



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0025]

Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing a public meeting entitled "Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc." The purpose of the public meeting is to discuss and obtain scientific information on topics related to testing methodologies, terminology, and criteria that can be applied to characterize and measure asbestos and other potentially harmful elongate mineral particles (EMPs) that may be present as contaminants in talc and cosmetic products manufactured using talc as an ingredient.

DATES: The public meeting will be held on February 4, 2020, from 8:30 a.m. to 5 p.m. Eastern Time, or until after the last public commenter has spoken, whichever occurs first. Submit requests to make oral presentations and comments at the public meeting by January 17, 2020. Electronic or written comments on this meeting will be accepted until March 4, 2020. See the SUPPLEMENTARY INFORMATION section of this document for information about early registration, requesting special accommodations due to disability, and other information regarding meeting participation.

ADDRESSES: The public meeting will be held at the Food and Drug Administration, White Oak Campus, 10903 New Hampshire Ave, Building 31 Conference Center, The Great Room

(Rm 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed.

For parking and security information, please refer to

<https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2020-N-0025. The docket will close on March 4, 2020. Submit either electronic or written comments on or before March 4, 2020. The electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 4, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date. Please note that late, untimely filed comments will not be considered.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact

information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed below (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-N-0025 for "Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will

include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Denise Hodge, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr. (HFS-125), College Park, MD 20740, 301-796-7739, email: TalcMeeting@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Talc is used in a wide variety of consumer products, including cosmetics. Talc is mined as a naturally occurring hydrous magnesium silicate and may be contaminated with asbestos fibers due to the proximity of asbestos to talc deposits. Asbestos is a known human carcinogen, and its health risks are well documented. Inhalation of asbestos is a safety concern because it can cause the formation of scar-like tissue in the lung, resulting in asbestosis, or it may lead to the development of lung cancers and malignant mesothelioma.

In 1976, the cosmetics industry implemented voluntary asbestos testing of talc raw materials using the Cosmetic, Toiletry, and Fragrance Association (CTFA) J4-1 (Ref. 1) method in response to test results indicating asbestos to be present. Talc suppliers to the pharmaceutical industry use a similar method to certify that talc meets the United States Pharmacopeia's (USP's) requirement for "Absence of Asbestos" (Ref. 2). To date, both methods, which rely on the use of x ray diffraction (XRD) or infrared (IR) spectroscopy followed by polarized light microscopy (PLM) only if XRD or IR is positive for amphibole or serpentine minerals in talc, remain standard test methods despite long-recognized shortcomings in specificity and sensitivity compared with electron microscopy-based methods. In 2010, FDA asked the USP to consider revising the current tests for asbestos in talc to ensure adequate specificity, and, in 2014, the Talc USP expert panel recommended an update of the Talc USP monograph to require an electron microscopy method for the measurement of asbestos in talc (Refs. 3 and 4). Recent testing of cosmetics by private laboratories¹ using transmission electron microscopy (TEM) has revealed

¹See AMA testing results at FDA's Investigation of Reports of Asbestos Contamination in Cosmetics 2017-2019 tab at <https://www.fda.gov/cosmetics/cosmetic-ingredients/talc>.

the presence of asbestos fibers in samples that had negative findings for the same products using polarized light microscopy, thus highlighting the shortcomings of optical microscopy methods.

FDA monitors for asbestos in talc-containing cosmetic products, including directing its sampling of products toward confirming reports from various laboratories that have reported asbestos using electron microscopy. For example, in 2010, shortly after reports of asbestos contaminated talc-containing products in Asia, FDA surveyed 34 cosmetic products,² including body powders, face powders, foundation, eye shadow, blush, and samples from four major talc suppliers and found no asbestos contamination using the most sensitive techniques available. FDA's survey was limited in scope but served to provide data from testing using TEM, currently regarded by many experts as the most reliable technique for detecting asbestos fibers (see Ref. 4). In July 2017, FDA began investigating reports of asbestos contamination of cosmetic products that contained talc, presumably originating from talc that was used as an ingredient in the cosmetic products. In 2019, FDA surveyed 50 talc-containing cosmetic products. In March, June, August, and October 2019, FDA confirmed the presence of chrysotile and/or tremolite asbestos in several cosmetic products, which were voluntarily recalled by the companies. The use of TEM was critical in detecting asbestos in these cosmetic products.

Even when using the most sensitive electron microscopy methods, laboratories testing the same product may reach different conclusions about the presence of asbestos. These differences may be attributed to a lack of a uniform standard for testing which provides unambiguous guidelines for identifying and counting asbestos fibers. Thus, at FDA's request, on November 28, 2018, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) convened an "Asbestos in Talc" symposium to provide a forum for experts in asbestos mineral analysis,

²<https://www.fda.gov/cosmetics/cosmetic-ingredients/talc>.

academicians, and government officials to share knowledge and experience.³ The discussions focused on the toolbox of available testing methods for analysis of asbestos in talc and talc-containing cosmetic products, criteria used for asbestos fiber identification and counting in current published methods, and how analytical microscopy data might be interpreted in making decisions about the suitability of cosmetic products found to contain asbestos and other potentially harmful mineral particles.

During the fall of 2018, FDA formed an interagency working group on asbestos in consumer products (IWGACP). The IWGACP consists of 38 subject matter experts from the following U.S. federal agencies: FDA, National Institute for Occupational Safety and Health (NIOSH), National Institutes of Health/National Institute of Environmental Health Sciences, Occupational Safety and Health Administration, Environmental Protection Agency, Consumer Product Safety Commission, National Institute of Standards and Technology, and Department of Interior's U.S. Geological Survey. The IWGACP was asked to support the development of standardized testing methods for asbestos and other mineral particles of concern that could potentially affect consumer product safety. The IWGACP was tasked to address terminology and definitions of asbestos and other EMPs of health concern in talc and talc-containing consumer products, recommend methodological improvements for measuring asbestos in talc and talc-containing consumer products, and recommend laboratory reporting standards for testing talc and talc-containing consumer products. The IWGACP is also addressing issues regarding asbestos contamination in talc-containing cosmetic products, the presumptive source of asbestos, as well as scientific and technical information shared at the JIFSAN Symposium and how that information could be used by different government agencies. The IWGACP is

³<https://jifsan.umd.edu/events/2018-asbestos-in-talc-symposium>

comprised of three subgroups formed to address the following topics: (1) terminology and definitions of asbestos and other EMPs of health concern in talc; (2) development of a robust analytical protocol for detecting asbestos and other EMPs of health concern in talc and consumer products containing talc; and (3) data reporting and analysis.

II. Purpose of the Public Meeting

FDA is interested in obtaining information to further the development of standardized testing methods to improve sensitivity, consistency, and inter-laboratory concurrence of asbestos testing of talc used in cosmetic products and of talc-containing cosmetic products. Toward this end, at the public meeting, IWGACP members will present preliminary recommendations (summarized in section IV.C) on testing methods, including criteria to be used for asbestos fiber identification and counting. We will also seek additional information on these topics at the meeting. We do not intend for this meeting to produce any decisions or new positions on specific regulatory questions. However, we expect this meeting to be an important step in our continued efforts to gather information, including data to improve the consistency in terminology, analytical protocols, and data reporting for asbestos and other potentially harmful mineral particles that may be present as contaminants in talc and cosmetic products containing talc and provide information that can be used for future discussions on health effects.

III. Participating in the Public Meeting

Registration: To register to attend the public meeting on "Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc," either in person or by webcast, please register at <https://www.fda.gov/cosmetics/cosmetics-news-events/meetings-conferences-workshops-cosmetics> by January 28, 2020, at 11:59 p.m. Eastern Time. Please provide complete contact information for each attendee, including name, title, affiliation, and email and whether you want

to attend in person or by webcast. The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and based on space and availability. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted for in-person attendance. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 7:30 a.m. We will inform registrants if registration closes before the day of the public meeting. Persons attending this meeting are advised that FDA is not responsible for providing access to electrical outlets. FDA will make every effort to accommodate persons with physical disabilities or special needs. If you need special accommodations due to a disability, please contact Denise Hodge (see FOR FURTHER INFORMATION CONTACT) no later than January 17, 2020.

Requests for Oral Presentations: During online registration you may indicate if you wish to make a formal presentation (with up to five slides) or present oral comments during the public comment session (with no slides), and you may indicate which topic(s) you would like to address. Oral presentations can only be made in person at the meeting. FDA will do its best to accommodate requests to make public presentations. We seek a broad representation of ideas and issues presented at the meeting. We urge individuals and organizations with common interests to consolidate or coordinate their presentations and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each presentation is to begin and will select and notify participants by January 21, 2020. All requests to make oral presentations must be received by January 17, 2020, 11:59 p.m. Eastern time. Typically, presentations are between 3 and 5 minutes. If selected for a formal oral presentation (with slides), each presenter must submit an

electronic copy of their presentation (PowerPoint or PDF) to TalcMeeting@fda.hhs.gov on or before January 28, 2020. Those who are not giving electronic presentations are encouraged to submit a single slide (PowerPoint or PDF) with their name, affiliation, and topic. No commercial or promotional material will be permitted to be presented or distributed at the public meeting. Persons notified that they will be presenters are encouraged to arrive early and check in at the onsite registration table to confirm their designated presentation times. Actual presentation times may vary based on how the meeting progresses in real time. An agenda for the public meeting and any other background materials will be made available at least 5 days before the meeting at <https://www.fda.gov/cosmetics/cosmetics-news-events/meetings-conferences-workshops-cosmetics>. Those without internet or email access can register and/or request to participate by contacting Denise Hodge (see FOR FURTHER INFORMATION CONTACT) no later than January 17, 2020.

Transcripts: A transcript of the public meeting will be made available as soon as feasible. It will be accessible at www.regulations.gov and <https://www.fda.gov/cosmetics/cosmetics-news-events/meetings-conferences-workshops-cosmetics>. It may be viewed at the Dockets Management Staff (see ADDRESSES). A transcript will also be made available in either hardcopy or on CD-ROM, in response to a Freedom of Information Act request. A Freedom of Information Act request may be submitted by visiting <https://www.accessdata.fda.gov/scripts/foi/foirequest/requestform.cfm> or by submitting an email request to FDAFOIA@fda.hhs.gov.

IV. Issues for Consideration and Request for Information

We encourage public comments and presentations at the public meeting. In submitting information to the docket, please provide available references for the information.

A. Testing Methodologies and Criteria

As previously discussed, laboratories may reach different conclusions as to whether asbestos and other potentially harmful EMPs are present when testing consumer products. We are seeking scientific information on the following topics related to testing methodologies and criteria that can be applied to characterize and measure asbestos and other potentially harmful EMPs present as contaminants in talc and cosmetic products manufactured using talc as an ingredient. We invite comments on the following:

1. The sensitivity of PLM as a test method, including whether the test method can lead to a false negative result for asbestos particles.
2. The sensitivity of TEM as a test method, including the ability of the test method to identify asbestos particles in comparison to PLM.
3. Criteria for identification of the specified asbestos minerals, noting that different minerals with the same chemical composition can exist in samples.

B. Research Needs to Promote the Reliability of Analytical Methods

The IWGACP identified the following as areas for directing efforts to promote reliability of the analytical methods for asbestos and other EMPs of health concern in talc and talc-containing consumer products. We invite such information to be presented during the public comment section of the meeting:

1. Validation of analytical methods (XRD, PLM, TEM) specific to talc and cosmetic products containing talc that minimize false positive and false negative results.
2. Research and validation of methods of sampling that maximize sample representativeness and minimize error and false positives and false negatives.

3. Research on methods for sample preparation, in particular treatment (e.g., "concentration methods") that improves sensitivity while leaving covered minerals unchanged with respect to identity and dimensions.
4. Development of talc-specific reference standards with known concentrations of specific EMPs that can be used to assess laboratory and analyst proficiency, increase inter-laboratory concurrence in method validation, minimize reporting errors, and potentially provide for improved reliability of quantitative analysis.

C. IWGACP's Preliminary Recommendations

We invite comments related to the following preliminary recommendations from the IWGACP:

1. Adoption of the term EMP as *"any mineral particle with a minimum aspect ratio of 3:1"*, consistent with how this term is defined in NIOSH Bulletin 62 (Ref. 5).
2. Testing laboratories should report all EMPs having length ≥ 0.5 micrometers (500 nanometers (nm)).
3. Test methods should specify reportable EMPs identified as amphibole or chrysotile particles as covered minerals.
4. Test methods should include the counting and reporting of covered EMPs as a function of sample mass. In counting, guidelines such as ISO 10312, "Ambient air--Determination of asbestos fibres--Direct transfer transmission electronic microscopy method" (Ref. 6), classify primary and secondary structures. Individual fibers in secondary structures can be counted recording the dimensions of each fiber.
5. Use of TEM at nominally 20,000 \times magnification, in addition to PLM, to resolve the issues of sensitivity that cause reporting of false negatives for covered EMPs. Use of

TEM with energy dispersive x ray spectroscopy and selected area electron diffraction analyses may reliably detect and identify chrysotile and asbestiform and non-asbestiform amphibole minerals, including EMPs whose narrowest width is < 200 nm. Scanning electron microscopy might be useful as a complementary method, but has significant shortcomings for identification of chrysotile and visualization of the narrowest particles in the population that can only be overcome by using TEM.

6. "Mass percent", a unit that is frequently used to express content of asbestos in commercial bulk materials, is not appropriate for measurement of EMPs in talc and consumer products containing talc because mass percent does not correlate with the number of fibers, and one large fiber could dominate the mass percent value.

V. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. The Cosmetic, Toiletry and Fragrance Association, Inc. (CTFA) 1990. Method, J 4-1, "Asbestiform Amphibole Minerals in Cosmetic Talc" in Compendium of Cosmetic Ingredient Composition: Specifications Personal Care Products Council, Washington DC (1976) (revised in 1990). See

<http://www.asbestosandtalca.com/EMP%20Detection%20Limits%20ASTM/PCPC000960.pdf>.

2. USP, Revision Bulletin, "Talc," dated August 1, 2011, at page 2. See <https://www.usp.org/sites/default/files/usp/document/harmonization/excipients/m80360talca.pdf>.

*3. Woodcock, J. (2010). Letter to Roger L. Williams, CEO of USP (October 12, 2010). See <https://www.usp.org/sites/default/files/usp/document/get-involved/monograph-modernization/2010-10-12-letter-from-dr-janet-woodcock.pdf>.

4. Block L. H., D. Beckers, J. Ferret, G. P. Meeker, et al. (2014). "Stimuli to the Revision Process, Modernization of Asbestos Testing in USP Talc," USP-PF 40(4).

*5. NIOSH 2011. "Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research," *Current Intelligence Bulletin 62*. Department of Health and Human Services. Centers for Disease Control and Prevention. National Institute for Occupational Safety and Health. Publication No. 2011-159 (March 2011). <https://www.cdc.gov/niosh/docs/2011-159/pdfs/2011-159.pdf>.

6. International Organization for Standardization, "ISO 10312:2019(en) Ambient air--Determination of asbestos fibres--Direct transfer transmission electron microscopy method." See <https://www.iso.org/obp/ui/#iso:std:iso:10312:ed-2:v1:en>.

Dated: January 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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