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MoCRA Stakeholders Reminded Registration Enforcement Begins 1 July: 'Do Not Delay!'

by Eileen Francis

The Independent Beauty Association urged stakeholders at its Cosmetic Convergence Symposium to take action to ensure they are meeting requirements of the Modernization of Cosmetics Regulation Act come 1 July, when FDA's enforcement of the facility and product registration deadline begins. Presenters offered tips from companies that have already completed the process.

The US Food and Drug Administration's deferred enforcement for facility and product registration under the Modernization of Cosmetics Regulation Act (MoCRA) is quickly coming to an end, meaning it is high time for companies to submit their information to the agency, says the Independent Beauty Association.

"The banner headline here is: do not delay, please!" said IBA President and CEO Don Frey at IBA's 10 April Cosmetic Convergence Symposium, addressing the fast-approaching 1 July date when the FDA will begin enforcing facility registration and product listing requirements in the online portal created for MoCRA compliance activities, Cosmetics Direct.

In November, the agency announced it would delay enforcement of facility and product registration until 1 July to 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 FDA Establishment Identifiers (FEIs) to associate with cosmetic product listings. (Also see "*FDA Has Early Holiday Gift For Cosmetics Industry: More Time To Register Under MoCRA*" - HBW Insight, 8 Nov, 2023.)

"I know, there is a tendency to see the extension and breathe a sigh of relief and, you know, worry about that later. Please, please get all of your information gathered and start submission

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and soon as possible, whether you're handing that internally with your team or if you're working with a third party," Frey said.

> *"July will be here before you know it."*

He urged companies to ensure the facilities they use are already registered or are preparing to register in Cosmetics Direct and they have all other required product and ingredient data ready for registration.

"We highly recommend, if you have not already started, to begin that process, because July will be here before you know it," Frey said.

Meredith Petillo, IBA's VP of technical-regulatory affairs, added companies working with third-party service providers to meet the requirements of MoCRA must exchange any necessary data on products as quickly as possible. "If there are true reasons why something is not in there by July 1, it really needs to be documented. If it's 'I didn't get my provider the information until the end of June,' I don't know how much water that's going to hold," she said.

Frey reminded stakeholders the delayed enforcement was only for facility registration and product listing, and not for all MoCRA provisions with 29 December 2023 effective dates, including requirements related to safety substantiation, adverse event reporting and recordkeeping, as well as labeling for professional-use products. Companies should already be compliant with those elements.

Some stakeholders have been looking for FDA to extend the enforcement timeline yet again beyond July, but there have been no indications to date that that will happen. Wade Ackerman, a partner at Covington & Burling in Washington, D.C. who advises companies and trade associations on complex novel FDA regulatory issues, noted in a recent interview that while the agency could exercise discretion and extend the deadline, "all indications are that the agency wants to continue to make progress on MoCRA implementation." (Also see "*MoCRA Implementation In US Election Year: Q&A With Attorney Wade Ackerman*" - HBW Insight, 25 Mar, 2024.)

FDA issued a guidance document in November 2023 on facility and product registration that also addressed frequently asked questions from stakeholders, ahead of the opening of Cosmetics Direct on 29 December. (Also see "*Tis The Season (For Data Entry): FDA Opens Cosmetics Direct*

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Portal, Issues Final Registration Guidance" - HBW Insight, 21 Dec, 2023.) Frey said the guidance document and a *Cosmetics Direct Users Guide* – in addition to the law itself – are very helpful for registrants to read as they complete requirements, especially if they have problems.

To assist in the process, Frey and Petillo provided observations and suggestions to stakeholders based on input from registrants who have already used Cosmetics Direct:

- Facility registration must precede product listing. "Any facilities that may be waiting to complete their [facility registration] obligation, please know that there's a massive volume of product listings that follows on after that facility registration," noted Petillo, adding that some companies are waiting on a manufacturer to register a facility that makes their product before they can list their products. "And there's two parts of a facility being registered: one is for them to get an FEI [FDA Establishment Identifier] number, and the other is to actually register as a cosmetic manufacturing facility."

- Facilities that already have FEI numbers for manufacturing OTC products like sunscreens must still register in Cosmetics Direct. "That's a key step that many facilities were missing, at least early on," Petillo said. "And it will block you from doing your product listings if they do not register."

- There are some snafus with uploading formulas using spreadsheets. While FDA has continued making improvements in the portal, it is not always allowing registrants to upload their spreadsheets if they do not enter the Unique Ingredient Identifiers, though those identifiers are optional and FDA cannot require them, noted Frey. He advises registrants who run into that problem to notify the FDA.

- Establish written agreements with contract manufacturer. "That may sound obvious, but we know that there are a lot of companies out there who in the past have just worked off a purchase order and don't necessarily have written agreements," said Frey. "So it's very important to make sure that when you're assuming someone is responsible for one thing, that's written down and people know they're responsible for it."

- Reach out to FDA for help with Cosmetics Direct. "The portal has been challenging for many," said Petillo. "If you're getting errors or you're having challenges, there may be ingredients that don't have a unique code, or you're seeing discrepancies there and you just want to input the ingredients as listed on your label. We recommend highly engaging first with FDA" before reaching out to trade associations. "For anybody who's working in the regulatory capacity or interfacing with departments that are helping to support MoCRA, your organization reaching the right person at FDA is really helpful to get things done efficiently."

According to IBA, FDA has been responding to email inquiries within one to two days, "as long as

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they go to the right boxes," Frey said. FDA contact points, depending on registration issue, include:

- For help with validation errors in the portal: *cosmeticsdirect@fda.hhs.gov*;
- General questions about facility registration and product listing: eRLC@fda.hhs.gov; and
- General MoCRA questions: QuestionsAboutMoCRA@fda.hhs.gov.

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