February 26, 2020

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2020-N-0025; "Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc"; Request for Comments

Dear Sir/Madam,

The United States Pharmacopeia (USP)[1] appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) on testing methods for asbestos in talc. Our comments focus on clarifying the Federal Register Notice (FRN) in two places as it pertains to USP.

In the first instance, the FRN states that talc suppliers to the pharmaceutical industry use a method for testing asbestos in talc raw materials to certify that talc meets the USP's requirement for Absence of Asbestos, and it references a USP Revision Bulletin dated August 1, 2011. USP wishes to clarify that this Revision Bulletin does not represent the language in the current, official version of the USP talc monograph, which was published in 2013, and can be found in the current *USP-NF*.

In the second instance, the FRN states that in 2014, the Talc USP Expert Panel recommended an update of the USP talc monograph to ***require*** an electron microscopy method for the measurement of asbestos in talc, and it references the 2014 USP Stimuli article titled: *Stimuli to the Revision Process, Modernization of Asbestos Testing in USP Talc*. USP wishes to clarify that the referenced article discusses the Expert Panel's recommendation for revision of the currently official test for Absence of Asbestos in the USP talc monograph to include omission of the infrared spectroscopy test and inclusion of a revised x-ray diffraction procedure, to be used in combination with one or more microscopic evaluations, which ***may*** include polarized-light microscopy, transmission electron microscopy, or scanning electron microscopy methods.

USP currently has a Talc Methods Expert Panel that is addressing the task of identifying appropriate analytical methods and reference standards for testing Absence of Asbestos in talc for use in pharmaceutical products.

USP is also planning a roundtable meeting on March 13, 2020, where representatives from industry, regulators, and academia will be invited to discuss the recommendations of the Talc Methods Expert Panel on modernization approaches

[1] USP is an independent, scientific, nonprofit organization dedicated to improving health through the development of public standards for medicines, foods, and dietary supplements. Through a longstanding collaboration with FDA, we have worked continuously to benefit public health through accessible quality medicines.

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using appropriate analytical methods and limits for testing Absence of Asbestos in talc for use in pharmaceutical products. Thereafter, the USP Talc Expert Panel plans to publish their recommendations and approach for updating the USP talc monograph in a stimuli article for public comment.

We look forward to continuing to work with FDA and industry on testing methods for asbestos in talc and thank you for the opportunity to comment. For more information, please contact Marissa Chaet Brykman, Director, U.S. Regulatory Engagement, at marissa.brykman@usp.org; (301) 692-3660.

Sincerely yours,

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