performance, with possible impact with terrain or obstacle.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2024–0137, dated July 11, 2024 (EASA AD 2024–0137).

(h) Exceptions to EASA AD 2024–0137

(1) Where EASA AD 2024–0137 refers to its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0137.

(3) Where paragraph (2) of EASA AD 2024–0137 specifies corrective actions if ''any discrepancy, as defined in the SB, is detected,'' for this AD, replace that text with ''any corrosion, crack, dent, nick, deformation, or measurement not within specified dimensions of the SB is detected.''

(4) Where paragraph (3) of EASA AD 2024–0137 specifies additional actions if ''any discrepancy is detected,'' for this AD, replace that text with ''any discrepancy, which includes corrosion, cracks, dents, nicks, and deformation, is detected.''

(5) Paragraph (4) of EASA AD 2024–0137 specifies to report inspection results to Deutsche Aircraft GmbH within a certain compliance time. For this AD, report inspection results at the applicable time specified in paragraph (h)(5)(i) or (ii) of this AD.

(i) If the inspection was done on or after the effective date of this AD: Submit the report within 30 days after the inspection.

(ii) If the inspection was done before the effective date of this AD: Submit the report within 30 days after the effective date of this AD.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to: *AMOC@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Deutsche Aircraft GmbH's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Additional Information

For more information about this AD, contact Joe Salameh, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 206–231–3536; email: *joe.salameh@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the material listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this material as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0137, dated July 12, 2024.

(ii) [Reserved]

(3) For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov*.

Issued on December 19, 2024.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2024–30763 Filed 12–26–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 730

[Docket No. FDA–2023–N–4225]

RIN 0910–AI82

Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to require testing of talc-containing cosmetic products using standardized testing methods for detecting and identifying asbestos that may be present as a contaminant in talc. We are also proposing corresponding adulteration provisions. Asbestos is a potential contaminant in talc, which is used in certain cosmetic products, and is a known human carcinogen. This proposed rule, if finalized, will help protect users of talc-containing cosmetic products from harmful exposure to asbestos given the potential for contamination of these products.

DATES: Either electronic or written comments on the proposed rule must be submitted by March 27, 2025. Submit written comments (including recommendations) on information collection issues under the Paperwork Reduction Act of 1995 by January 27, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 27, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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 (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–2023–N–4225 for ''Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products.'' 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, 240–402–7500.

• 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.'' The Agency will review this copy, including the claimed confidential information, in its 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, the plain language summary of the proposed rule of not more than 100 words as required by the ''Providing Accountability Through Transparency Act,'' 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, 240–402–7500.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (PRA) to the Office of Management and Budget (OMB) at *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently Under Review—Open for Public Comments'' or by using the search function. The title of this proposed collection is ''Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products.''

FOR FURTHER INFORMATION CONTACT:

With regard to the proposed rule: Jennifer Ross, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–4880 (this is not a toll-free number), *QuestionsAboutMoCRA@fda.hhs.gov.*

With regard to the information collection: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

We are issuing this proposed rule pursuant to the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), which requires the promulgation of proposed and final regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. This proposed rule, if finalized, will help protect users of talc-containing cosmetic products from harmful exposure to asbestos given the potential for asbestos contamination of these products.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule describes the test methods that, if finalized, manufacturers of talc-containing cosmetic products will be required to use to detect and identify asbestos in these products. The proposed rule would require manufacturers to test a representative sample of each batch or lot of a talc-containing cosmetic product for asbestos using both Polarized Light Microscopy (PLM) (with dispersion staining) and Transmission Electron Microscopy (TEM)/Energy Dispersive Spectroscopy (EDS)/Selected Area Electron Diffraction (SAED).

The proposed rule also contains provisions that would allow manufacturers flexibility to either test each batch or lot of the talc cosmetic ingredient, or rely on a certificate of analysis for each batch or lot from a qualified talc supplier prior to using the talc to manufacture a talc-containing cosmetic, provided that the analytical methods used to test the talc include both PLM and TEM/EDS/SAED. It is FDA's understanding based on discussions and meetings with industry representatives that it is common industry practice to test talc prior to adding it during the manufacture of cosmetic products so as to avoid manufacturing and distributing talc-containing cosmetic products that contain asbestos. We specifically invite comment on existing industry practices and the utility of this approach.

Additionally, the proposed rule contains provisions that would require manufacturers to keep records to demonstrate compliance with the rule.

Finally, the proposed rule contains enforcement provisions. Failure of a manufacturer to operate in compliance with both the testing and recordkeeping requirements would render the product adulterated under the Federal Food, Drug, and Cosmetic Act (FD&C Act.) Further, because there is no established safe level below which asbestos could not cause adverse health effects, FDA has determined that asbestos at any level in talc-containing cosmetic products may render these products injurious to users. As such, the proposed rule would codify in regulations 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 FD&C Act. Likewise, if asbestos is present in talc intended for use in a cosmetic, the talc is adulterated under the FD&C Act.

We seek comments on all aspects of this proposed rule.

C. Legal Authority

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 into law, which included MoCRA. Among other provisions, MoCRA mandated the establishment and requirement of standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. We are also issuing these regulations pursuant to section 601(c), section 601(a), and section 701(a) of the FD&C Act.

D. Costs and Benefits

This proposed rule, if finalized, would require testing of talc-containing cosmetic products using standardized testing method(s) for detecting and identifying asbestos that may be present as a contaminant in talc. Benefits include potential public health benefits to consumers from fewer asbestos exposures. To the extent the proposed rule would reduce exposures, the health benefits would include fewer illnesses, such as mesothelioma, lung cancer, larynx cancer, and ovarian cancer. We lack data to quantify these public health benefits, so we instead discuss qualitatively. Additionally, we quantify benefits to manufacturers of talc-containing cosmetics from fewer recalls. We quantify costs to talc suppliers and to cosmetics manufacturers to read and understand the rule and to test talc for asbestos. We estimate that the annualized monetized benefits over 10 years would range from $0.00 million to $1.39 million at a 7 percent discount rate, with a primary estimate of $0.06 million, and from $0.00 million to $1.39 million at a 3 percent discount rate, with a primary estimate of $0.06 million. The annualized costs would range from $1.29 million to $6.78 million at a 7 percent discount rate, with a primary estimate of $3.54 million, and from $1.30 million to $6.78 million at a 3 percent discount rate, with a primary estimate of $3.55 million.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/ acronym	What it means
APA	Administrative Procedure Act.
CTFA	Cosmetic, Toiletry, and Fragrance Association.
EDS	Energy Dispersive Spectroscopy.
EO	Executive Order.
EPA	Environmental Protection Agency.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
IEC	International Electrotechnical Commission.
IR	Infrared Spectroscopy.
ISO	International Organization for Standardization.
IWGACP	Interagency Working Group on Asbestos in Consumer Products.
MoCRA	Modernization of Cosmetics Regulation Act of 2022.
OIRA	Office of Information and Regulatory Affairs.
OMB	Office of Management and Budget.
PLM	Polarized Light Microscopy.
SAED	Selected Area Electron Diffraction.
SEM	Scanning Electron Microscope.
TEM	Transmission Electron Microscope.
USP	U.S. Pharmacopeia.
XRD	X-Ray Diffraction.

III. Background

A. Introduction

MoCRA, enacted on December 29, 2022, requires the promulgation of proposed and final regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products.

B. Need for the Regulation

Talc is used in various cosmetic products. Talc is mined as a naturally occurring hydrous magnesium silicate. Asbestos is found in the same rock types that host talc deposits (Refs. 1, 2) and so may be found in commercial talc mines and may be inseparable from talc in the mining process. As a result, talc used in cosmetic products sometimes contains asbestos fibers from serpentine or amphibole minerals present in proximity to talc deposits (Refs. 3, 4).

Asbestos is a known human carcinogen, and its health risks are well-documented (Refs. 5 to 10). There is general agreement among U.S. Federal Agencies (Refs. 8, 11), and the World Health Organization (Ref. 12), that there is no established safe threshold for adverse health effects from asbestos exposure. Because there is no established safe level below which asbestos could not cause adverse health effects, asbestos at any level in talc-containing cosmetic products may render these products injurious to users. For this reason, we conduct testing for asbestos in talc-containing cosmetic products and have issued safety alerts when such products have tested positive for asbestos (see: *https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-advises-consumers-stop-using-certain-cosmetic-products*). In addition, we are concerned about even low levels of asbestos in cosmetics, given that such products are applied to the body and used by many people on a regular, daily basis, throughout their lives. The risk of harmful effects from asbestos is higher with repeated and long-term exposure to the carcinogen (Ref. 8).

Inhalation is the primary pathway of exposure to asbestos in talc-containing cosmetic products, although ingestion and perineal exposures also occur. Exposure to asbestos by inhalation can cause sequelae ranging from inflammation to pleural disease and diseases such asbestosis, lung cancer, and mesothelioma. These effects rarely occur acutely, but they typically occur one or more decades later. Once inside the body through inhalation, ingestion, or perineal exposure, asbestos can migrate through tissues and organs to secondary sites of exposure where progressive cell damage can occur that may lead to diseases in other parts of the body that are remote from the sites of primary exposure, including cancers of the larynx, gastrointestinal tract, and ovaries (Refs. 9, 13, 14, 15, 16). Positive associations have been observed between exposure to asbestos and cancer of the pharynx, stomach, and colorectum (Ref. 9).

The presence of asbestos found as a result of independent testing of talc-containing cosmetics products indicates any asbestos that may be present in the talc ore is difficult to remove during processing to manufacture talc for use in cosmetics (Ref. 17). FDA monitors for asbestos in talc-containing cosmetic products, including sampling of products reported to contain asbestos by various laboratories using PLM and TEM/EDS/SAED microscopy methods. For example, in 2010, FDA's contract laboratory tested 34 talc-containing cosmetic powder products, including body powders, face powders, foundation, eye shadow, and blush, and samples of talc as an ingredient used in

cosmetics from suppliers and found no asbestos contamination using PLM and TEM/EDS/SAED (Ref. 18). In 2019, 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. In March, June, August, and October 2019, FDA confirmed the presence of asbestos in nine talc-containing cosmetic products, which were voluntarily recalled by the companies (Ref. 19).

In considering existing voluntary consensus standards or published methods for testing for asbestos in talc, we did not find any standardized testing method that laboratories can follow without modification to test for asbestos in talc-containing cosmetic products. Specifically, we found that the published standards and methods to test for asbestos in talc (*i.e.,* Talc USP monograph and CTFA method J4–1) have long-recognized shortcomings in specificity and sensitivity compared with electron microscopy-based methods (Refs. 17, 20, and 21). Furthermore, even when the most sensitive electron microscopy methods are used, laboratories testing the same product may reach different conclusions about the presence of asbestos. These differences may be attributed to a lack of a standardized testing method that provides unambiguous guidelines for detecting and identifying asbestos fibers and lack of homogeneity of asbestos found in samples. The absence of a standardized testing method for the determination of the presence of asbestos in talc and talc-containing cosmetic products has led many analytical laboratories to combine and/or adapt published test methods developed for the determination of the presence of asbestos in air or building materials (Refs. 20, 21). This could, at least in part, account for discrepancies in laboratory findings that have been reported.

This proposed rule, if finalized, would require testing of talc-containing cosmetic products, and would require such testing be performed for detecting and identifying asbestos that may be present as a contaminant in talc using both PLM and TEM/EDS/SAED microscopy methods. The proposed rule would also require referring to images in standards for identifying asbestos fibers to help ensure that the results are accurately and consistently interpreted. Using both of these test methods for detecting and identifying asbestos would substantially improve a manufacturer's ability to detect the presence of asbestos in talc-containing cosmetic products as compared to testing using only one of the methods alone, or not testing at all. Such testing would in turn improve a manufacturer's ability to take action to prevent the distribution of such products if asbestos is detected.

C. History of Rulemaking

In developing this proposed rule, FDA carefully considered the scientific evidence and complex policy issues related to detecting and identifying asbestos in talc and talc-containing cosmetic products. FDA's activities have included forming an Interagency Working Group on Asbestos in Consumer Products (IWGACP) in the fall of 2018 and holding a public meeting entitled ''Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc'' in February 2020 where preliminary scientific opinions of the IWGACP were presented. Subsequently, FDA released the IWGACP's final scientific opinions in a White Paper (Ref. 22) and related Technical Appendices in January 2022 (Ref. 13), both of which were peer-reviewed (Ref. 23). The IWGACP concluded that X-ray diffraction (XRD) or infrared (IR) spectroscopy followed by PLM if XRD or IR is positive for amphibole or serpentine minerals are not specific or sensitive enough to detect the presence of asbestos (Ref. 22). This proposed rule is based in part on FDA's consideration of those scientific opinions and is also informed by presentations/comments at a Public Meeting on Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc (Ref. 24) and comments to the docket from that public meeting. Additionally, FDA relied on other studies reported in the scientific literature as noted in the reference section (including for example Refs. 25 to 30), as well as on FDA's scientific and regulatory experience in overseeing the safety of cosmetic products containing talc. Further, FDA is promulgating this proposed rule pursuant to section 3505 of MoCRA, which requires FDA to promulgate proposed regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products.

D. Incorporation by Reference

We propose to incorporate by reference the following annexes from consensus standards, with the approval of the Director of the Federal Register in accordance with the Administrative Procedure Act (APA), 5 U.S.C. 552(a), and 1 CFR part 51:

- Annex D in ISO 22262–1:2012(E), ''Air quality—Bulk materials—Part 1: Sampling and qualitative determination of asbestos in commercial bulk materials,'' First edition, July 1, 2012 (Ref. 31).
- Annex C in ISO 10312:2019(E), ''Ambient air—Determination of asbestos fibres—Direct-transfer transmission electron microscopy method,'' Second edition, October 10, 2019 (Ref. 32). Specifically, we would require the use of Figure C.1 in ISO 10312:2019(E), Annex C.

The International Organization for Standardization (ISO) is an independent, nongovernmental international organization with a membership of national standards bodies. For an overview of ISO 22262–1:2012(E) and ISO 10312:2019(E), see section V.C of this document.

The annexes of the consensus standards proposed to be incorporated by reference are available to the public in two different ways. Interested parties may: (1) examine these readily available standards at Dockets Management Staff, administered by the Federal Dockets Management System (FDMS), at (see **ADDRESSES**), (2) purchase copies of these standards from International Organization for Standardization, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; phone: +41–22–749–01–11; email: *customerservice@iso.org;* website: *https://www.iso.org/store.html.*

FDA is proposing to incorporate by reference the specified annexes in ISO 22262–1:2012(E) and ISO 10312:2019(E). Any future revisions to these standards affecting the specified annexes would need to be evaluated to determine the impact of the changes and whether this proposed rule, if finalized, should be amended. If deemed necessary and appropriate, FDA will update the final regulation in accordance with the APA (5 U.S.C. 553) and obtain approval of any changes to the incorporation by reference in accordance with 1 CFR part 51.

IV. Legal Authority

We are issuing this proposed rule pursuant to section 3505 of MoCRA, under section 601 of the FD&C Act (21 U.S.C. 361), and under section 701 of the FD&C Act (21 U.S.C. 371). Section 3505 of MoCRA requires the promulgation of proposed and final regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. These proposed regulations would require testing of talc-containing cosmetic products using PLM and TEM/

EDS/SAED testing methods for detecting and identifying asbestos that may be present as a contaminant in talc.

Section 201 (i) of the FD&C Act defines cosmetics as ''articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering the appearance.'' This definition includes skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, deodorants, and components of cosmetic products, but excludes soap.

Under section 601(c) of the FD&C Act, a cosmetic is adulterated if ''it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.'' Asbestos is a known human carcinogen, and its health risks are well-documented (Refs. 5 to 10). Because there is no established safe level below which asbestos could not cause adverse health effects (Refs. 8, 11, 12), asbestos at any level in talc-containing cosmetic products may render these products injurious to users. In addition, we are concerned about even low levels of asbestos in cosmetics, given that such products are applied directly to the body and used by many people on a regular, daily basis, throughout their lives. The risk of harmful effects from asbestos is higher with repeated and long-term exposure to the carcinogen (Ref. 8). Exposure to asbestos can cause a range of adverse health effects that may injure users, including causing sequelae ranging from inflammation to pleural diseases and diseases such asbestosis, lung cancer, and mesothelioma. Once inside the body through inhalation, ingestion, or perineal exposure, asbestos can migrate through tissues and organs to secondary sites of exposure where progressive cell damage can occur that may lead to diseases in other parts of the body that are remote from the sites of primary exposure, including cancers of the larynx, gastrointestinal tract, and ovaries (Refs. 9, 13, 14, 15, 16). Positive associations have been observed between exposure to asbestos and cancer of the pharynx, stomach, and colorectum (Ref. 9).

There is no established safe exposure threshold for asbestos (Refs. 8, 11, 12). Asbestos is found in the same rock types that host talc deposits from which the talc in talc-containing cosmetic products is mined (Refs. 1, 2). As a result of the mining process, talc used in cosmetic products may contain asbestos fibers from serpentine or amphibole minerals present in proximity to talc deposits (Refs. 3, 4). Indeed, FDA has confirmed the presence of asbestos in some talc-containing cosmetic products. Specifically, in 2019, FDA surveyed 52 talc-containing cosmetic products and confirmed the presence of asbestos in nine of these products (Ref. 19). FDA considers the proposed testing techniques to be suitable methods for detecting and identifying asbestos in talc or cosmetic products that contain talc. FDA is not aware of any other equally suitable methods. Therefore, we are proposing this rule to codify in our regulations that a talc-containing cosmetic product is adulterated under section 601(c) of the FD&C Act if the product has been prepared, packed, or held under conditions that could allow the product to contain asbestos, including by not testing and maintaining records of such testing for asbestos, a substance that is injurious to the health of consumers and known to be naturally occurring in talc.

Under section 601(a) of the FD&C Act, a cosmetic is adulterated if ''it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary or usual . . .''. Individuals can be exposed to asbestos during use of cosmetics that contain talc, should the talc used to manufacture the product contain asbestos. As such, asbestos may cause injury to users under the expressly indicated, customary, or usual conditions of use of a cosmetic product. Therefore, FDA currently considers that a cosmetic product that is manufactured using talc that contains asbestos contains a poisonous or deleterious substance that may be injurious to users under expressly indicated, customary, or usual use conditions. To make this conclusion explicit in our regulations, we are proposing to codify in our regulations that if asbestos is present in a talc-containing cosmetic product, or in talc used in a cosmetic product, that cosmetic product is adulterated under section 601(a) of the FD&C Act. Likewise, as section 201(i)(2) of the FD&C Act (21 U.S.C. 321(i)(2)) states that ''cosmetic'' includes ''articles intended for use as a component'' of a cosmetic, we are also proposing to codify in our regulations that if asbestos is present in talc intended for use in a cosmetic, that talc, as an article intended for use as a component ingredient of a cosmetic, is an adulterated cosmetic under 601(a) of the FD&C Act.

Under section 701(a) of the FD&C Act, we may promulgate regulations for the efficient enforcement of the FD&C Act. A regulation that requires testing methods to detect and identify asbestos in talc-containing cosmetics and that clearly establishes FDA's conclusion that a cosmetic containing asbestos is adulterated would help prevent talc-containing cosmetics from containing asbestos, a substance that may injure users. This would allow for the efficient enforcement of the FD&C Act.

Further, we are proposing to use our authority under 701(a) of the FD&C Act to promulgate requirements to keep asbestos testing records for at least 3 years after the date the record was created. We are proposing under 701(a) of the FD&C Act to require that records be made available within 1 business day for inspection and copying upon request, either at the place of business of the manufacturer during inspection or remotely through electronic delivery. We chose 1 business day to be largely consistent with other FDA regulations that require production within 1 business day. As an example, 21 CFR 1.1455(c) regarding food traceability records requires records production within 24 hours. We seek comment on this proposed timeframe.

The proposed recordkeeping requirements are necessary for both FDA and manufacturers to ensure that manufacturers are complying with the testing requirements of the proposed rule. Therefore, these proposed recordkeeping requirements are necessary for the efficient enforcement of the FD&C Act because they will aid both manufacturers and FDA in ensuring that a talc-containing cosmetic is not adulterated.

In addition, because the underlying testing requirements are necessary to minimize the likelihood of adulteration of a talc-containing cosmetic product, access to records that demonstrate that a manufacturer has followed those requirements is essential to the efficient enforcement of the FD&C Act as it allows us to confirm compliance. Likewise, the ability to copy these records is essential to the efficient enforcement of the FD&C Act as this allows FDA to confirm compliance. This may be necessary, for example, if our investigator needs assistance in reviewing a certain record from relevant experts in headquarters. Otherwise, we would have to rely solely on our investigator's notes and reports when drawing conclusions. In addition, copying records will facilitate followup regulatory actions. Therefore, at this

time, we have concluded that the ability to access and copy records is necessary to efficiently enforce the rule and thereby help prevent the introduction into interstate commerce of adulterated talc-containing cosmetics. We also conclude at this time that requiring delivery within 1 business day through electronic means rather than solely during in-person inspections will enable us to efficiently and effectively monitor compliance with the testing requirements to help prevent adulteration of talc-containing cosmetics and is therefore also authorized by section 701(a) of the FD&C Act. We seek comment on the proposed timeframes.

V. Description of the Proposed Rule

We propose to amend chapter I of title 21 of the Code of Federal Regulations by adding part 730 to subchapter G entitled ''Requirements for Talc-Containing Cosmetic Products.'' If finalized, proposed § 730.3 entitled ''Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products'' would require testing of talc-containing cosmetic products using standardized testing methods for detecting and identifying asbestos that may be present as a contaminant in talc, pursuant to section 3505 of MoCRA and sections 601 and 701 of the FD&C Act.

A. Who is subject to this section? (Proposed § 730.3(a))

We propose that the requirements under this rule would apply to all manufacturers of a talc-containing cosmetic product. We note that section 3505 of MoCRA is not included in the exemptions provided under section 613(a) of the FD&C Act for certain cosmetic products and facilities that are subject to the requirements of chapter V of the FD&C Act (Drugs and Devices). Therefore, cosmetic products that are subject to the requirements of chapter V of the FD&C Act, such as cosmetic products that are also drugs, are subject to this proposed rule.

B. What definitions apply to this section? (Proposed § 730.3(b))

For the purpose of this regulation, we propose to define two terms in this rule: ''asbestos'' and ''representative sample.'' Asbestos refers to a unique asbestiform morphology that occurs when certain minerals crystallize. We define ''asbestos'' to mean amosite, chrysotile, crocidolite, asbestiform tremolite, actinolite, anthophyllite, winchite, and richterite, and other amphibole minerals in the asbestiform habit (Ref. 26, 27). We consider an asbestiform habit to be a habit of growth that ultimately leads to formation of respirable narrow fibers that are hazardous.

Many published definitions of asbestos, including certain definitions in other Federal Agencies' regulations, were considered in defining asbestos in this proposed rule (Refs. 26, 27). Generally speaking, published definitions of asbestos can be categorized as either commercial or mineralogical. For commercial uses, the term asbestos encompasses six minerals that are valued both because of their unique properties and because their abundance in certain regions makes it commercially feasible to mine them. The six commercial minerals targeted for detection and identification in other Federal asbestos regulations are the serpentine mineral chrysotile and the following five amphibole minerals: ''amosite'' (cummingtonite-grunerite asbestos), crocidolite (riebeckite asbestos), tremolite asbestos, actinolite asbestos, and anthophyllite asbestos. In a strictly mineralogical sense, asbestos also refers to minerals identifiable as being among the amphibole or serpentine group and having a unique fibrous morphology resulting from an asbestiform habit of growth (Ref. 27). Therefore, we propose applying a mineralogical definition of asbestos in talc and talc-containing cosmetic products because the commercial definitions of asbestos in other federal regulations do not include all hazardous asbestiform amphibole minerals that might be detected and identified using the proposed testing methods.

In applying the mineralogical approach to identifying asbestos in talc and talc-containing cosmetic products, we propose to add winchite and richterite to the six commercial minerals in our definition of asbestos. Winchite and richterite have been identified in samples of talc taken from certain regions (Refs. 13, 17, 28), and asbestiform winchite and richterite as impurities in other minerals have been associated with the same diseases associated with commercial asbestos types (Refs. 6, 7).

We also propose to include ''other asbestiform amphibole minerals'' in our definition of asbestos. Inclusion of all asbestiform amphibole minerals is based on the cumulative understanding developed over the past five decades indicating association of the particle morphology of asbestiform amphiboles with adverse health effects (Refs. 29, 30). Our proposal is also in recognition that amphiboles are extremely diverse in chemical composition (Ref. 33) and subtle differences in chemical composition have been observed in amphibole asbestos minerals found in association with talc (Ref. 28).

Because all types of amphibole minerals in cosmetic products have potential to release fibers exhibiting size and shape consistent with asbestiform morphology, the inclusion of ''other asbestiform amphibole minerals'' in our definition of asbestos would help ensure that testing for asbestos in talc-containing cosmetic products would detect and identify these fibers as asbestos even if mineral nomenclature (Ref. 33) changes over time.

We propose to define ''representative sample'' to mean a sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled. Rather than specify an exact number of units necessary to comprise a ''representative sample'', this definition provides firms with the flexibility to determine the appropriate sample amount-for any given testing situation, that would ensure the sample represents the material. This definition is also near- identical with FDA's existing regulations defining ''representative sample'' in other product areas (See 21 CFR 210.3(b)(21) and 106.3).

We request comment on the proposed definitions and if they provide sufficient clarity for manufacturers.

C. What test methods must you use? (Proposed § 730.3(c))

We propose to require manufacturers of talc-containing cosmetic products to test for asbestos using PLM (with dispersion staining) and TEM/EDS/SAED. The requirement for the use of PLM and TEM/EDS/SAED in tandem is consistent with established scientific opinions recognizing the limitations of PLM in the realm of analysis for asbestos in talc and talc-containing cosmetic products, which may result in false negative test results. Such limitations are mentioned and discussed in, *e.g.,* Cosmetic, Toiletry, and Fragrance Association (CTFA) Method J4–1 ''Asbestiform Amphibole Minerals in Cosmetic Talc'' (Ref. 34), a *Notice of Intent to Revise* the Talc U.S. Pharmacopeia monograph (Talc USP) test for asbestos (Ref. 35), and ''IWGACP Scientific Opinions on Testing Methods for Asbestos in Cosmetic Products Containing Talc'' (Refs. 13, 22). For the reasons described below, we have determined the additional use of TEM/EDS/SAED will ensure sensitivity and specificity not afforded by PLM alone.

We propose that manufacturers must use an analytical approach that includes PLM and TEM/EDS/SAED. TEM/EDS/

SAED and PLM are complementary methods, giving different information about the different particles (size ranges). Although PLM has much lower magnification than TEM/EDS/SAED by about two orders of magnitude, PLM provides for a larger amount of sample to be analyzed in comparison to when a sample is prepared for TEM/EDS/SAED analysis. Therefore, combining TEM, which enables detection of smaller fibers, with PLM, which enables testing of larger samples, gives the best chance of detecting asbestos. Thus, we are proposing that both methods must be used.

For PLM testing, detecting and identifying asbestos would be required to be based on comparison of optical crystallographic properties (*i.e.,* color and pleochroism, refractive indices, birefringence, extinction characteristics, and sign of elongation) and particle morphology with data for and images of asbestos in indicated references. Specifically, we would require reference to PLM images of asbestos from ISO 22262–1:2012(E) (Annex D) as visual aids to assist the analyst for identifying asbestos particles (Ref. 31). For TEM/EDS/SAED, detecting and identifying asbestos would be required to be based on comparison of elemental composition, crystal structure of particles, and particle morphology with data for and images of asbestos in indicated references. Specifically, we would require reference to images of asbestos ISO 10312:2019(E) (Figure C.1 in Annex C) (Ref. 32) for TEM/EDS/SAED analysis of asbestos as visual aids to assist the analyst for classifying various types of asbestos structures (*i.e.,* particles).

In developing the proposed rule, we considered whether existing voluntary consensus standards for testing talc for asbestos were suitable for inclusion in the proposed rule as the standardized testing method for detection and identification of asbestos in talc-containing cosmetic products. For the purposes of this proposed rule, in line with the ISO/International Electrotechnical Commission (IEC)'s Guide 2:2004, ''Standardization and related activities—General vocabulary,'' we consider a standard to be a document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context (Ref. 36). Among standards, we consider a voluntary consensus standard to be one that is developed or adopted by standards development organizations according to strict consensus principles. Taken together as such, we evaluated existing voluntary consensus standards by reviewing published asbestos testing methods established by nationally or internationally recognized standard development organizations and that generally only apply to the context of very narrow or specific situations in which asbestos is known to be present.

In addition to these standards, we also evaluated other existing published methods, such as those that had not been developed or adopted by consensus, for testing talc for asbestos. As discussed below, among such published standards and methods reviewed by FDA at the time of writing this proposed rule, including those applicable to ''talc'' as an ingredient in consumer products, we did not find any that can be recognized in its entirety as an appropriate standardized testing method to test for asbestos in talc or talc-containing cosmetics.

The CTFA method entitled ''Asbestiform Amphibole Minerals in Cosmetic Talc'' (J4–1) and the Talc USP test for asbestos are the only published methods to test for asbestos in talc used in cosmetics and pharmaceuticals, respectively. As described below, we concluded these methods are not suitable for the purpose of this proposed rule.

The J4–1 method was developed as a PLM test method for asbestos in talc used as a cosmetic ingredient and was not intended to be used to test cosmetic products containing talc. As a result, J4–1 does not include a method of sample preparation intended to remove ingredients in cosmetic products that may interfere with the detection and identification of asbestos.

Additionally, J4–1 has significant shortcomings with respect to testing for asbestos in talc to be used as an ingredient in a cosmetic product. First, as its title notes, it is intended only to test for asbestiform amphibole minerals and not for chrysotile asbestos. On review of the protocol, we did not find it to have any utility to test for chrysotile or detect chrysotile with adequate sensitivity. Second, the J4–1 protocol requires that talc first be screened for amphibole by X-Ray Diffraction Analysis (XRD). J4–1 only requires the talc to be subsequently tested by PLM for asbestiform amphibole if the sample is found to first contain amphibole by the XRD screening. As stated in the J4–1 protocol, the XRD screening method has a nominal limit of detection of amphibole of 0.5 percent by weight. Thus, if the talc contains less than 0.5 percent asbestos by weight, potentially representing billions of asbestos fibers per gram of talc, the asbestos would not be detected (Ref. 37). In summary, reliance on XRD, absent any additional microscopic analysis, can lead to false-negative results for talc containing chrysotile asbestos at any level or amphibole asbestos at levels below 0.5 percent.

If XRD testing of talc comes up positive, the talc then has to be tested by PLM to determine if the amphibole is asbestiform. FDA is concerned that a PLM method alone does not provide sufficient sensitivity to enable detection of chrysotile and asbestiform amphibole minerals at the levels that might be present in talc intended for use in cosmetics and talc-containing cosmetics. Asbestos mineral particles in talc and talc-containing cosmetics can be too small to be detected and identified by PLM alone. Use of TEM/EDS/SAED in tandem with PLM is intended to improve detection of chrysotile and asbestiform amphibole should any of these minerals be present in talc intended for use in cosmetics or cosmetics manufactured using that talc raw material.

We also evaluated a test entitled ''Absence of Asbestos'' in the current Talc USP monograph (Talc USP test for asbestos) that includes three procedures, including a pair of optional procedures to screen for amphibole and serpentine. In the current Talc USP test for asbestos (Ref. 38), analysts are given the option to perform either Procedure 1—infrared spectroscopy (IR) (Identification Tests—General Chapter USP <191>)—or Procedure 2—XRD [Characterization of Crystalline and Partially Crystalline Solids by X-Ray Powder Diffraction (XRPD)—General Chapter USP <941>]. If the procedure chosen gives a positive result, then optical microscopy (Optical Microscopy—General Chapter USP <776>) must be performed to confirm whether the sample is to be regarded as meeting the requirement for *Absence of Asbestos.* It appears that the XRD method has a nominal limit of detection of no less than 0.5 percent and that the IR method might have a limit of detection of nominally 1 percent. Like explained above regarding the J4–1 method, reliance on screening using XRD, or IR as in the USP method, absent any additional microscopic analysis, can lead to false-negative results. Moreover, the optical microscopy method specified in USP <776> does not require the use of polarized light. Use of optical microscopy without polarized light lacks specificity, so could lead to misidentification of the mineral particles present in talc or a talc-containing cosmetic product.

Amid concerns pertaining to lack of sensitivity and specificity in the test for *Absence of Asbestos,* USP has formed two successive expert panels to develop improvements to the Talc USP test for asbestos. Each expert panel has highlighted concerns with the IR, XRD, and optical microscopy methods in the Talc USP test (Refs. 21, 35). Culminating the efforts of these two expert panels, in March 2022 USP published a proposal in Pharmacopeial Forum (Ref. 39), which aims to change the name of the ''Absence of Asbestos'' test to ''Test for Asbestos'' to account for residual limitations in sensitivity and specificity. In addition, the proposal aims to improve the analytical approach by deleting the optional IR test, improving the XRD test to deal with interference that hinders detection of serpentine, and improving the optical microscopy test to require the use of polarized light for the detection and identification of asbestos.

Lastly, USP's proposed protocol will require the analyst to use PLM, even if the XRD test is negative. To accommodate this proposal to amend the Talc USP monograph, USP has issued two new General Chapters. General Chapter <901> (Ref. 40) describes the analytical procedures for XRD and PLM in detail and a complementary General Information Chapter <1901> (Ref. 41) includes images of chrysotile and tremolite asbestos detected by PLM. Additionally, in the briefing to <901>, USP proposes that a third talc expert panel be convened to develop an electron microscopy test method to complement the PLM method, which promises to improve the sensitivity and specificity of the protocol for asbestos even further. However, as noted above, despite demonstrated improvements in sensitivity and specificity, the capability for detection and identification of asbestos in talc used to manufacture cosmetic products using the XRD and PLM techniques described in chapters <901> and <1901> (*i.e.,* without using TEM/EDS/SAED) remains limited.

FDA is proposing to require the use of TEM/EDS/SAED in addition to PLM with dispersion staining because many of the particles of chrysotile and asbestiform amphibole minerals that might be found in raw material talc and talc-containing cosmetic products are not detectable by PLM. Electron microscopy, including transmission electron microscopy (TEM/EDS/SAED) and scanning electron microscopy (SEM/EDS), overcomes the resolution limitations of PLM and has the ability to detect extremely small asbestos fibers. The minimum fiber width that can be routinely characterized by TEM/EDS/SAED is on the order of 0.04 µm, corresponding to the typical width of single chrysotile fibrils. SEM/EDS can be a complementary approach to TEM/EDS/SAED to provide additional information on amphibole mineral particle morphology. However, due to its limitations with respect to obtaining high-quality SAED patterns helpful to identify chrysotile and amphibole minerals, SEM/EDS can only be regarded as a complementary technique but not as a substitute for TEM/EDS/SAED. To have a comprehensive assessment, the IWGACP had advised that the development of a standardized approach should include both optical and electron microscopy. FDA's proposal to require manufacturers of talc-containing cosmetic products to test for asbestos using PLM (optical microscopy) and TEM/EDS/SAED (electron microscopy) is therefore aligned with IWGACP scientific opinions no. 1 and no. 3 on testing approach (Ref. 22).

Since 2019, FDA's contract laboratory has tested more than 200 samples of talc-containing cosmetic products using a TEM/EDS/SAED method that can reliably detect a single asbestos fiber in a sample aliquot, providing the confidence needed in the method proposed. All laboratory reports representing testing of samples of cosmetic products by FDA's contract laboratory from 2019–2023 are posted on the FDA website (*https://www.fda.gov/news-events/fda-brief/fda-brief-fda-releases-final-report-talc-containing-cosmetic-products-tested-asbestos*). These reports provided an estimated limit of detection as the smallest single asbestos fiber that can be detected and identified by TEM/EDS/SAED, and provide an estimated limit of quantification by TEM/EDS/SAED as four such fibers.

The limit of detection and limit of quantification calculation is dependent upon the amount of sample viewed by the analyst on a TEM grid, which is based on the method of sample preparation. Recognizing that laboratories may prepare samples for TEM/EDS/SAED differently depending on the type of sample, we propose to require that, when testing talc or talc-containing cosmetics for asbestos, at least 0.1 micrograms of talc or talc-containing cosmetic product be viewed on a TEM grid on which the sample is uniformly distributed. Based on our discussions with our own and other contract testing labs, we believe this requirement would be consistent with general practice by asbestos testing laboratories expert in TEM/EDS/SAED microscopy and would help ensure consistency across laboratories.

The testing of over 200 samples by FDA's contract laboratory established the TEM/EDS/SAED method's sensitivity to detect one asbestos particle (*i.e.,* fiber) per 0.1 micrograms of talc. Further, under our proposed requirement to analyze at least 0.1 micrograms of the sample, detection of a single asbestos fiber corresponds to an estimated 10^7 fibers per gram of talc or talc-containing cosmetic product, representing approximately 10^{-5} percent of asbestos by weight (Ref. 19). Therefore, we believe that the limit of detection of a single asbestos fiber in a sample is the appropriate basis for determining if a sample should be regarded to be positive for asbestos. When testing for asbestos in talc or a talc-containing cosmetic product, suitable negative controls (use of laboratory blanks) can provide assurance that a single asbestos fiber detected is a true positive finding.

We note that FDA has used the limit of quantification as the basis for determining that a sample is positive. However, based on FDA's historical testing data and our current better understanding of the sensitivity, accuracy, and precision of the methods discussed above, we are proposing to use the limit of detection corresponding to detection of a single asbestos fiber as the basis for a positive sample. We request comment on this proposed requirement.

FDA acknowledges that there may be significant challenges in developing reference materials for the identification of asbestos in talc and talc-containing cosmetics. FDA finds that printed images or drawings depicting morphology of asbestos fibers and bundles, appearing in certain published asbestos testing standards, especially those written to address situations in which asbestos is known to be present, provide useful visual aids for comparison. For example, ISO 22262–1:2012(E) specifies methodology for using PLM to detect and identify asbestos added to fabricate commercial bulk materials such as fireproofing and thermal insulation (see Annex A). With respect to asbestos morphology, Annex D in ISO 22262–1:2012(E) (Ref. 31) appears to contain useful PLM images of chrysotile and asbestiform amphiboles. ISO 13012:2019(E) specifies a TEM/EDS/SAED method for the determination of airborne asbestos fibers and structures in a wide range of ambient air situations, including the interior atmospheres of buildings undergoing removal of previously installed asbestos insulation. Figure C.1

in Annex C in ISO 10312:2019(E) (Ref. 32) appears to contain useful depictions of the morphology of asbestos detected and identified by TEM/EDS/SAED. Therefore, FDA is proposing to require the use of these images to assist the analyst in detecting and identifying asbestos.

D. How does one determine if a sample has tested positive for asbestos? (Proposed § 730.3(d))

We propose to require manufacturers to test for asbestos using both PLM and TEM/EDS/SAED. If asbestos is detected using either method, then the sample would be required to be regarded as positive for asbestos. As explained above, we are proposing that the limit of detection of asbestos would be the basis for determining that a sample has tested positive. Thus, we propose that if any asbestos is detected when the sample is tested as required in § 730.3(c), the sample must be regarded as positive for asbestos.

E. Is there an alternative to performing finished product testing for detecting and identifying asbestos in a talc-containing cosmetic product? (Proposed § 730.3(e))

We propose to provide manufacturers flexibility to test the talc or rely on a certificate of analysis from the talc supplier, prior to using the talc in the manufacture of a talc-containing cosmetic product. We are proposing that a manufacturer relying on such a certificate would satisfy the testing requirements of the rule. If a manufacturer chooses to rely on a talc certificate of analysis, they must qualify the supplier by establishing and maintaining the reliability of the supplier's certificate of analysis through verification of the results of the supplier's tests for asbestos in accordance with § 730.3(f). Testing of the talc intended to be used as a cosmetic ingredient can help prevent the manufacturing of cosmetic products that contain asbestos. Thus, FDA is providing talc-containing cosmetic product manufacturers with a flexible and efficacious approach to testing that will enable them to comply with the proposed requirements and minimize the likelihood that their talc-containing cosmetic products will contain asbestos.

F. How frequently must tests be performed? (Proposed § 730.3(f))

We propose, at a minimum, that a manufacturer test a representative sample of each batch or lot of each talc-containing cosmetic product or talc ingredient for asbestos in accordance with § 730.3(c). If a manufacturer relies on the supplier's certificate of analysis in accordance with § 730.3(e), a manufacturer must at least, upon receipt of the supplier's initial certificate of analysis and subsequently annually thereafter, verify the reliability of the reported asbestos test results based on testing by the manufacturer or another laboratory as required in § 730.3(c).

G. Proposed Records/Record Retention Requirements (Proposed § 730.3(g))

The record requirements section would establish certain requirements for manufacturers to keep records of testing for asbestos that show test data, including raw data, and to describe in detail how samples were tested. Raw data would include microscopy images, spectra, diffraction patterns and bench sheets that are used by the manufacturer or another asbestos testing lab in accordance with standardized methods the manufacturer or testing lab follow and the manufacturer or the testing lab's requirements for quality assurance. If the manufacturer chooses to rely on a certificate of analysis for the talc supplier, records must include any certificate of analysis received from the supplier for testing of the talc used to make the finished product, and documentation of how the manufacturer qualified the supplier by establishing and maintaining the reliability of the supplier's certificate of analysis through verification of the results of the supplier's tests for asbestos in accordance with § 730.3(f).

This section would also require that records be made available within 1 business day, upon request, to an authorized FDA representative for inspection and copying and that they be written in English or an English translation be made available upon request. Records that would be required under this section must be retained for a period of 3 years after the date such record was created. FDA is soliciting comment on whether the timeframe for manufacturers to retain the records under this section is sufficient for FDA to ensure compliance with the rule, including specific comment on the length of time between when talc used in cosmetic products is tested and when such cosmetic products reach consumers, and specific comment on the length of time consumers retain or use their cosmetic products. FDA generally verifies compliance with recordkeeping requirements during inspections. Thus, the timeframe for recordkeeping is based upon consideration of the estimated inspection timeframe. FDA monitors for asbestos in talc-containing cosmetic products by sampling a relatively small number of products annually, and conducts ''for cause'' inspections. Thus, FDA estimates a period of up to 3 years from the time the record was created to when FDA may request the record.

Records would be retained either as originals or as true copies such as photocopies, microfilm, microfiche, or other reproductions that preserve the content and meaning of the data, including associated metadata and audit trails. Electronic records would be required to comply with 21 CFR part 11. Where reduction techniques are used, suitable reader, computer, and copying equipment should be readily accessible to FDA during an inspection. Documents and records that can be immediately retrieved from another location as originals or true copies, including by computer or other electronic means, would meet the requirement to make these records available to FDA. We also propose to require that records be sent electronically, or through another delivery method that delivers the records within 1 business day, to FDA upon request, rather than provide such records at the place of business. We believe that remote access by FDA would be relatively less burdensome on manufacturers compared to an FDA visit to a manufacturer's place of business.

H. Proposed Enforcement Provisions (Proposed § 730.3(h), (i), and (j))

Manufacturers would be required to keep testing records, including any certificates of analysis and qualification and verification documentation, for 3 years after the record was created. Manufacturers would be required to provide these records to us, including electronically, within 1 business day upon request. Failure to test for asbestos in a talc-containing cosmetic product or to maintain testing records would render the product adulterated under section 601(c) of the FD&C Act. Further, if asbestos is present in a talc-containing cosmetic product, or in talc used in a cosmetic product, that cosmetic product is adulterated under section 601(a) of the FD&C Act. Likewise, if asbestos is present in talc intended for use in a cosmetic, that talc is adulterated under section 601(a) of the FD&C Act. Finally, confirmation of asbestos presence, for example through testing conducted on behalf of FDA, similarly means the talc or talc-containing cosmetic product tested is adulterated under section 601(a) of the FD&C Act. It is a prohibited act under section 301(a) of the FD&C Act to introduce or deliver for introduction an adulterated cosmetic into interstate commerce.

VI. Proposed Effective Date

We propose that any final rule that may be issued based on this proposal become effective 30 days after the date of publication of the final rule in the **Federal Register**.

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order (E.O.) 12866, E.O. 13563, E.O. 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

E.O.s 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under E.O. 12866, section 3(f)(1) (as amended by E.O. 14094), if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this proposed rule is not a significant regulatory action under E.O. 12866, section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would impose small costs on affected firms, relative to annual revenue, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The 2023 threshold after adjustment for inflation is $183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

The proposed rule, if finalized, would require testing of talc-containing cosmetic products using standardized testing method(s) to detect and identify asbestos that may be present as a contaminant in talc. We summarize the benefits, costs, and transfers of the proposed rule in table 1.

The benefits of the proposed rule include potential public health benefits from fewer asbestos exposures. To the extent the proposed rule would reduce exposures to asbestos, health benefits would include fewer asbestos-related illnesses, such as mesothelioma, lung cancer, larynx cancer, and ovarian cancer. We lack data to quantify these public health benefits, so we instead discuss them qualitatively. Benefits would also include cost savings to manufacturers of talc-containing cosmetics from fewer recalls each year. At a 7 percent discount rate, the present value of monetized benefits over 10 years would range from $0.00 million to $10.42 million, with a primary estimate of $0.48 million.[1] At a 3 percent discount rate, the present value of monetized benefits over 10 years would range from $0.00 million to $12.25 million, with a primary estimate of $0.56 million. Annualized monetized benefits over 10 years would range from $0.00 million to $1.39 million at a 7 percent discount rate, with a primary estimate of $0.06 million, and from $0.00 million to $1.39 million at a 3 percent discount rate, with a primary estimate of $0.06 million.

The costs of the proposed rule include monetized costs to read and understand the rule, monetized asbestos testing costs, and monetized costs of subsequent testing conducted on new batches of talc when an initial sample of talc tests positive for asbestos. We expect that talc producers, talc suppliers, and manufacturers of talc-containing cosmetics would all read and understand the rule. Also, we assume that all manufacturers of talc-containing cosmetics would rely on certificates of analysis from talc suppliers to comply with asbestos testing requirements in the proposed rule. As a result, talc suppliers would incur costs to regularly test lots or batches of talc for asbestos, and manufacturers of talc-containing cosmetics would incur costs to maintain qualified talc-suppliers. At a 7 percent discount rate, the present value of monetized costs over 10 years would range from $9.72 million to $50.97 million, with a primary estimate of $26.58 million. At a 3 percent discount rate, the present value of monetized costs over 10 years would range from $11.41 million to $59.85 million, with a primary estimate of $31.20 million. Annualized monetized costs over 10 years would range from $1.29 million to $6.78 million at a 7 percent discount rate, with a primary estimate of $6.78 million, and from $1.30 million to $6.81 million at a 3 percent discount rate, with a primary estimate of $3.55 million.

We request both comment and data on the assumptions underlying our analysis.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE

[millions of dollars]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized ($m/year)	$0.06	$0.00	$1.39	2023	7	10	
	0.06	0.00	1.39	2023	3	10	
Annualized Quantified				2023	7		
				2023	3		

[1] From the Office of Management and Budget's Circular A–4, the ''ending point for your analysis should be far enough in the future to encompass, to the extent feasible, all the important benefits and costs likely to result from all regulatory alternatives being assessed.'' We estimate that this proposed rule would have one-time costs immediately following the publication of the rule, then recurring benefits and costs following the effective date of the proposed rule. We therefore choose a 10-year time horizon to encompass all important benefits and costs.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE—Continued
[millions of dollars]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Qualitative	Benefits from reduced consumer exposure to asbestos.						
Costs:							
Annualized Monetized ($m/year)	3.54	1.29	6.78	2023	7	10	
	3.55	1.30	6.78	2023	3	10	
Annualized Quantified							
Qualitative							
Transfers:							
Federal Annualized Monetized ($m/year)							
	From:			To:			
Other Annualized Monetized ($m/year)							
	From:			To:			
Effects:							
State, Local, or Tribal Government: None.							
Small Business: Not significant.							
Wages: None.							
Growth: None.							

We have developed a Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 42) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the OMB under the PRA (44 U.S.C. 3501–3521). The title, description, and respondent description of these provisions are shown in the following paragraphs with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Recordkeeping of Tests for Asbestos in Talc-Containing Cosmetic Products.

Description of Respondents: The respondents to this information collection are manufacturers of a talc-containing cosmetic products marketed in the United States.

Description: The proposed rule would add 21 CFR part 730 to subchapter G to require manufacturers of a talc-containing cosmetic product to make and keep written records of testing for asbestos to verify that talc-containing cosmetic products comply with requirements of the FD&C Act. Examples of these records include test data including raw data, detail of how samples of the talc-containing cosmetic product or talc used in the product were tested, the test method used, the result of the test, and if applicable, a supplier's certificate of analysis. Raw data must include microscopy images, spectra, diffraction patterns, and bench sheets. If a manufacturer relied on a supplier's certificate of analysis from a qualified talc supplier, records must include any certificate of analysis received from the supplier for testing of the talc used to make the finished product, and documentation of how a manufacturer qualified the supplier by establishing and maintaining the reliability of the supplier's certificate of analysis through verification of the results of the supplier's tests for asbestos.

Manufacturers must provide these records upon request from FDA for inspection and copying. Upon request, manufacturers must provide to FDA within a reasonable time an English translation of records maintained in a language other than English. If requested in writing by FDA, a manufacturer must send records electronically, or through another means that delivers the records within 1 business day, rather than making the records available for review at their place of business.

We estimate the recordkeeping burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (hours)	Total hours
730; recordkeeping of tests for asbestos in talc-containing cosmetic products including certificate of analysis	801	17.43	13,961	18	251,298

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimates in table 2 are consistent with the analysis in table 5 of the Preliminary Regulatory Impact Analysis (Ref. 42). In table 5 of the Preliminary Regulatory Impact Analysis, FDA estimates that there are 801 manufacturers and 13,961 products adjusted for private label products. For the purpose of this analysis, we are assuming that each batch of talc or lot of talc will supply a cosmetic product for 1 year, or that each batch or lot of talc-containing cosmetic product will be 1 year's supply of cosmetic product. Each batch or lot of talc or product, as applicable, must have a record of testing for asbestos. With 13,961 products, we estimate that each batch or lot of talc or product, as applicable, will be tested annually, creating 13,961 records. With this estimation, we calculate that each of the 801 manufacturers will create and maintain 17.43 (17–18) records. We estimate that creating and maintaining such records takes about 18 hours, based on FDA's experience with retail sampling of talc-containing cosmetic products for the presence of asbestos. Thus, we calculate the total burden will be 251,298 hours (801 manufacturers × 17.43 records/manufacturer = 13,961.43, rounded to 13,961 records; 13,961 × 18 hours).

To ensure that comments on information collection are received, OMB recommends that comments be submitted at *https://www.reginfo.gov/public/do/PRAMain* (see **ADDRESSES**). Find this particular information collection by selecting ''Currently Under Review—Open for Public Comments'' or by using the search function. The title of this proposed collection is ''Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products.''

In compliance with the PRA (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. 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. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

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List of Subjects in 21 CFR Part 730

Cosmetics, Incorporation by reference, Recording and recordkeeping requirements, Testing.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend chapter I of title 21 of the Code of Federal Regulations by adding part 730 to subchapter G to read as follows:

PART 730—REQUIREMENTS FOR TALC-CONTAINING COSMETIC PRODUCTS

Subpart A—Testing Methods

Authority: 21 U.S.C. 321, 331, 352, 355, 361, 362, 371, 374; sec. 3505, Pub. L. 117–328, 136 Stat. 4459.

Subpart A—Testing Methods

§§ 730.1–730.2 [Reserved]

§ 730.3 Testing methods for detecting and identifying asbestos in talc-containing cosmetic products.

(a) *Who is subject to this section?* You are subject to this section if you manufacture a talc-containing cosmetic product.

(b) *What definitions apply to this section?* For purposes of this section:

(1) *Asbestos* means amosite, chrysotile, crocidolite; asbestiform tremolite, actinolite, anthophyllite, winchite, and richterite; and other asbestiform amphibole minerals.

(2) *Representative sample* means a sample that consists of a number of units that are drawn based on rational criteria, such as random sampling, and intended to ensure that the sample accurately portrays the material being sampled.

(c) *What test methods must you use?* (1) You must use an analytical approach that includes both Polarized Light Microscopy (PLM) (with dispersion staining), and Transmission Electron Microscopy (TEM)/Energy Dispersive Spectroscopy (EDS)/Selected Area Electron Diffraction (SAED). You must conduct the tests on either a representative sample of each batch or lot of the talc-containing cosmetic product or on a representative sample of each batch or lot of the talc ingredient that will be incorporated into the talc-containing cosmetic product.

(i) *Use of PLM method.* Detecting and identifying asbestos must be based on comparison of optical crystallographic properties (*i.e.,* color and pleochroism, refractive indices, birefringence, extinction characteristics and sign of elongation) and particle morphology with data for and images of asbestos in Annex D of ISO 22262–1:2012(E). Images of asbestos from ISO 22262–1:2012(E) (Annex D) for PLM analysis of asbestos must be used as visual aids to assist the analyst.

(ii) *Use of TEM/EDS/SAED method.* You must examine an area containing at least 0.1 micrograms of talc on a TEM grid on which the sample is uniformly distributed. Detecting and identifying asbestos must be based on comparison of elemental composition, crystal structure of particles, and particle morphology with data for and images of asbestos in Figure C.1 in Annex C of ISO 10312:2019(E). Images of asbestos from ISO 10312:2019(E) (Figure C.1 in Annex C) must be used as visual aids to assist the analyst.

(2) [Reserved]

(d) *How does one determine if a sample has tested positive for asbestos?* If asbestos is detected based on use of PLM or based on the use of TEM/EDS/SAED as required in paragraph (c) of this section, the sample must be regarded as positive for asbestos and therefore asbestos must be regarded as present in the material represented by that sample.

(e) *Is there an alternative to performing finished product testing for detecting and identifying asbestos in your talc-containing cosmetic product?* If you manufacture a talc-containing cosmetic product and do not perform testing for detecting and identifying asbestos in your talc-containing cosmetic product before you release the product, all the talc in your product must have been tested in accordance with paragraph (c) of this section prior to using the talc in the manufacture of a talc-containing cosmetic product. You may rely on a certificate of analysis from the supplier of the talc ingredient if you qualify the supplier by establishing and maintaining the reliability of the supplier's certificate of analysis through verification of the results of the supplier's tests for asbestos in accordance with paragraph (f) of this section. The certificate of analysis must at minimum state that:

(1) The supplier uses an analytical approach that includes both PLM and TEM/EDS/SAED as described in paragraph (c) of this section; and

(2) The certificate of analysis is specific to the talc purchased by the manufacturer, including identification of a lot or batch number for the talc being tested, the date or date range when the test(s) were performed, and the results of each test.

(f) *How frequently must tests be performed?* At a minimum, you must test a representative sample of each batch or lot of each talc-containing cosmetic product or talc ingredient for asbestos in accordance with paragraph (c) of this section. If you rely on the supplier's certificate of analysis in accordance with paragraph (e) of this section, you must at least upon receipt of the supplier's initial certificate of analysis and subsequently annually thereafter verify the reliability of the reported asbestos test results based on testing by you or another laboratory as required in paragraph (c).

(g) *What records must be kept?* You must keep records of testing for asbestos that show test data, including raw data. The record must describe in detail how samples of the product or talc used in your product were tested, the test method used, and the result of the test. Raw data must include microscopy images, spectra, diffraction patterns and bench sheets. If you rely on a supplier's certificate of analysis, records must include any certificate of analysis received from the supplier for testing of the talc used to make the finished product, and documentation of how you qualified the supplier by establishing and maintaining the reliability of the supplier's certificate of analysis through verification of the results of the supplier's tests for asbestos in

accordance with paragraph (f) of this section. You must keep such records for, at a minimum, 3 years after the date such record was created. You must make all records required under this subpart available within 1 business day to an authorized FDA representative, upon request, for inspection and copying. Upon FDA request, you must provide within a reasonable time an English translation of records maintained in a language other than English.

(1) Records must be kept as original records, as true copies (such as photocopies or other accurate reproductions of the original records), or as electronic records.

(2) Electronic records must comply with part 11 of this chapter.

(3) Documents and records must be retrieved as originals or true copies, and available for copying by FDA, including by computer or other electronic means, using equipment readily accessible to FDA during an inspection. If requested in writing by FDA, you must send records electronically, or through another means that delivers the records within 1 business day, rather than making the records available for review at your place of business.

(h) *What consequences result from failing to test talc ingredients or talc-containing product for asbestos or failing to rely on and verify a certificate of analysis from the talc ingredient supplier*? Failure of a manufacturer to test a talc ingredient or a talc-containing product in compliance with paragraph (c) of this section renders the product adulterated under section 601(c) of the Federal Food, Drug, and Cosmetic Act.

(i) *What consequences result from failing to comply with the recordkeeping requirements?* Failure of a manufacturer to operate in compliance with the requirements of paragraph (g) of this section renders the cosmetic product adulterated under section 601(c) of the Federal Food, Drug, and Cosmetic Act.

(j) *What consequences result from the presence of asbestos in a talc-containing cosmetic product, or in talc used in that cosmetic product, or from the presence of asbestos in talc intended for use in cosmetics?* If asbestos is present in a talc-containing cosmetic product or in talc used in that cosmetic product, that cosmetic product is adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act. If asbestos is present in talc intended for use in a cosmetic, that talc is adulterated under section 601(a) of the Federal Food, Drug, and Cosmetic Act.

(k) *Incorporation by reference.* Material listed in this paragraph (k) is incorporated by reference into this section with approval of the Director of the **Federal Register** under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration and at the National Archives and Records Administration (NARA). Contact the Food and Drug Administration between 9 a.m. and 4 p.m. Monday through Friday at: Dockets Management Staff, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; phone: 240–402–7500; email: *DMSInbox@fda.hhs.gov.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from The International Organization for Standardization (ISO), BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; phone: +41–22–749–01–11; email: *customerservice@iso.org;* website: *https://www.iso.org/store.html.*

(1) ISO 22262–1:2012(E), ''Air quality—Bulk materials—Part 1: Sampling and qualitative determination of asbestos in commercial bulk materials,'' Annex D, Asbestos identification by PLM and dispersion staining in commercial materials, First edition, July 1, 2012.

(2) ISO 10312:2019(E), ''Ambient air—Determination of asbestos fibres—Direct transfer transmission electron microscopy method,'' Annex C, Structure counting criteria, Figure C.1, Second edition, October 10, 2019.

§§ 730.4–730.100 [Reserved]

Subparts B Through K [Reserved]

Dated: December 17, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2024–30544 Filed 12–26–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF LABOR

Employment and Training Administration

29 CFR Parts 29 and 30

[Docket No. ETA–2023–0004]

RIN 1205–AC13

National Apprenticeship System Enhancements; Withdrawal

AGENCY: Employment and Training Administration, Labor.

ACTION: Withdrawal of proposed rule and termination of rulemaking proceeding.

SUMMARY: The Department of Labor (the Department) is withdrawing its notice of proposed rulemaking (NPRM or proposed rule), which proposed to revise the Federal regulations implementing the National Apprenticeship Act of 1937 (NAA).

DATES: The Department is withdrawing the proposed rule published on January 17, 2024 (89 FR 3118), as of December 27, 2024.

ADDRESSES: The docket is available at *https://www.regulations.gov*—Docket No. ETA–2023–0004.

FOR FURTHER INFORMATION CONTACT: Michelle Paczynski, Administrator, Office of Policy Development and Research, U.S. Department of Labor, Employment and Training Administration, 200 Constitution Avenue NW, Room N–5641, Washington, DC 20210, Telephone: 202–693–3700 (voice) (this is not a toll-free number). For persons with a hearing or speech disability who need assistance to use the telephone system, please dial 711 to access telecommunications relay services.

SUPPLEMENTARY INFORMATION:

Background

The NAA (29 U.S.C. 50) authorizes the Secretary of the Department of Labor (the Secretary) to ''formulate and promote the furtherance of labor standards necessary to safeguard the welfare of apprentices, to extend the application of such standards by encouraging the inclusion thereof in contracts of apprenticeship, to bring together employers and labor for the formulation of programs of apprenticeship, [and] to cooperate with State agencies engaged in the formulation and promotion of standards of apprenticeship.'' Under this authority, the Department established the registered apprenticeship program. The Department set forth labor standards designed to facilitate these statutory directives through its implementing regulations at 29 CFR part 29. Those regulations prescribe minimum quality and content requirements with respect to a program's standards of apprenticeship and its apprenticeship agreements; establish procedures concerning the registration, cancellation, and deregistration of apprenticeship programs; and set forth a mechanism for the recognition of State Apprenticeship Agencies (SAAs) as Registration Agencies authorized to register and