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ALERT

# FDA's Catch-Up Plan on Cosmetics Faces Likely Regulatory Delays with Change in Administrations

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The U.S. Food and Drug Administration (FDA) has been playing catch-up on three long-delayed proposed rules required under the Modernization of Cosmetics Regulation Act of 2022 (MoCRA):

- Standardized test methods to detect asbestos in talc-containing products;
- Identification of certain fragrances deemed "fragrance allergens"; and
- Good manufacturing practices for cosmetics.

While FDA in the final weeks of the Biden Administration has made some progress in advancing these three proposed rules, one of which has now been published, the change in Administrations on January 20 will likely create more delays and uncertainty.

In addition to updating its plan to catch up on these three required proposed rules, the Fall 2024 Unified Agenda of Regulatory and Deregulatory Actions issued by the Office of Management and Budget (OMB) in mid-December also provided an updated FDA proposal to issue a proposed rule to ban the use of formaldehyde and formaldehyde-releasing ingredients in hair smoothing and straightening products. And just days before the end of the year, FDA finally issued its proposed testing requirements for talc-containing cosmetics.

*Talc-Containing Cosmetics (Section 3505 of MoCRA)*

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MoCRA required FDA to promulgate proposed regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetics by December 29, 2023, and to finalize those regulations within 180 days after public comment closure. Despite FDA's best efforts, the proposed rule languished at OMB from January 2024 until December 16 – and in another holiday season surprise, FDA issued the proposed rule on December 27, 2024, with a three-month comment period **ending on March 27, 2025**.

The FDA proposal would require manufacturers to test a representative sample of each batch or lot of a talc-containing cosmetic product for asbestos using both Polarized Light Microscopy (PLM) (with dispersion staining) and Transmission Electron Microscopy (TEM)/Energy Dispersive Spectroscopy (EDS)/Selected Area Electron Diffraction (SAED). Manufacturers can either test each batch or lot of the talc cosmetic ingredient, or they may rely on a certificate of analysis for each batch or lot of talc from a qualified talc supplier prior to using the talc to manufacture a talc-containing cosmetic. The manufacturer must confirm that the supplier talc testing also includes both the PLM and TEM/EDS/SAED methods. Manufacturers would be required to maintain records to confirm compliance with the rule for a period of three years.

The proposed rule also includes enforcement provisions. Failure to comply with the testing and recordkeeping requirements would render the product adulterated under the Federal Food, Drug, and Cosmetic Act (FD&C Act). In addition, since FDA is not aware of any safe level below which asbestos could not cause adverse health effects, the proposed rule states that talc-containing cosmetic products or talc used in a cosmetic product that are confirmed to have asbestos are adulterated under the FD&C Act.

In the proposal, the FDA adopted the "mineralogical approach" to defining "asbestos" as inclusive of amosite, chrysotile, crocidolite, asbestiform tremolite, actinolite, anthophyllite, winchite, and richterite, and the Agency also included all other asbestiform amphibole minerals. The Agency noted that its definition is more expansive than other agencies' regulatory definitions of asbestos, which do not include winchite and richterite, because these two additional substances have been associated with the same health risks as the six other substances. FDA also intends to cast a broad net "to help ensure that testing for asbestos in talc-containing cosmetic products would detect all asbestiform amphiboles" since all such substances "have potential to release similar fibers" of concern. FDA noted that the catch-all "all other asbestiform amphibole minerals" will ensure capture of all such substances in the event of mineral nomenclature changes in the future.

If you have an interest in commenting on this proposed rule and require assistance, please reach out to the authors of this alert.

*Fragrance Allergens Labeling Requirement (Section 609(b)) of the FD&C Act)*

Under MoCRA, FDA has the authority to determine by regulation that certain fragrances are fragrance allergens, and therefore must be disclosed on the product label. MoCRA required FDA to issue a notice of proposed rulemaking on this topic by June 29, 2024, and to issue a final rule no later than 180 days after the date the public comment period closes. FDA must consider international, state, and local requirements for allergen disclosures, including requirements in the European Union (EU), and it can establish allergen

threshold levels subject to labeling disclosure in the final regulation.

The June 2024 statutory deadline has come and gone, but the Fall 2024 Unified Agenda indicates that FDA hopes to issue a proposed rule on this topic this month. To date, the proposed rule has not been submitted to OMB for review, so this is highly unlikely to be issued this month in light of next week's change in Administrations. However, in the Fall 2024 Unified Agenda, the FDA is already signaling its interest in a shortened compliance date once this rule is finalized, as well as its initial opinion that a more general allergen statement would present lesser benefits to consumers. We will be watching out for this proposal.

*Cosmetic Good Manufacturing Practices (Section 606 of the FD&C Act)*

MoCRA required FDA to issue a proposed rule to establish cosmetic good manufacturing regulations by December 29, 2024, and to establish the final rule on December 29, 2025.

The regulations must be consistent with national and international standards, with the intent to protect public health, and ensure cosmetics are not adulterated. The regulations may allow FDA to inspect records necessary to assure compliance with Good Manufacturing Practice (GMP) regulations under Section 704 of the FD&C Act. Cosmetic products produced in a manner that do not comply with the final GMP requirements will be deemed adulterated under FD&C Act Subsection 601(f).

FDA must take the following considerations into account in developing GMP regulations:

1. Size and scope of the business;
2. Risks posed by such cosmetics;
3. Flexibility sufficiently practicable for all sizes and types of facilities;
4. The need for simplified GMPs for "smaller businesses" to avoid undue economic hardship; and
5. Longer compliance times can be established for smaller businesses.

MoCRA required FDA to engage in consultation with cosmetic manufacturers, including smaller businesses, consumer organizations, and other experts selected by the FDA/Secretary in promulgating such regulations. FDA held a public listening session in June 2023 and opened a docket to receive written comments by July 2023 to satisfy this requirement. A significant number of public comments supported adoption of ISO 22716 (Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices), which is the GMP standard required in the EU countries. Obviously, the statutory deadlines to issue the proposed rule have recently passed, and only in the Fall 2024 Unified Agenda did FDA finally announce that it is planning to issue a proposed rule in October 2025. Thus, at the earliest, a final GMP rule should not be expected until October 2026. We can anticipate delays in implementation once the rule is finalized, particularly as it concerns smaller businesses.

*Use of Formaldehyde and Formaldehyde-Releasing Chemicals as an Ingredient in Hair Smoothing Products or Hair Straightening Products*

In the Spring 2023 Unified Agenda, FDA provided notice of a plan to issue a proposed rule in April 2024 that would ban formaldehyde (FA) and other FA-releasing chemicals (e.g., methylene glycol) as ingredients in hair smoothing or hair straightening products marketed in the United States. FDA states that these chemicals are linked to both short-term adverse health effects (e.g., sensitization reactions and breathing problems) and long-term adverse health effects (such as increased risk of certain cancers). FDA's notice of intention to engage in rulemaking to ban these ingredients follows Agency outreach on this topic since 2010, in which it sought to educate salon customers as well as employees regarding the health risks associated with use of these products. In 2021, FDA received a citizen petition from the Environmental Working Group and Women's Voices for the Earth requesting that FDA take regulatory action to ban formaldehyde, formaldehyde equivalents, and other chemicals that emit high levels of formaldehyde in hair smoothing products and hair straightening products. Despite missing the April 2024 deadline, this proposed rule remained a high priority in the Fall 2024 Unified Agenda, which noted March 2025 as the new target date to issue a proposed rule to ban the ingredients.

*FDA May Face Obstacles in Achieving Its Regulatory Priorities in the Near Term*

In light of the upcoming change in Administration next week, it is very likely that there will be further delays in proposing or finalizing required cosmetic regulations, and more difficulty with promulgating regulations not specifically called for in the FD&C Act. Separate and apart from the Congressional Review Act, which results in a review of final rules in the last few months of a prior Administration, a fairly common measure that has become a practice for new Administrations is to issue an Executive Order directing Executive branch agencies to freeze any pending rulemakings. This involves a request, frequently issued on day one of the new Administration, to all departments and agencies to withdraw proposed rules that have been sent to the Federal Register but have not yet been published. It can also include a request to postpone the effective dates of rules that have been published but have not yet taken effect. This allows the new Administration to have the opportunity to fully review any new or pending regulations to determine alignment with the Administration's mission. More to come on this next week.

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Please do not hesitate to reach out to the authors of this alert if you have any questions about these or other FDA rules under MoCRA.