



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; Withdrawal

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

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the withdrawal of the proposed rule entitled "Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products," which published in the *Federal Register* of December 27, 2024. FDA is taking this action in response to comments received during the comment period for the proposed rule that warrant further consideration and assessment prior to issuing final regulations to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products pursuant to the Modernization of Cosmetics Regulation Act of 2022.

DATES: The proposed rule published December 27, 2024 (89 FR 105490) is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Elizabeth Anderson, Senior Policy Analyst, Food and Drug Administration, 240-402-4565, QuestionsAboutMoCRA@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of December 27, 2024 (89 FR 105490), FDA issued the proposed rule entitled "Testing Methods for Detecting and Identifying Asbestos in Talc-Containing Cosmetic Products" as part of its implementation of

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.

The proposed rule, if finalized, would require manufacturers of talc-containing cosmetic products to test their talc-containing cosmetic products or the talc cosmetic ingredient prior to using the talc to manufacture a talc-containing cosmetic for asbestos, and to keep records to demonstrate compliance with the rule. Failure to comply with the rule's testing or recordkeeping obligations would result in FDA deeming a cosmetic product to be adulterated under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as would the presence of any asbestos in a talc-containing cosmetic product, talc used in a cosmetic product, or talc intended for use in a cosmetic. FDA received 49 comments on the proposed rule.

FDA proposed that the rule would apply to all manufacturers of talc-containing cosmetic products, including cosmetic products that are subject to the requirements of chapter V of the FD&C Act (Drugs and Devices). Therefore, the proposed rule, if finalized, would apply to cosmetic products that are also drugs. FDA received comments that suggested the proposed rule would have unintended consequences for many consumer products containing talc, including but not limited to talc-containing cosmetic products.

FDA proposed to define "asbestos" to include "amosite, chrysotile, crocidolite; asbestiform tremolite, actinolite, anthophyllite, winchite, and richterite; and other asbestiform amphibole minerals." FDA received comments that requested consistency with the established definitions or approaches used by other Federal agencies, including the Department of Labor (Occupational Safety and Health Administration and Mine Safety and Health Administration) and Environmental Protection Agency, to avoid unnecessary confusion.

MoCRA requires FDA to establish and require standardized testing methods for detecting and identifying asbestos in talc-containing cosmetic products. The proposed rule was issued pursuant to MoCRA and sections 601 and 701 of the FD&C Act. FDA received

comments regarding the Agency's statutory authority under law to add a specific adulteration provision relating to talc testing and regarding its authority to consider a cosmetic containing any amount of asbestos to be adulterated.

Good cause exists to withdraw the proposed rule at this time. On the basis of the Make America Healthy Again (MAHA) priorities to ensure safe additives in the American food and drug supply, the highly scientific and technical issues addressed in public comments the Agency has received, and the complexity of asbestos testing and legal considerations under the Administrative Procedure Act, we are withdrawing the proposed rule to reconsider best means of addressing the issues covered by the proposed rule and broader principles to reduce exposure to asbestos, and to ensure that any standardized testing method requirements for detecting asbestos in talc-containing cosmetic products help protect users of talc-containing cosmetic products from harmful exposure to asbestos.

While the Agency is withdrawing the proposed rule, FDA will issue a proposed rule to meet its statutory obligations under section 3505 of MoCRA.

Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services.

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