companies must compile, particularly for brands comprising hundreds of products, has urged the FDA to use enforcement discretion on the first deadline under MoCRA, which was enacted in late 2022 as part of the 2023 omnibus bill (Also see "[Industry Seeks FDA Flexibility Around MoCRA Registration And Listing; Attorneys Discuss](#)" - HBW Insight, 16 Aug, 2023.)

In 20 October comments to the agency, Independent Beauty Association president and CEO Don Frey requested flexibility "in the event that technical difficulties significantly impact the ability for industry [to] complete all requisite product listings" by the deadline.

Concern grew as October came and went without the launch of Cosmetics Direct.

In an 8 November statement to HBW, Frey said independent beauty companies, "many of which are small- and medium-sized businesses," appreciated the FDA's decision to delay enforcement.

"This six-month enforcement delay will help ensure companies of all sizes are able to properly comply with the new registration and listing requirements," he said.

The association "values the accessibility of" FDA chief scientist Namandje Bumpus and Office of Cosmetics and Colors Director Linda Katz "to hear the voice of small business," he added.

"Our members' top priority is getting this right and IBA's priority is to be a resource for our members and the FDA as MoCRA implementation progresses. We were grateful to have a seat at the table and applaud the FDA for listening to the concerns of independent beauty brands," Frey said.

Kelly Bonner, a trial attorney in Duane Morris LLP's Philadelphia office, noted in an 8 November blog [post](#) on her law firm's site that the guidance does not mention whether FDA also will be flexible on additional requirements under MoCRA subject to the 29 December deadline, including professional product labeling requirements.

According to MoCRA, any cosmetic product introduced in the US and intended for use by a professional must bear a label that contains a "clear and prominent" statement that the product is "administered or used only by licensed professionals."

"Likewise, FDA has not advised whether delayed enforcement changes the December 29, 2023 effective date for companies to maintain records of adverse events, report serious adverse events to FDA, or maintain adequate safety substantiation records," Bonner said.

Also by 29 December, FDA is required under the regulation to issue a proposed regulation for talc testing and must finalize the rule 180 days later. (Also see "[MoCRA Talc-Testing Rule Brings Clarity While Raising Target For Class Action Complaints](#)" - HBW Insight, 7 Nov, 2023.)