

Locke Lord QuickStudy: FDA Extends Some MoCRA Deadlines

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On November 8, 2023, FDA issued a Final Guidance entitled *Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing* ("FDA Guidance") extending some upcoming deadlines set forth in the Modernization of Cosmetic Regulations Act of 2022 ("MoCRA"), 21 U.S.C. §§ 361-364j. These deadlines are set forth in our prior Quick Studies: [Amendments to Section VI of the Federal Food and Drug and Cosmetics Act in the Omnibus Bill](#) and [Preparing for the December 2023 MoCRA Deadlines: What You Should Do Now](#).

What deadlines have been extended?

The FDA Guidance extends the deadlines for submitting facility registrations and product listings under 21 U.S.C. § 364c from December 29, 2023 to **July 1, 2024**. FDA Guidance at 4. FDA states that it will be ready to accept such submissions by December 29, 2023, but does not detail when its electronic database or paper forms will be available for public use. *Id.*

What deadlines have not been extended?

The FDA Guidance limits the extension only to the submission of facility registrations and product listings. The following statutory deadlines in MoCRA are still in force:

1. **December 29, 2023** – Possession of documentation meeting the requirements for adequate safety substantiation under 21 U.S.C. § 364d; record-keeping requirements for notice of adverse events and requirements for submission of severe adverse event reports under 21 U.S.C. § 364a;
2. **June 29, 2024** – Inclusion of contact information for a responsible person and identification of fragrance allergans in labeling information on all products as set forth in 21 U.S.C. § 364e;
3. **December 29, 2025** – Compliance with current good manufacturing practices (cGMPs) as set forth in 21 U.S.C. § 364b.

Will more extensions be granted?

At this time, FDA has refused to confirm whether the deadline for compliance for any additional obligations under MoCRA will be extended. The Locke Lord FDA Regulatory and Cosmetic and Personal Care Products' teams will continue monitoring the issue and advise industry on any further extensions should they become available.

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