Johnson&Johnson

October 27, 2026

Kyle Diamantas
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Proposed Rule on Talc Testing

Dear Commissioner Diamantas,

We write on behalf of Johnson & Johnson ("J&J") regarding any rule regarding testing talc for the presence of asbestos that the U.S. Food and Drug Administration ("FDA") may be considering.

FDA previously issued a proposed rule on talc testing for cosmetics pursuant to the Modernization of Cosmetics Regulation Act, known as MoCRA.[1] As the comments submitted in response reflect, we and many others strongly advocated against the proposed rule on the grounds that (1) the contemplated testing methodology would generate false positives by classifying non-asbestos minerals—including even potentially talc itself—as "asbestos", and (2) the economic impact analysis failed to account for the significant adverse economic impact such false positives would have on US citizens, consumers and companies. FDA ultimately withdrew that proposed rule approximately a year later "to reconsider best means of addressing the issues covered by the proposed rule and broader principles to reduce exposure to asbestos, and 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."[2] At that time, FDA noted that it would be issuing a new proposed rule in the future.[3]

While the proposed cosmetics rule was under consideration, the Center for Drug Evaluation and Research ("CDER"), the division of FDA charged with regulating over-the-counter and prescription drugs, made its views regarding the appropriate approach to talc testing known in a number of public forums. CDER reiterated its position that talc sourced for use in pharmaceutical products should be tested at least once a year in

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1 89 Fed. Reg. 105490

2 90 Fed. Reg. 54603

3 *Id.*

accordance with United States Pharmacopeia ("USP") testing protocols. J&J fully supports and has long utilized USP protocols in its own talc testing.

J&J stands united with FDA that an appropriate testing protocol—one that accurately identifies asbestos and is based on the best available science—is important for public health and the public good. We write to express J&J's views regarding the best approach to talc testing in light of all available science and technology, and to urge FDA to ensure that any future testing rule proposed under MoCRA be harmonized with CDER's guidance.

Background On Talc And Asbestos

Talc itself is not asbestos. Talc is a naturally occurring silicate mineral. The concern regarding the possibility of asbestos contamination in talc derives from the fact that in some mineral deposits and in certain very rare circumstances, talc may exist alongside other types of minerals that can transform into asbestos when unique conditions are present. Under one analysis, "the likelihood of encountering rocks, in the conterminous United States, that contain asbestos is on the order of 0.0001 or 0.01%."[4]

There is a well-established set of minerals that can form into asbestos in those rare circumstances, which include an extreme and particular combination of temperature, pressure, and time. Those same minerals can also and much more commonly form in a manner such that they are *not* asbestos. Thus, science has long recognized both "asbestiform" (asbestos) and "nonasbestiform" (not asbestos) versions of certain minerals.

For example, this chart sourced from an EPA regulation outlines the asbestos minerals and their non-asbestiform (i.e., non-asbestos) analogs:[5]

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[4] Wylie, A. and Candela, P, *Methodologies for Determining the Sources, Characteristics, Distribution, and Abundance of Asbestiform and Nonasbestiform Amphibole and Serpentine in Ambient Air and Water*, Journal of Toxicology and Environmental Health, Part B: Critical Reviews, 18:1, 1-42, http://dx.doi.org/10.1080/10937404.2014.997945. One author subsequently served as an expert witness for Johnson & Johnson after the article was published.

[5] 40 C.F.R. 763, Subpt. E, App E, Tbl. 2-1 (Asbestos Hazard Emergency Response Act regulations)

TABLE 2–1—THE ASBESTOS MINERALS AND THEIR NONASBESTIFORM ANALOGS

Asbestiform	Nonasbestiform
SERPENTINE	
Chrysotile	Antigorite, lizardite
AMPHIBOLE	
Anthophyllite asbestos	Anthophyllite
Cummingtonite-grunerite asbestos ("Amosite")	Cummingtonite-grunerite
Crocidolite	Riebeckite
Tremolite asbestos	Tremolite
Actinolite asbestos	Actinolite

The term "asbestiform" refers to a habit of growth—how the mineral formed in nature—not merely a particle's size and shape. Every federal statute or regulation that defines asbestos does so in this way, *i.e.*, as the asbestiform version of the mineral.[6] Put another way, if a mineral particle has not formed in nature as asbestos, nothing that happens to that mineral that may affect the particle's size and shape (such as crushing it, milling it, or grinding it) can ever result in the particle transforming into asbestos.

To properly identify and classify minerals as asbestos, testing methodologies must be able to identify the type of mineral and whether it exists in an asbestiform state. Those testing methodologies exist. That is, "asbestiform and nonasbestiform amphiboles can be efficiently differentiated" with the appropriate testing.[7]

J&J's Proposed Talc Testing Protocol

J&J has maintained that analysts testing talc for the presence of asbestos should avail themselves of all the tools available. That is why J&J has consistently believed that any proposed rule on talc testing should require using three analytical techniques:

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[6] *See* 15 U.S.C. § 2642(3) (Toxic Substances Control Act); 40 C.F.R. § 763.163 (EPA); 40 C.F.R. § 61.141 (EPA); 29 C.F.R. § 1910.1001(b) (OSHA); 30 C.F.R. § 56.5001(b) (MSHA); 73 Fed. Reg. 11284, 11292 (2008) (MSHA); 39 Fed. Reg. 24317, 24317-18 (1974) (Bureau of Mines).

[7] *See, e.g.*, USP <901> and <1901>.

- X-Ray Diffraction (XRD);
- Polarized Light Microscopy (PLM); and
- Transmission Electron Microscopy (TEM).

An additional tool—Scanning Electron Microscopy (SEM)—may also be helpful in certain circumstances to provide additional information.

In March 2024, J&J met with FDA and provided a proposed testing protocol to effectuate these concepts, which was made and remains publicly available.[8] Now that USP has finished revising its talc monograph to include newer talc testing protocols, J&J has updated its own proposed protocol, incorporating those USP methods and fleshing out more detail. *See* Ex. A, J&J Updated Talc Testing Protocol.

At a high level, J&J' proposes the following testing protocol:

1. "Asbestos" means amosite, chrysotile, crocidolite, asbestiform tremolite, actinolite, anthophyllite, winchite, and richterite in the asbestiform growth habit.[9]

2. "Asbestiform" means a unique growth habit, in which the fibers possess high tensile strength and flexibility. A particle is not "asbestiform" simply based on its size and shape (such as a length greater or equal to .5 micrometers and/or an aspect ratio of greater or equal than 3:1).

3. Talc samples should be analyzed by XRD, PLM, and TEM for asbestos as defined above (i.e. the asbestiform versions of the relevant minerals).

4. If the analyst identifies anthophyllite by TEM, the analyst shall use dual zone axis diffraction to confirm the particle is anthophyllite and not talc.[10]

5. The analyst should tabulate and report all chrysotile and amphibole particles of the above types with a length of 0.5 microns or greater and an aspect ratio of 3:1 or

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[8] https://www.reginfo.gov/public/do/viewEO12866Meeting?viewRule=true&rin=0910-AI82&meetingId=278623&acronym=0910-HHS/FDA (J&J Proposal Talc Test For Asbestos) (Exhibit B).

[9] An amphibole particle is not "asbestos" simply because it is in the size and shape of a "fiber" (such as a length greater or equal to .5 micrometers and/or an aspect ratio of greater or equal than 3:1).

[10] The crystal structure of anthophyllite can appear similar to talc's under certain circumstances using the SAED component of TEM. A dual-zone axis helps ensure that talc is not misclassified as anthophyllite.

greater.

6. Chrysotile particles (which is by definition "asbestiform") meeting the criteria above should be reported as asbestos.

7. Amphibole particles meeting the criteria above should only be reported as "asbestos" if the analyst is able to confirm that the amphibole is asbestiform. The particles should be reported as "Non-Asbestos EMP" if testing confirms that it is non-asbestiform.[11] And if there is ambiguity regarding whether the amphibole is asbestiform, the analyst should conduct further PLM, TEM, or SEM analysis to try to confirm the growth habit.[12]

USP's Testing Protocols And CDER

As noted above, USP has issued its own XRD and PLM protocols regarding testing talc for the presence of asbestos: the USP <901> methodology and <1901> guidance. USP is currently in the process of finalizing its TEM talc testing protocol, which is not yet complete.

CDER has announced its support for and adoption of USP's testing methodologies. As recently as August 2026, at USP's Talc Stakeholder Forum, a CDER representative addressed the group as the Regulatory Keynote Speaker and reiterated that CDER requires talc in pharmaceutical products to be tested under the two available USP protocols.[13]

J&J completely endorses FDA's adoption of USP's XRD and PLM testing methods to test for asbestos in talc.

J&J also believes FDA is best served by adopting a uniform and harmonized approach to testing for asbestos in talc, whether in pharmaceuticals or cosmetics. Critically, the talc used in pharmaceuticals can be the *same talc* used in cosmetics products—from the same sources and suppliers. Testing of talc when destined for cosmetics products

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[11] "EMP" stands for Elongated Mineral Particle.

[12] A sample should be considered "positive" if asbestos is reported that surpasses the limits of detection set by statistically valid principles for the particular analytical technique used where asbestos was identified. *See, e.g.* ASTM D6620.

[13] Also in June 2026, CDER sent out a series of Warning Letters and Untitled Letters to pharmaceutical manufacturers reciting the companies' failure to comply or document their compliance with USP in testing for asbestos in talc. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters (Warning Letters issued June 2, 2026).

should follow the same testing regime that is used when the very same talc is destined for a medication. Otherwise, a single lot of talc could be subject to different testing protocols, which not only require duplicative investments in testing procedures and compliance, but would risk confusion and inconsistency across FDA regulated industries.

Johnson & Johnson's Recommendation

As things currently stand, CDER has adopted USP's XRD and PLM talc testing protocols, and USP is in the process of finalizing its TEM protocols. While J&J believes its proposed protocol—which utilizes all available technology, is consistent with the USP methodology established to date, and provides a methodology for deployment of TEM microscopy—provides a responsible and scientifically sound path forward, J&J also is mindful of FDA's mandate to harmonize its regulations. Under these circumstances, J&J recommends that the best approach for any rule on testing talc in cosmetics is to match CDER's approach to drug related talc testing.

In other words, FDA should adopt the USP <901> methodology and <1901> guidance for testing talc for cosmetics using XRD and PLM. Once USP finishes its work on its TEM protocols, FDA should then evaluate those protocols for adoption and inclusion in a single, cohesive and harmonized talc testing rule. Again, Johnson & Johnson fully believes that talc should be tested using XRD, PLM, *and* TEM. But pending the completion of USP's TEM testing protocols, FDA should ensure the talc testing for cosmetics matches the talc testing for pharmaceuticals.

In short, while USP is working on its TEM testing protocols, Johnson & Johnson requests that for any proposed rule on testing talc for cosmetics:

1. FDA adopt the USP <901> methodology and <1901> guidance for testing using XRD and PLM; and

2. FDA evaluate USP's TEM testing protocols for adoption when they are complete.

cc: Michael Davis, MD, PhD
Karim Mikhail, BPharm
Michelle E. Tarver, MD, PhD

Exhibit A

Johnson & Johnson Updated Talc Testing Protocol

I. Executive Summary

This protocol describes a method for testing talc that is used in cosmetics or intended to be used in cosmetics for the presence of asbestos. Under this protocol, talc must be tested using three microscopic techniques: X-Ray Diffraction (XRD); Polarized Light Microscopy (PLM); and Transmission Electron Microscopy (TEM). This ensures analysts have a full array of information at their disposal to determine whether or not a particle is asbestos.

US Pharmacopeia (USP) has published methodologies and guidance for testing talc with XRD and PLM. Therefore, the XRD and PLM components of testing must be conducted according to those protocols. Because USP is currently in the process of evaluating its TEM methodologies, the TEM component must be conducted according to the International Organization for Standardization methodology ISO 22262-2.

Asbestos is defined by all federal regulations and statutes to mean the asbestiform variety of certain minerals.[1] "Asbestiform" means a unique growth habit, in which the fibers possess high tensile strength and flexibility—not merely the particle's size and shape.

Therefore, analysts under this protocol report particles as "asbestos" if they can confirm they are asbestiform and "non-asbestos EMP" if the particles are not asbestiform. If there is ambiguity, an analyst may perform additional testing, including by Scanning Electron Microscopy (SEM). If ambiguity still remains regarding an amphibole particle, analysts report the particle as "Amphibole EMP (Habit of Growth Inconclusive)".

II. Definitions

A. **Asbestos**: "Asbestos" means amosite, chrysotile, crocidolite, asbestiform tremolite, actinolite, anthophyllite, winchite, and richterite in the asbestiform growth habit. An amphibole particle is not "asbestos" simply because it is in the size and shape of a "fiber" (such as a length greater or equal to .5 micrometers and/or an aspect ratio of greater or equal than 3:1).

B. **Asbestiform**: "Asbestiform" means a unique growth habit, in which the fibers possess high tensile strength and flexibility. A particle is not "asbestiform" simply based on its size and shape (such as a length greater or equal to .5 micrometers and/or an aspect ratio of greater or equal than 3:1).

C. **Elongated Mineral Particle (EMP)**: "Elongated Mineral Particle" or "EMP" means a mineral particle having a length $\geq$ 0.5 micrometer (μm) and an aspect ratio >3:1. If an amphibole particle meets the definition of an Elongated Mineral

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[1] 15 U.S.C. § 2642(3) (Toxic Substances Control Act); 40 C.F.R. § 763.163 (EPA); 40 C.F.R. § 61.141 (EPA); 29 C.F.R. § 1910.1001(b) (OSHA); 30 C.F.R. § 56.5001(b) (MSHA); 73 Fed. Reg. 11284, 11292 (2008) (MSHA); 39 Fed. Reg. 24317, 24317-18 (1974) (Bureau of Mines).

Particle, that does not necessarily mean the particle is asbestos.

D. **Habit**: Characteristic crystal growth form of a mineral as it is found in nature.

III. Mandatory Analyses For Every Talc Sample

All three of the following analyses shall be conducted for any talc sample:

A. X-Ray Diffraction (XRD) according to the USP <901> methodology and <1901> guidance.

B. Polarized Light Microscopy (PLM) according to the USP <901> methodology and <1901> guidance.

C. Transmission Electron Microscopy (TEM) according to the ISO 22262-2 methodology.

IV. Supplemental Analyses For Ambiguous Results

Two additional analytical steps may be taken by the analyst if amphibole particles have been identified but ambiguity as to habit of growth remains following the three mandatory analyses:

A. Additional PLM and/or TEM analyses to obtain further information that assists in resolving ambiguity as to the habit of growth of amphibole identified; and/or

B. Scanning Electron Microscopy (SEM) review of ambiguous amphibole particles.

V. Reporting Requirements

A. Analysts shall report and document all chrysotile and amphibole particles having a length $\geq$0.5 micrometer (μm) and an aspect ratio $\geq$3:1 in talc-containing cosmetic products and talc intended for use in cosmetics as detailed below. Particles that do not meet this criteria shall not be reported.

B. Analysts shall report as "**Asbestos**":

1. All chrysotile particles having a length $\geq$0.5 micrometer (μm) and an aspect ratio $\geq$3:1; and

2. All amphibole particles (i) having a length >0.5 micrometer (μm) and an aspect ratio >3:1, and (ii) confirmed by the analyst to be asbestiform.

Particles not meeting all the above criteria shall not be reported as asbestos.

C. Analysts shall report as "**Non-Asbestos EMP**":

All particles having a length $\geq$0.5 μm and an aspect ratio $\geq$3:1 that are not asbestiform. The analyst shall report the specific mineral species where possible

based on the available data. (A finding of Non-Asbestos EMP is not an asbestos finding.)

D. Analysts shall report as "**Amphibole EMP (Habit of Growth Inconclusive)**":

All amphibole particles having a length ≥0.5 micrometer (μm) and an aspect ratio ≥3:1 where—after reviewing all of the chemical composition and morphology information from all analytical techniques used by the analyst—ambiguity remains as to whether the amphibole is asbestiform. (A finding of Amphibole EMP (Habit of Growth Inconclusive) is not an asbestos finding.)

Exhibit B

J&J PROPOSAL: TALC TEST FOR ASBESTOS

MANDATORY FOR EVERY TALC SAMPLE

- Analysis by X-Ray Diffraction (XRD)
- Analysis by Polarized Light Microscopy (PLM)
- Analysis by Transmission Electron Microscopy (TEM)

ADDITIONAL ANALYSIS

If, after the three mandatory test methods, amphibole particles have been identified where there is ambiguity as to habit of growth, two additional analytical steps may be taken by the analyst:

- Further PLM and/or TEM analysis to gather additional information that may remove any ambiguity as to the habit of growth of the amphibole particles at issue; and
- Scanning Electron Microscopy (SEM) analysis on ambiguous particles identified during TEM analysis.

REPORTING REQUIREMENTS

- Tabulate and report all amphibole and chrysotile particles having a length $\geq$ 0.5 micrometer (µm) (500 nanometer (nm)) and a ratio of length to width, i.e., aspect ratio (AR), $\geq$ 3:1 in talc-containing cosmetic products and talc intended for use in cosmetics,
- Only report as "Asbestos": chrysotile particles that meet the counting criteria, and amphibole particles (1) that meet the above counting criteria, and (2) where the analyst is able to confirm that the amphibole is "asbestiform" (as defined by the 2022 IWGACP White Paper).
- If—after reviewing all of the chemical composition and morphology information from all analytical techniques used by the analyst—ambiguity remains as to certain amphibole particles, then the amphibole will be reported as "Amphibole (Habit of Growth Inconclusive)."
- Tabulate and report all non-asbestiform particles having a length $\geq$ 0.5 micrometer (µm) (500 nanometer (nm)) and a ratio of length to width, i.e., aspect ratio (AR), $\geq$ 3:1 identified in talc-containing cosmetic products and talc intended for use in cosmetics as "Non-Asbestos EMPs," including reporting the specific mineral species where possible based on the available data.