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MoCRA Implementation In US Election Year: Q&A With Attorney Wade Ackerman

by Eileen Francis

Wade Ackerman, partner at Covington & Burling who served previously as senior FDA counsel to US Senate Health Education, Labor & Pensions (HELP) Committee leadership, discusses expectations for FDA activity under modernized cosmetics regulations in 2024.

The US Food and Drug Administration is working to meet regulatory and guidance deadlines in its second year implementing the Modernization of Cosmetics Regulation Act (MoCRA).

Wade Ackerman, partner at Covington & Burling in D.C., advises companies and trade associations on complex and novel FDA regulatory issues. He also co-leads Covington's multi-disciplinary Digital Health Initiative. He served until June 2016 as senior FDA counsel to US Senate Health Education, Labor & Pensions Committee ranking member Patty Murray, D-WA, and prior to that, chairman Tom Harkin, D-IA.

Murray, a leading proponent of MoCRA, stated in February 2023 that she would watch closely to ensure FDA is implementing the regulation properly and using new tools effectively. (Also see "*Tis The Season (For Data Entry): FDA Opens Cosmetics Direct Portal, Issues Final Registration Guidance*" - HBW Insight, 21 Dec, 2023.)

It remains to be seen how factors including the US presidential election affect the FDA's activities in 2024.

MoCRA Steps Achieved, Targets Ahead

In this Q&A, which follows a related update Ackerman provided at the Personal Care Products Council's 2024 annual conference in Coral Gables, FL, he addresses the likelihood of another deadline enforcement shift for facility and product registration, timing of proposed rulemakings

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on talc, fragrance allergen labeling and good manufacturing practices, and how companies can best prepare for coming changes.

Q HBW Insight: What's the likelihood that FDA provides another enforcement extension for MoCRA's facility and product registration deadline?

A Wade Ackerman: We are advising cosmetics companies to prepare for the July 1, 2024 deadline. While FDA could exercise discretion and extend the deadline, all indications are that the agency wants to continue to make progress on MoCRA implementation.

Q What's your view on required rulemaking proposals in 2024 for talc in cosmetics, fragrance allergens, and GMPs?

A On the talc-related rule, FDA already submitted the proposed rule to OMB for review, so it could issue at any time. I will also add that

Early in 2023, in an effort to implement its new authorities under MoCRA, FDA moved cosmetics from the Center for Food Safety and Applied Nutrition into the Office of the Chief Scientist. (Also see "*FDA Announces New Home For Cosmetics Under Proposed Food Program Restructuring*" - HBW Insight, 1 Mar, 2023.)

The first deadline under MoCRA for registering facilities and listing products and ingredients was 29 December 2023, but the FDA announced in a November compliancy policy that enforcement will not kick in until 1 July 2024. (Also see "*Tis The Season (For Data Entry): FDA Opens Cosmetics Direct Portal, Issues Final Registration Guidance*" - HBW Insight, 21 Dec, 2023.)

2023 end-of-year deadlines stayed in place for other requirements related to safety substantiation, adverse event reporting and recordkeeping, and labeling for professional-use products.

FDA was required to issue a proposed rule on methods for detecting and identifying asbestos in talc-containing products by 29 December. The Office of Management and Budget's website notes it received the proposed rule from the agency on 2 January 2024.

According to Katlin McKelvie and Carlo Felizando, partner and associate attorney at the Washington, D.C. office of Gibson, Dunn & Crutcher, LLP, the OMB has eight FDA rules currently under review. "[T]here is some

administration review and clearance of rules – particularly in an election year – can slow down agency rulemaking, even when there are statutory deadlines, so there is some uncertainty in the background. MoCRA directs FDA to issue a proposed rule on fragrance allergen labeling this summer and a proposed rule on good manufacturing practices at the end of the year. I hope FDA will stay on track for those important MoCRA rules, as they are key pillars of the modernized federal regulatory framework under the new law.

likelihood that the talc proposed rule will not issue this year, especially given the timing of the mandatory 60-day Congressional review period for rules under the Congressional Review Act, combined with the longer, election-year recess starting in August," they said in a 27 February *MoCRA update*.

Looking at mid-year FDA deadlines, MoCRA requires the agency to issue a proposed rulemaking for cosmetic allergen labeling by 29 June 2024 and a final rulemaking 180 days after the proposed rule's public comment period ends. The new law mandates proposed rules for cosmetic good manufacturing practices by 29 December 2024 and a final rule one year later.

"Neither of these proposed rules appeared in the most recent editions of the Unified Agenda … which means there is little chance they will issue in 2024, especially given competing priorities for the agency," according to the Gibson, Dunne & Crutcher attorneys.

Further out, the FDA is directed to issue a report summarizing research on per- and polyfluoroalkyl substances (PFAS), including assessment of use and risks, by December 2025.

Q **What input should industry be providing to the FDA to help shape cosmetics GMP rulemaking? Are there concerns that cosmetic GMPs could come out too similar to drug GMPs?**

A In MoCRA deliberations on the Hill, Congress recognized that the cosmetics industry has long been committed to making sure that cosmetics products are made under safe conditions. With this in mind, Congress enacted a directive in MoCRA for FDA to leverage current cosmetics industry GMP standards, including international standards. While the drug category,

of course, already had mandatory GMPs, drugs generally present a different risk profile than cosmetics, so we'd expect that FDA will tailor the MoCRA GMP rule to cosmetics.

Q **Where should companies be in their compliance work relative to new adverse event reporting requirements?**

A Mandatory serious adverse event reporting and adverse event recordkeeping are some of the key consumer safety pillars of MoCRA. While many people had already been reporting serious adverse events to FDA voluntarily, MoCRA makes this a requirement for all companies, effective as of the end of 2023. Related to the adverse event requirements, MoCRA also mandated that cosmetics product labels include a way for consumers to report adverse events to manufacturers. Congress gave the industry an extra year for this new requirement – until the end of 2024 – to come into compliance, given the lead time needed to make label changes. I'd expect that companies have already made significant process in implementing this new requirement and do not anticipate a deadline extension.

Q **By the end of 2024, FDA expects to develop two key guidance documents on circumstances in which it can exercise new authorities granted by MoCRA: accessing and copying records relating to a cosmetic product, and ordering a company to cease distribution of a product and initiate a recall. How do you expect the FDA to interpret these new authorities?**

A The statutory language is pretty clear on records access for FDA. I expect this draft guidance to focus more on process considerations around FDA inspections and records access, which is what we have seen from FDA in other product categories.

Q **What advice do you have for companies working to elevate recordkeeping in accordance with MoCRA provisions and prepare for FDA inspections?**

A A good way to prepare for inspections and ensure proper recordkeeping is through an internal audit. Conducting an internal inspection would help companies understand

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how to best manage the records that FDA might seek during an inspection, ensure they can provide appropriate records in an efficient manner, train personnel, and determine which company processes can be improved. Companies also should keep in mind that FDA staff also are getting up to speed on MoCRA, and inspectional personnel may not be all that familiar with the scope of FDA's new authorities. Each product category has different, tailored FDA authorities, which is no different for cosmetics under MoCRA. It will be important for company personnel to be educated as the new law is implemented by FDA in the field.

Q **Any other advice for stakeholders in terms of prioritizing MoCRA responsibilities this year?**

A While everyone in the cosmetics sector was focused on MoCRA in 2023 – right after enactment – in some ways 2024 and 2025 will be even more important years to follow implementation closely. There will be multiple regulations and guidance documents for public comment, and I encourage companies to provide comments to FDA, including working with PCPC to provide industry feedback.