wiley

ALERT

FDA Withdraws "Standardized" Asbestos Testing Proposal for Talc-Containing Cosmetics, With Intent to Reexamine and Reissue

December 5, 2025

On November 28, 2025, the U.S. Food and Drug Administration (FDA) withdrew its 2024 proposed rule entitled "Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products." 90 FR 54603. The proposed rule sought to establish specific asbestos testing requirements for talc-containing cosmetics. Talc is an ingredient used in numerous cosmetics, like pressed powders.

Certain stakeholders issued immediate criticism after FDA released the pre-publication version of the withdrawal on November 24, 2025. NGOs voiced concerns that FDA's withdrawal of the proposed rule would reduce or even eliminate the testing requirements for asbestos in talc, despite the statutory mandate and safety reasons for the testing. However, FDA's statements and actions do not appear to indicate such intentions and instead may represent a fitting response to significant public opposition to the proposed rule during the Administrative Procedure Act's notice-and-comment rulemaking process.

On previous occasions, FDA stressed the importance of testing, as well as the potential hazards from asbestos in talc. For example, in a July 10, 2025, statement, FDA Commissioner Marty Makary, M.D., M.P.H., listed the hosting of an expert panel to assess the "potential health risks associated with talc used in foods, drugs and cosmetics" among the highlights of his first 100 days as FDA Commissioner.[1] Further, in the withdrawal of the proposed rule, FDA stated that it

Authors

Ann M. Begley
Partner
202.719.4585
abegley@wiley.law

Rebecca L. Dandeker
Partner
202.719.3417
rdandeker@wiley.law

Martha E. Marrapese
Partner
202.719.7156
mmarrapese@wiley.law

Edith Nagy
Environment & Product Regulation Practice
Attorney
202.719.4248
enagy@wiley.law

Practice Areas

Environment & Product Regulation

Food & Drug

wants "to ensure that any standardized testing method requirements for detecting asbestos in talc-containing cosmetic products help protect users of talc-containing cosmetic products from harmful exposure to asbestos." As such, the withdrawal of the proposed rule does not indicate FDA's opposition to testing for asbestos in talc, but instead its reconsideration of how best to accomplish that goal.

Moreover, since the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) mandates asbestos testing for talc-containing cosmetics via a regulation, FDA is required to implement one. Thus, while we expect that FDA will reissue standardized testing requirements in the future, when it will issue them is less clear.

Background

Talc is a naturally occurring mineral ingredient used in many consumer products, including cosmetics, dietary supplements, and drugs. Because asbestos, a known carcinogen that is also a naturally occurring mineral, may be found in proximity with mining locations for talc, mining practices are in place worldwide to generally avoid deposits that are likely to contain asbestos minerals.

Congress included a provision in MoCRA requiring FDA to promulgate a regulation for standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. Under this statutory mandate, FDA published the (now withdrawn) proposed rule on December 27, 2024. 89 FR 105490. See our prior client alert on the proposed rule.

The withdrawn proposed rule would have required manufacturers to test a representative sample of each batch or lot of a talc-containing cosmetic product using two separate tests, in tandem: Polarized Light Microscopy (PLM) (with dispersion staining) and Transmission Electron Microscopy (TEM)/Energy Dispersive Spectroscopy (EDS)/Selected Area Electron Diffraction (SAED). FDA rejected other testing types, claiming they were not sensitive enough (i.e., X-ray diffraction (XRD) and infrared (IR) spectroscopy).

While the mandate in MoCRA was narrowly focused on FDA developing a standard testing methodology for detecting asbestos in talc that is used in cosmetics, the proposed rule contained an overly broad definition for "asbestos" that lacks scientific consensus. Many commenters urged FDA to rely on the definition that is used by other federal agencies, which encompasses six regulated varieties of asbestos, each of which has its own prescribed chemical identity.

Failure of a manufacturer to comply with the testing and related recordkeeping requirements would have rendered a product adulterated under Sections 601 and 701 of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under the proposed rule, if asbestos is present at any detectable level in a talc-containing cosmetic product or in talc used in a cosmetic product, the cosmetic would be considered adulterated under the FD&C Act.

What Comes Next?

1. A More Accurate Testing Standard?

After reviewing the public comments received during the notice and comment period, FDA decided to reexamine and reissue the proposed rule based on its determination that "good cause exists to withdraw the proposed rule at this time." The single most important concern expressed by the United States Pharmacopeia (USP), as well as other commenters, was that the proposed TEM method is not sufficiently sensitive to distinguish asbestiform and non-asbestiform amphibole particles in all circumstances, which would result in many false positives. In contrast, the USP method for identifying asbestos relies on the use of PLM with XRD to detect asbestos at low levels and to accurately differentiate the different types of asbestos. Commenters suggested that the false positives that would result from the use of the less precise method in FDA's proposed rule could lead to unnecessary and costly reformulation, reputational harm, or even litigation. Moreover, drug and medical device companies expressed concern that if the testing method for cosmetics is extended to their products in the future, the false positives would result in unnecessary removal of valuable health care products from the market to the detriment of consumers. We expect that FDA will want to ensure that the issue of false positives is adequately addressed in a reissued proposed rule.

2. A More Consistent Definition Across Agencies?

Another concern that FDA has been urged to address is to align its definition of "asbestos" with the established definition used by other federal agencies, including the Occupational Safety and Health Administration, the Mine Safety and Health Administration, and the U.S. Environmental Protection Agency. Consistency across agencies would avoid unnecessary confusion regarding the meaning of "asbestos" and the difficulty of complying with disparate standards for the same cosmetic product.

Conclusion

The FDA is required to issue a regulation establishing a standardized test method to detect asbestos in talc-containing cosmetic products, and its responsibility to issue this regulation is long overdue under the MoCRA provisions.[2] While our crystal ball provides no insight on when FDA will issue a new proposal, if the agency waits too long it runs the risk of being the target of litigation by interested parties claiming that FDA has failed to comply with its statutory duties. More importantly, clear direction from FDA to test for asbestos in talc-containing cosmetic products using a method that has achieved scientific consensus would benefit the safety profile of such products.

When FDA reissues the proposed rule, stakeholders can submit comments again to provide feedback and express concerns.

* * *

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.

[1] FDA, "*A Statement from FDA Commissioner Marty Makary, M.D., M.P.H: 100 Days of Embracing Gold-Standard Science, Transparency and Common Sense*" (July 10, 2025).

[2] The initial December 2024 proposed rule was already one year behind the statutory deadline. Section 3505 of MoCRA provides that FDA must promulgate proposed regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products "not later than one year after the date of enactment of this Act," which was December 2022.