

MEMORANDUM

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DATE: October 1, 1974

TO : Virgil O. Wodicka, Ph.D.
Director, Bureau of Foods (HFF-1)
Through: Associate Director
for Technology (HFF-400) RAF

FROM : Acting Director
Division of Cosmetics Technology (HFF-440)

SUBJECT: Asbestos Contamination of Cosmetic Talc

1. In answer to your verbal request, the following is a review of the current status of the asbestos in talc project. The review includes a summary of DCST's analytical efforts and highlights the activities of others interested in this subject matter.
2. On October 1, 1973, I reported that Dr. Seymour Z. Lewin of New York University had analyzed 195 commercial cosmetic talc products under FDA contract and that some of the 195 samples had also been investigated by Pfizer, Inc., Minerals, Pigments and Metals Division, by Columbia Scientific Industries, and by Arnold E. Schulze of the Division of Microbiology, FDA.
3. Dr. Lewin had determined that 17 of these 195 samples contained up to 15% chrysotile. Many of the chrysotile-containing samples were reported to contain also up to 12% tremolite. Tremolite alone was detected in 23 samples. The chrysotile content could not be confirmed with certainty by the other investigators, and tremolite was detected by the others in only a few instances.
4. The discrepancies in the analytical results, particularly in regard to the chrysotile content, were thought to have been caused by the interference of chlorite, a talc mineral, in the determination of chrysotile by x-ray diffractometry and by the marginal sensitivity of the analytical methods in general.
5. We attempted to resolve these discrepancies in two ways, namely, through:
 - (a) Analysis of the 40 samples implicated by Dr. Lewin (as well as of other samples randomly selected from Dr. Lewin's inventory) by optical microscopy in accordance with the method proposed by FDA in the Federal Register notice of September 28, 1973 (38 FR 37076), and

(b) Development of improved or new instrumental methods to increase the analytical reliability and to permit the determination of asbestiform minerals at very low concentrations. Our goal was to determine tremolite at a level of at least 0.1% and chrysotile at 0.01% (in accordance with the Federal Register notice of 9/28/73).

6. A total of 34 samples of the Lewin inventory were investigated by optical microscopy. Of these, 18 samples were from the group which Dr. Lewin reported to contain chrysotile or tremolite. Although the fiber count cannot be readily translated to weight concentration (the Federal Register proposal suggests 1000 fibers per mg of talc being equivalent to 0.1%), our results for tremolite agreed, in a general way, with Dr. Lewin's findings. The chrysotile content, however, could not be confirmed. Chrysotile fibers could not be detected by optical microscopy because of their small size and narrow diameter. Other investigators reported similar difficulties.

7. Considerable effort was invested in the development of improved instrumental methodology. The current status may be summarized as follows:

(a) Tremolite can be determined reliably at the 0.1% - 0.2% level by step-scanning x-ray diffraction. Fibrous tremolite, however, cannot be distinguished from the non-fibrous form. This has to be accomplished by optical microscopy. The determination can be carried out in 3 - 4 hours. The method is unsuitable for the determination of chrysotile because of chlorite interference.

(b) Chrysotile can be determined by differential thermal analysis (DTA), however, the current detection limit is only 1%. The analysis can be carried out in one hour.

(c) Attempts are under way to improve the sensitivity of the DTA method to bring the detection level down to 0.5%. Further improvement of the detection limit will involve sample enrichment techniques (i.e., specific gravity concentration of asbestos minerals by means of ultrasonic treatment, centrifugation, or use of heavy liquids).

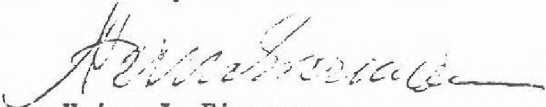
8. The industry was urged to participate in the search for improved analytical methodology. CTFA's Talc Subcommittee has become actively involved in this project, however, significant progress has not yet been reported. Liaison is being maintained with this committee.

9. A study was undertaken to determine the amount of talc an infant may inhale when powder is applied to the child. It was hoped that this information would provide a better perspective of the health hazard potential of asbestos-contaminated talc. The use conditions were simulated and exaggerated to obtain data reflecting the most severe circumstances. Under extreme conditions (highest amount of talc dispensed experimentally during the shortest time period, both at the 95% level of confidence), the talc concentration in air was 0.275 mg/liter (275 fibers/ml). The average concentration was 0.08 mg/l (80 fibers/ml). In a similar study, Johnson & Johnson reported an average of 0.008 mg/l (8 fibers/ml). The difference in talc concentration of one order of magnitude may be explained in part by the difference in height of the talc application between the FDA and the J&J studies (10" vs 2" distance between container and surface).

10. Current OSHA regulations permit occasional levels of 10 asbestos fibers per ml air. Accordingly, if the air contained 275 talc particles per ml, the asbestos content could not exceed 3.6%, and 12.5% if the talc content in the air were 80 fibers/ml (0.08 mg/l). If J&J data were applied, the dispensed powder may consist entirely of asbestos. According to J&J's statistical interpretation, the application of asbestos powder when related to OSHA standards, would then still provide a safety factor of 483. On the basis of this data, the company suggested a maximum permissible concentration of 1% asbestos in talc, providing a safety factor of 48,300.

11. J&J's estimate of a safe level of asbestos in baby powder talc leaves much to be desired in regard to the application and interpretation of OSHA standards. Furthermore, J&J established the dangerous precedent of extrapolating mathematically an exposure standard for industrial workers to determine an exposure standard for infants. The latest epidemiological study of the Mount Sinai Medical Center raises serious questions concerning the effects of exposure to less than intense levels of asbestos and of short-term exposures.

12. If a regulation has to be proposed at this time concerning the asbestos content in cosmetic talc, our recommendation would be to require that no asbestos could be detected in the talc under the prescribed test conditions. This would mean, in effect, that talc contained less than 1% chrysotile and less than 0.2% tremolite. As test methods were improved, the permissible asbestos levels would be reduced in accordance with the sensitivity of the new methods.


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