

MEMORANDUM OF TELEPHONE CONVERSATION

Friday, February 27, 1976

BETWEEN: Marion Burros
Reporter
The Washington Post

and

Heinz J. Eiermann, Director
Division of Cosmetics Technology
Food and Drug Administration

Subject: Asbestos in Talc

Ms. Burros called at approximately 10:30 a.m. to inquire about the current status of our efforts with regard to the regulation of asbest in cosmetic talc products. She indicated that she had already talked to Dr. Shapiro (HFF-108) on this subject on February 10 and that she had had a conversation before that with Dr. I. Selikoff of Mt. Sinai School of Medicine. The following account covers the essential point of our conversation:

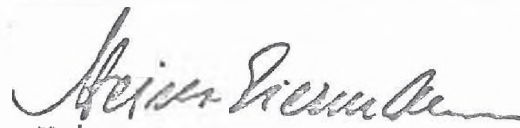
(1) Analytical Evaluation of Commercial Talc Samples. In 1973, t agency had Dr. S. Z. Lewin, New York University, evaluate 195 samples of commercial talc products by x-ray diffraction. Dr. Lewin reported Chrysotile in 17 samples and Tremolite in 23. Other investigators, including the FDA, using other analytical methods, could not confirm the Lewin results, particularly in regard to Chrysotile. None of the Chrysotile results could be duplicated. In addition, DCST evaluated samples and consumer complaint samples for Tremolite and Chrysotile by DTA and optical microscopy and none was detected at the detectable level of approximately 0.5%.

(2) Analytical Methodology. Currently available instrumental methodology which is suitable for routine quality control of talc is diffe thermal analysis (DTA) for the determination of Chrysotile at a level sensitivity of about 0.5 - 1.0% and stepscanning x-ray diffraction fo the determination of Tremolite at a concentration of 0.3 - 0.5% (and Chrysotile when the talc is free of Chlorite, a common talc component. These methods do not differentiate between fibrous and non-fibrous asbestos, and samples would have to be further analyzed by optical microscopy to confirm fibrous asbestos. In the case of Chrysotile where fil are usually too small to be visible under the microscope, this determination is not always successful. Electron microscopy is not a suitable method for routine evaluation of talc because of the time-consuming methodology and the nature of talc mining and processing which demand multiple, continuous sampling to arrive at statistically meaningful results. Accordingly, our efforts during the past year, aside from analyzing commercial samples, concentrated on improvement in the

sensitivity of detection of asbestos by the aforementioned methods. Flootation techniques for sample enrichment were investigated, however, the results were not encouraging for reasons of problems in separation of talc and asbestos particles due to similarity in densities. - A special scientific committee of the CTFA has been engaged in similar studies and arrived at essentially the same conclusions.

(3) Questions Concerning Toxicity of Talc. Ms. Burros inquired whether we had conducted or have under way, inhalation studies to determine the threshold concentration of asbestos that produced lung cancer. The answer was that such studies had not been conducted and were not under way. She expressed also concern that talc itself was toxic when inhaled. I replied that we had no scientific data demonstrating adverse effects from inhalation of talc, and I informed her of a recently completed 2-year inhalation study in hamsters at Battelle for Johnson & Johnson. The results of this study showed no adverse effects from inhalation of exaggerated dose levels. Toward the end of the conversation she asked whether we were concerned about the toxic effects of Nickel in talc. I replied that we had no knowledge of the presence of Nickel in talc, and I had no information on the inhalation toxicity of Nickel. She intimated that she had heard about the presence of Nickel in talc and that it was found to be toxic.

(4) Regulations Concerning Asbestos. Mrs. Burros wanted to know why we did not finalize the proposed regulation on asbestos in food and talc used as a food additive which was published on September 28, 1973 (38 FR 37076). My response was that it was my understanding that the method of determination (optical microscopy) was unsatisfactory for the aforementioned reasons and that other methods were under investigation. When asked what our regulatory plans were, I replied that I could not provide specific information, however, we would continue our efforts in the analytical field, both in improving methodology and in the evaluation of commercial samples. As already explained, we were unable in recent investigations to find asbestos-contaminated commercial cosmetic talc samples.



Heinz J. Eiermann

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