Updates

On December 27, 2024, the U.S. Food and Drug Administration (FDA) published a proposed rule under Modernization of Cosmetics Regulation Act (MoCRA) to require manufacturers to (1) test talc-containing cosmetic products or any talc ingredient used for the presence of asbestos and (2)?maintain certain records regarding this testing. Comments are due to the agency by March 27, 2025.

FDA's Prior Asbestos Monitoring

This is the first proposed rule that the agency has published as part of its implementation of MoCRA. Under MoCRA Section 3505, FDA is required to issue proposed regulations to establish and enforce standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products.

Prior to the enactment of MoCRA, FDA monitored asbestos in talc-containing cosmetic products by sampling products reported to contain asbestos using polarized light microscopy (PLM) and transmission electron microscopy (TEM)/energy dispersive spectroscopy (EDS)/selected area electron diffraction (SAED) methods. In 2019, for instance, the FDA's contract laboratory tested 52 talc-containing powder cosmetic products, including body powders, face powders, eye shadows, blushes, bronzers, and face makeup using PLM and TEM/EDS/SAED. Subsequently, FDA confirmed the presence of asbestos in nine talc-containing cosmetic products, which were then voluntarily recalled by the companies.

Proposed Rule

The newly published proposed rule encompasses cosmetic products, including cosmetic products that are also drugs and proposes to define “asbestos” to include “amosite, chrysotile, crocidolite; asbestiform tremolite, actinolite, anthophyllite, winchite, and richterite; and other asbestiform amphibole minerals.”

FDA outlines two test methods that are both required for testing a representative sample of each batch or lot of a talc-containing cosmetic product for asbestos: (1) PLM (with dispersion staining) and (2) TEM/EDS/SAED. The proposed rule also allows manufacturers the flexibility to either test each batch or lot of the talc cosmetic ingredient or rely on a certificate of analysis from a qualified talc supplier, provided that supplier also used both PLM and TEM/EDS/SAED.

In addition, manufacturers must also keep records of the aforementioned asbestos testing or supplier certification. If a manufacturer conducted its own testing, its records must include raw data and describe how the samples were tested. If a manufacturer instead relied on a supplier’s certificate of analysis, its records must include these supplier certificates and documentation of how the manufacturer verified the reliability of the supplier’s testing. These records must be kept for three years and made available to FDA within one business day of FDA’s request.

Failure of a manufacturer to comply with both the testing and recordkeeping requirements would render the product adulterated under the Federal Food, Drug, and Cosmetic Act (FDCA). Furthermore, because there is no established safe level of asbestos that does not cause adverse health effects, FDA has determined that any level of asbestos in talc-containing cosmetic products may render these products injurious to users. Consequently, the proposed rule would codify that if asbestos is present in a talc-containing cosmetic product, or in talc used in a cosmetic product, that cosmetic is adulterated under the FDCA.

Next Steps

Manufacturers of talc-containing asbestos products should review the proposed rule in detail to understand its implications, evaluate the practicality of adopting the test methods outlined in the proposed rule, and submit comments to FDA within the 90-day window (*i.e.*, by March 27, 2025).

Authors

Brien McMahon

Of Counsel
BMcMahon@perkinscoie.com 415.344.7165

Brian P. Sylvester

Partner
BSylvester@perkinscoie.com 202.434.1669

Kristine E. Kruger

Senior Counsel
KKruger@perkinscoie.com 206.359.3111

Sichang (Cathie) Chen

Associate
SChen@perkinscoie.com

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