Background

Talc is used in a wide variety of consumer products including cosmetics, foods, drugs, and medical devices regulated by the Food and Drug Administration (FDA). It is mined as a naturally occurring hydrous magnesium silicate and may be contaminated with asbestos fibers due to the proximity of asbestos in/near talc deposits. Asbestos fiber inhalation has been associated with mesothelioma in humans, and as such, asbestos is classified as carcinogenic according to International Agency for Research on Cancer (IARC). In the 1970s, questions were raised about the possible presence of asbestos in talc-containing cosmetics, as well as which methods and criteria should be used to test talc used in cosmetics for the presence of asbestos fibers. As a result of these discussions, the cosmetics industry, in 1976, implemented voluntary testing using the Cosmetic, Toiletry, and Fragrance Association (CTFA) J-4-1 method for measuring asbestiform amphiboles in talc.

To date, CTFA J-4-1 remains the cosmetic industry's standard test method for asbestos in talc despite recognized shortcomings in specificity and sensitivity compared with electron microscopy methods. The CTFA J-4-1 and the closely-related USP method are, in general, used by talc suppliers to indicate suitability for use in manufacturing FDA-regulated products and generally help preclude fibrous amphiboles. However, on occasions when the more sensitive electron microscopy methods are used, and elongated amphibole particles are identified, there have been differences of opinion regarding whether such particles should be regarded as being harmful.

The FDA conducted a survey of talc-containing cosmetic products in 2010 using Polarized Light Microscopy (PLM) and Transmission Electron Microscopy (TEM) and did not find asbestos fibers in any of the tested samples: whereas, during 2017-18, multiple laboratories reported finding elongated tremolite particles in cosmetic makeup products using PLM and TEM. In these recent publicized reports, the majority of the testing laboratories characterized the identified particles as "tremolite asbestos" leading to recalls of various cosmetic products in the US, Canada and Europe.

Even applying acceptable definitions and terms germane to commercial forms of asbestos, experts in microscopy and geology still do not uniformly agree whether detected elongated amphibole particles in talc-containing cosmetics are asbestiform, or whether they are cleavage fragments. It is important to recognize this distinction as only asbestos fibers are considered to be carcinogenic by inhalation. As noted above, lack of consensus on terminology and methodology applicable to testing of talc for asbestos has persisted since the first reports indicating it might be present in talc used in cosmetics. Standardization of terminology, certified reference materials and multilab validated methods for testing asbestos in talc and talc-containing cosmetics would enable concurrence in characterization of elongated particles of tremolite, anthophyllite and chrysotile that might be present in talc. An agreeable method(s) of characterization, along with the availability of reference standards, are prerequisites for microscopy data interpretation and

evaluation of potential safety concerns whenever amphiboles are detected in FDA-regulated cosmetic products.

The purpose of this symposium is to provide a forum for experts in asbestos mineral analysis, academicians and regulators to share knowledge on testing approaches aimed at adequately analyzing talc-containing products for the presence of asbestos fibers. The symposium will include presentations and concurrent breakout sessions on test methods, characterization and interpretation of data.

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