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Cosmetics Regulation – Where Are We Going, Where Have We Been?

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This update highlights steps taken by the Food and Drug Administration to implement the Modernization of Cosmetics Regulation Act since its enactment in 2022 as well as actions expected in the cosmetics space this year. **In December 2022, Congress passed the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), which overhauled the Food and Drug Administration (FDA) framework for the regulation of cosmetics.** MoCRA granted FDA new authorities and imposed a series of new requirements on the cosmetics industry, including with respect to adverse event recordkeeping and reporting, facility registration and product listing, good manufacturing practices (GMPs), safety substantiation, fragrance allergen labeling, facility suspension, records access, and mandatory recall authority. FDA is required to develop multiple regulations and guidances to implement the new law, a number of which issued in 2023 and are expected to issue in 2024, with opportunities for stakeholder comment and feedback. This client alert highlights three steps FDA has taken to implement MoCRA since its enactment and eight actions to expect from FDA on cosmetics in 2024. **In 2023, FDA took several measures to implement its new authorities under MoCRA, most notably**:

1. **Moving the regulation of cosmetics out of the Center for Food Science and Nutrition (CFSAN) and into the Office of Chief Scientist (OCS)**. This shift out of CFSAN and into OCS, with the Chief Scientist publicly leading MoCRA's implementation, signals that, post-enactment of MoCRA, the regulation of cosmetics is now a higher priority for the agency. In addition, FDA has explained that moving cosmetics regulation to the Office of the Commissioner will leverage FDA's areas of expertise across the agency as it works to implement its new authorities.
2. **Holding a public listening session and seeking written comments on GMPs for cosmetic products**. Under MoCRA, FDA is required to issue regulations establishing GMPs for facilities that manufacture cosmetic products. While, as discussed below, it is doubtful that FDA will meet its statutory deadlines for issuance of the proposed and final GMP regulations (December 2024 and December 2025, respectively), the listening session is a critical first step in their development.
3. **Issuing guidance on cosmetic product facility registration and cosmetic product listing**. Under MoCRA, for the first time, FDA has the authority to require the registration of facilities where cosmetic products are manufactured and the submission of cosmetic product listings, including a list of ingredients used in the products. In December 2023, FDA issued guidance detailing who is responsible for making the registration and listing submissions and what, where, when, and how to submit the information. FDA also announced that it will not enforce the registration and listing requirements until July 1, 2024.

In 2024, FDA will continue to ramp up implementation of MoCRA, including by issuing guidance for industry, launching new systems for submission of information to FDA, and taking steps to enforce new requirements. **Look for FDA to take the following actions in the cosmetics space in 2024**:

1. **Focusing on microbiological contamination in cosmetic products**. FDA has

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long expressed concerns about the risks of contamination of cosmetic products with microorganisms and has expressed a renewed focus on the issue post-enactment of MoCRA. In June 2023, FDA issued a draft guidance for industry on insanitary conditions in the preparation, packing and holding of tattoo inks and the risk of microbial contamination. Over the course of 2023, the agency also added makeup products from three firms from China to an import alert due to microbiological contamination. In addition, FDA highlighted in a new cosmetics fact sheet for small businesses the importance of conducting testing to determine the safety of each ingredient, including microbiological safety. Expect FDA to take further action, including finalizing the tattoo ink guidance and possibly issuing untitled or warning letters, to address issues of microbiological contamination in cosmetic products over the coming year.

2. **Enforcing registration and listing requirements**. As noted above, FDA has announced that it will not take action to enforce cosmetic product facility registration and listing requirements until July 1, 2024. In advance of that date, FDA has issued guidance to industry on compliance with these requirements, as well as tools and options for making electronic submissions. FDA likely will give industry, especially smaller businesses, an additional, unofficial buffer to allow for industry (and agency) adjustment to the reporting requirements but, by the fall, will expect compliance with the new requirements. If and when FDA decides to enforce these requirements, consistent with its approach in other product areas, the agency is likely to prioritize companies whose products it believes pose a risk to the public health, such as manufacturers of contaminated, unsafe, or otherwise adulterated cosmetic products.
3. **Issuing guidance for industry on records access and mandatory recalls**. The Office of the Chief Scientist has announced that, by the end of 2024, FDA expects to develop, in conjunction with the Office of Regulatory Affairs, two key guidances for industry on the circumstances in which FDA can exercise new authorities granted by MoCRA: accessing and copying records relating to a cosmetic product and ordering a person to cease the distribution of and recall a cosmetic product. Industry will be particularly interested FDA's interpretation of its records access authority under the new statute, given the potential scope of the authority and FDA's previous lack of access to cosmetic product records. Interested stakeholders should consider participating in FDA's guidance development process by submitting comments on key concerns and issues.
4. **Standing up a system for the electronic submission of serious adverse event reports**. MoCRA imposes a new requirement that industry submit serious adverse event reports associated with the use of cosmetic products to FDA. As of December 2023, FDA has modified the current FDA paper form (Form MedWatch3500A) to make it easier for the cosmetics industry to complete the form. Last month, FDA announced that, over the course of the next several months, the agency will have an electronic means for submission of the reports.
5. **Conducting research on per- and polyfluoroalkyl substances (PFAS) in cosmetics**. Under MoCRA, by December 2025, FDA is required to issue a report summarizing the results of an assessment of the use of PFAS in cosmetic products and the evidence regarding the safety of such use, including any risks associated with their use. FDA has said that there is not much published data available on PFAS in cosmetics. Last month, FDA announced that it be working to fill certain scientific gaps through its own research, which can be expected to begin this year. Of note, this work comes as a bipartisan bill to ban PFAS in cosmetics has been introduced in the House, although its chances of passage are slim, given the limited amount of time for bill passage given this year's longer, election-year recess, Republican control of the House, and a lack of a companion bill in the Senate. In addition, on the state side, multiple state legislatures have taken, and are taking, steps to ban PFAS in cosmetic products.
6. **Issuing a proposed rule on testing methods for talc in cosmetics**. MoCRA

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required that FDA issue a proposed rule on testing methods for detecting and identifying asbestos in talc-containing cosmetic products by December 29, 2023. According to the Office of Management and Budget (OMB) website, OMB received the proposed rule from FDA for review on January 2, 2024. With eight FDA rules currently under review with OMB as of February 27, 2024, there is some 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. Nonetheless, because the proposed rule is being issued pursuant to a statutory mandate, there is a chance that OMB will complete its review in time for it to publish at some point this spring.

7. **Developing implementation and strategic workforce plans for MoCRA implementation**. In December 2023, the Government Accountability Office (GAO) issued a report entitled Cosmetic Safety: Better Planning Would Enhance FDA Efforts to Implement New Law. The report's recommendations centered around FDA's lack of organizational changes necessary to implement MoCRA. Within the next few months, FDA likely will respond to the recommendations in that report by developing implementation and strategic workforce plans, as called for by GAO.
8. **Hiring a new MoCRA lead?** Last, but not least, over the course of 2023, Dr. Namandje Bumpus, as FDA's Chief Scientist, made several public appearances and statements about her work and priorities as the agency lead on MoCRA's implementation. Earlier this month, Dr. Bumpus moved to her new role as Principal Deputy Commissioner. FDA is now looking for a new Chief Scientist to take Dr. Bumpus's place. She is continuing to hold the cosmetics portfolio for the moment, but, once hired, the new Chief Scientist is expected to take over the implementation of MoCRA. It remains to be seen whether her replacement will be hired within this calendar year and, if so, what priorities the new hire will have in the area of cosmetics regulation.

Finally, this year, there are several regulations that FDA is required to issue under MoCRA, or has indicated it is seeking to issue, that likely will not publish before the end of the year. **In 2024, do not expect to see FDA regulations on**:

1. **Cosmetics GMPs and fragrance allergen labeling**. MoCRA requires FDA to issue proposed rules regarding GMPs for cosmetics and fragrance allergen labeling by December 29, 2024, and June 29, 2024, respectively. Neither of these proposed rules appeared in the most recent editions of the Unified Agenda, the compilation of information about regulations under development by federal agencies, which means there is little chance they will issue in 2024, especially given competing priorities for the agency.
2. **Use of formaldehyde as an ingredient in certain hair products**. In 2023, FDA announced its intention to publish a proposed rule on the use of formaldehyde and formaldehyde-releasing chemicals as an ingredient in hair smoothing or hair straightening products. Dr. Bumpus emphasized the importance of the proposed rule to the agency in multiple postings to her official Twitter feed. Although FDA has given a target date of July 2024 for issuance of the rule, given the number of high priority regulations FDA has said it will issue by this spring, most if not all of which require review by OMB, as well as the 60-day review period mandated by the Congressional Review Act, it is unlikely that the formaldehyde proposed rule will publish this year.

The following Gibson Dunn lawyers assisted in preparing this update: Katlin McKelvie and Carlo Felizardo.

Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding the issues discussed in this update. Please contact the Gibson Dunn lawyer with whom you usually work, the authors, or any leader or member of the firm's FDA and

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