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Industry Seeks FDA Flexibility Around MoCRA Registration And Listing; Attorneys Discuss

by Eileen Francis

Companies have concerns about how the FDA will respond if struggles to obtain data, or hiccups in the cosmetic product facility registration or listing process, lead to errors or deadline misses under the Modernization of Cosmetics Regulations Act. Attorneys from Duane Morris and Covington & Burling provide views on FDA's related draft guidance, key challenges facing industry, and how the agency may proceed.

Stakeholders commenting on the US Food and Drug Administration's draft guidance on registration and listing requirements under the Modernization of Cosmetics Regulations Act (MoCRA) will urge the agency to use enforcement discretion as concerns grow over the approaching year-end deadline.

Two attorneys who spoke with HBW Insight on 10 August, three days after the *guidance* was released, said cosmetic manufacturers are relieved the guidance is finally available.

However, the portal for registering facilities and listing cosmetic products will not be available until October after a two-week pilot period in which the agency will test it with no more than nine participants. The agency shuttered its previous collection portal for cosmetic product data, the Voluntary Cosmetic Registration Program, in March. (Also see "*FDA Sunsets VCRP, Will Launch New Portal For Mandatory Cosmetics Registration Under MoCRA*" - HBW Insight, 28 Mar, 2023.)

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> *"This isn't an industry that's been sitting on its heels, not getting ready to comply."*

Meanwhile, companies have hordes of data to compile, and there are questions about how the FDA will respond if struggles to obtain data or hiccups in the registration and listing process lead to errors or deadline misses.

"Collecting all of the information for brands that have numerous products, I could see difficulty in collecting all that information, difficulties in identifying all contract manufacturers, negotiating who is going to submit facility registration – will it be the company or the contract manufacturer?" said Kelly Bonner, a trial attorney in the Philadelphia office of Duane Morris LLP whose practice focuses on consumer products, among other areas of law.

It will be challenge enough just gathering the copious data and preparing it for submission, and "we don't know quite what the portal looks like yet," Bonner noted.

Jessica O'Connell, a partner in the Washington office of Covington & Burling LLP said that while MoCRA's facility registration requirement is not expected to be particularly burdensome, the product listing requirement is. "Especially for companies that have a large volume of products, without seeing the system and understanding how information needs to be put into the system, in what format, and all of those other things, it's hard for companies to prepare right now," she said.

Enacted in late 2022 as part of the Consolidated Appropriations Act, MoCRA requires cosmetic product listings to include such information as the facility registration number of each facility where the product is manufactured or processed, the name and contact number of a responsible person, applicable cosmetic category or categories, and a list of ingredients in the product, including any fragrances, flavors, or colors. (Also see "*MoCRA Check-In: Unknowns Include How US FDA Will Address Potentially Noncompliant Ingredients*" - HBW Insight, 15 Aug, 2023.)

The FDA's draft guidance requests additional information including parent company name, an image of the product label, product webpage link, and whether the cosmetic product is for professional use.

Comments on the draft guidance are due by 7 September. (Also see "*US FDA Provides Guidance On MoCRA Facility Registration 17 Weeks Before Deadline To Register*" - HBW Insight, 7 Aug, 2023.)

Consider Food Facility Registration

O'Connell – who served previously as an associate chief counsel in the FDA's Office of Chief Counsel –believes the agency will be receptive to industry's concerns.

"This isn't an industry that's been sitting on its heels, not getting ready to comply," she said. "It's challenging to get ready to comply if they can't see the system, so I think it would be very reasonable to extend the compliance date by some period of time needed to give everyone a chance to do this."

The attorney believes the agency's approach could parallel what has happened for foods. She pointed to the FDA's *food facility registration guidance*, which has been revised seven times since 2003.

The FDA's most recent update in 2018 provided clarity on changes that came with the Food Safety Modernization Act of 2011, which amended food facility registration requirements under the Food, Drug and Cosmetics Act. "It has kind of evolved as FDA has learned what companies have questions about," O'Connell said.

In its seventh edition, the Q&A guidance addresses points including "registration requirements in situations where multiple entities are involved in the use of shared physical space, such as where one entity owns a building and lessees manufacture/process, pack or hold food in the building."

Per O'Connell, it has taken time for the FDA and industry to really understand what issues require clarification. "And that really comes from industry's experience using a system and FDA's experience reviewing submitted information. Based on this, I'd expect FDA to consider updating the [cosmetics registration and listing] draft guidance over the next few years to address questions similar to how FDA approached this in the food facility registration space," she said.

O'Connell expects some portion of stakeholder comments to be asking for guidance on issues the FDA has not touched on yet at all.

"I mean, that draft guidance in itself is pretty basic," she said.

O'Connell advises stakeholders to identify in their comments to the FDA the information required for product listing that they see as vulnerable trade secrets.

In its draft guidance, the agency says its response to a Freedom of Information Act request would not disclose information from a facility registration on the brand names under which cosmetic products manufactured or processed in the facility are sold. The agency also will keep

confidential information from a product listing on the facility registration number of the facility where the cosmetic product is manufactured or processed.

However, "all other information from cosmetic product facility registration and listing would be available for public disclosure, consistent with the FOIA," the FDA says.

Who's Responsible?

One area that Bonner believes needs to be addressed further is MoCRA's responsible person requirements.

Under MoCRA, the responsible person, defined as the manufacturer, packer, distributor or importer of a cosmetic product whose name appears on the label, must submit to the FDA the cosmetic product listing, as well as keep records of adverse events and report to the FDA all serious adverse events associated with a product's use.

"I could see some additional questions about whether a responsible person needs to be internal to the company or whether companies can retain third-party firms that can handle submissions," Bonner said.

FDA also should provide details on whether participants in the registration and listing pilot program receive some sort of credit or be afforded a simplified process for their actual registration activities, she said.

Bonner wonders how forgiving the FDA will be about mistakes made in the registration process. "Does FDA plan on being flexible? Or what will be the penalties for late or incomplete submissions?"

Immediate Steps

As to what industry stakeholders should be tackling now, O'Connell advises manufacturers to gather all the information they know they need so far to comply with registration.

Notably, facilities that do not already have an FDA Establishment Identifier (FEI), which the agency identifies in its draft guidance as needed before starting the registration process, should immediately move to obtain one, as required documentation and negotiation of the process could take time.

The draft guidance directs entities seeking an FEI number, or wanting to determine if they already have one, to this *webpage*.

O'Connell urges firms that use contract manufacturers to "really make sure that they've discussed with those manufacturers who's going to be submitting information. Making sure there

is a plan for compliance, kind of across the supply chain and with their partners." (Also see "*Getting A Jump On MoCRA Compliance; Due Diligence Now Will Lighten Load, Risks Later*" - HBW Insight, 21 Mar, 2023.)

Bonner reminds industry stakeholders that knowledge is power. "Read the statutes, read the guidance, read the draft guidance, read the supporting documents surrounding the draft guidance. Be prepared to participate in the draft comment period, to raise questions with FDA," she said.

Finally, it could behoove companies to consult with industry associations and seek legal counsel, Bonner said.