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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

February 24, 1975

Mr. Harold Romer
Consultant to the Commissioner
Department of Health Resources
120 Wall Street
New York, New York 13005

Dear Mr. Romer:

This letter is a follow-up to our telephone conversation of February 13, 1975, regarding the status of FDA's review of talc for asbestos contamination. Enclosed is a copy of Dr. S. Z. Lewin's report of July 10, 1973, regarding his work on the analysis of talc for asbestiform minerals. Dr. S. Z. Lewin of New York University analyzed 195 commercial cosmetic talc products under FDA contract.

Some of the 195 samples were also investigated by Pfizer Inc., Columbia Scientific Industries, and by the Division of Microbiology, Food and Drug Administration. Dr. Lewin's results indicated that 17 of the 195 samples contained up to 15% chrysotile. Many of the chrysotile containing samples were also reported to contain up to 12% tremolite. Tremolite alone was detected in 23 of the samples. The chrysotile content reported by Dr. Lewin could not be confirmed with certainty by other investigators; however, tremolite was detected by others in most instances. 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. A summary of the results of other investigators who have analyzed the samples which Dr. Lewin found contained either chrysotile or tremolite is also enclosed (see H. J. Eiermann Report 10-1-73).

Considerable effort is being invested at the present time in the development of improved instrumental methodology. The current status may be summarized as follows:

(1) 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.

(2) 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.

(3) 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).

(4) The Division of Cosmetics Technology (DCST) has analyzed by optical microscopy most of the same talc samples in which Dr. S. Z. Lewin reported the presence of chrysotile. Chrysotile was not detected in any of the talc samples. In addition, DCST analyzed approximately 60 of Dr. Lewin's samples by differential thermal analysis (DTA). DTA indicated the presence of a serpentine mineral in two of these talc samples. One of the two samples was examined by optical microscopy. Chrysotile was not detected. The remaining sample has not yet been examined by microscopy.

The industry was urged to participate in the search for improved analytical methodology. The Cosmetic, Toiletry and Fragrance Association talc subcommittee has become actively involved in this product; however, significant progress has not yet been reported. Liaison is being maintained with this committee.

If you desire further information concerning the activities of the Bureau of Drugs with regards to asbestos, I suggest you contact Dr. Armand R. Casola, Division of Anti-Infective Drug Products, HFD-140, Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852.

(b) (5)

Sincerely yours,

Robert H. Schaffner, Ph.D.
Associate Director for Technology
Bureau of Foods

Enclosures