Cristales and Nguyen in Happi Magazine: Let's Talc About Asbestos

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The FDA's proposed Talc Rule will mandate asbestos testing for talc cosmetics. Haynes Boone attorneys Kayla Cristales and Luke Nguyen wrote about the compliance and litigation risks potentially coming from the rule that brands should proactively manage in an article for *Happi Magazine*.

Read an excerpt below:

The relationship between talc and asbestos begins at the mining process. Talc is a naturally occurring mineral composed of magnesium, silicon, oxygen and hydrogen. It is a common ingredient in certain cosmetic products, such as baby powder, blush and eyeshadow.

Asbestos is also a naturally occurring mineral and is often found near talc. As a result, in the past 10-15 years, in particular, there have been reports of asbestos contamination in cosmetics containing talc. These reports lead to high-profile class action lawsuits, FDA-commissioned testing, recalls, and, ultimately, the Congressional mandate within the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) directing FDA to issue regulations to establish standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. The agency issued the proposed "Talc Rule" on December 27, 2024, which, per MoCRA, is set to become final as of June 25, 2025.

Testing Requirements and Compliance Options

If finalized, the rule will require cosmetic manufacturers to conduct asbestos testing on either a "representative sample" of each batch or lot of finished products containing talc or on all batches or lots of the talc ingredient prior to using it in the production of any finished products. Alternatively, finished product manufacturers may opt to rely on testing performed by their talc suppliers, as evidenced by a certificate of analysis (COA) for each batch or lot supplied, provided that the COA contains the minimum required information, and the manufacturer establishes and maintains the reliability of the talc supplier and the testing reflected in the COA.

Additional Details:

- "Representative Sample": The rule defines representative sample as "a sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled."
- Analytical Methodology: Regardless of which of the above options a manufacturer decides to utilize to comply with the rule, the required testing must be performed using both Polarized Light Microscopy (PLM) (with dispersion staining) and Transmission Electron Microscopy (TEM)/Energy Dispersive Spectroscopy (EDS)/Selected Area Electron Diffraction (SAED).
- Minimum Information Required in COAs: Each COA must state that (a) the supplier used an analytical approach that includes both PLM and TEM/EDS/SAED and (b) the COA is specific

to the talc purchased by the manufacturer, including identification of a lot or batch number for the talc being tested, the date or date range when the test(s) were performed and the results of each test.
- Establishing and Maintaining Talc Supplier/COA Reliability: Manufacturers may only rely on COAs provided by talc suppliers if they verify the reliability of such COAs by conducting or procuring (from an independent lab) confirmatory asbestos testing using both PLM and TEM/EDS/SAED at least (a) upon receipt of the initial COA from a given supplier and (b) annually thereafter.

Record-keeping

Manufacturers subject to the rule (if enacted as proposed) must maintain records of asbestos testing for talc-containing products that describe: (a) the testing procedures used on the sample and (b) the testing results, including raw data. If a manufacturer relies on a talc supplier's COA, the manufacturer must maintain records of (i) each COA and (ii) documentation showing how the manufacturer established and maintained the supplier's reliability through verification of the test results reflected in the COA upon initial receipt and annually thereafter.

The required records must be maintained for three years. The proposed rule also specifies that if FDA requests the records for inspection—a power granted under the new proposal—the manufacturer must produce the records within one business day.

Read the full article from *Happi Magazine* here.