

Wenzel

MEMORANDUM OF TELEPHONE CONVERSATION

March 8, 1976

Between: John D. Klein, Reporter
Channel 7 News
Washington, D.C.

and

Heinz J. Eiermann, Director
Division of Cosmetics Technology
Food and Drug Administration (HFF-440)

SUBJECT: Asbestos in Talc

Mr. Klein called in reference to the article "Asbestos Fibers Found in Baby Powders" by Marion Burros in the Washington Post of March 8. He wanted FDA's viewpoint on the story, and inquired about an interview with the writer on this subject.

I pointed out to Mr. Klein that the information on the commercial talc products mentioned in the article refers to samples collected by the Mt. Sinai researchers in 1973. At that time the FDA analyzed about 200 samples, and the results showed contamination of some samples with Tremolite but none with Chrysotile (the primary investigation determined Chrysotile but these results were not confirmed by others, including the FDA). During the past three years, the FDA conducted analytical research to develop analytical methods suitable for routine testing of talc for asbestos and continued to survey the market for asbestos-contaminated commercial talc products. In FY 1975, 73 talc products were sampled and tested for asbestos. None were found to contain Tremolite or Chrysotile.

In response to the question why FDA did not recall the asbestos contaminated talc sample and whether there was not sufficient concern to do so, I answered that, obviously, the potential hazard did not warrant a recall, otherwise the agency would have initiated this action at that time. However, there was continuing concern by the agency as expressed through the analytical research efforts and the continued sampling activities of talc products. Mr. Klein then requested an interview with the writer for a public discussion of these issues. I indicated that I would need clearance from the press office. This request for the interview was later denied by the Assistant Commissioner for Public Affairs, and Mr. Klein was informed accordingly.

Heinz J. Eiermann

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Schaffner
HFF-402

Honorable Norman F. Lent
House of Representatives
Washington, D.C. 20515

Dear Mr. Lent:

JUN 25 1976

This is in further response to your May 13 inquiry on behalf of Mr. Davis Husing, Westbury, New York, regarding a recent article in the New York Times about asbestos in cosmetic talc products. The Division of Cosmetics Technology provided us with the following explanation concerning the statement, attributed to Mr. Eiermann, that electron-microscopic testing of talc was too expensive and time consuming for the Food and Drug Administration (FDA) to use.

The New York Times allegation did not reflect accurately the comment made by Mr. Eiermann, perhaps because the reporter did not fully understand the complexity of the issue. It was explained to the reporter that electron-microscopic testing of talc for asbestos is an excellent analytical tool for research purposes, however, that it would be too time consuming and expensive for use in routine control testing of talc in the production of cosmetic talcum powders. Furthermore, the majority of manufacturers do not have this instrument and would not be able to purchase it for economic reasons. Accordingly, the Agency has been investigating other analytical procedures for the determination of asbestos. These methods should permit quick and reliable detection of asbestos in talc and should be useful for effective analytical control testing by all manufacturers.

You may inform your constituent also that the FDA has been investigating many cosmetic talc products in recent years, and none were found to contain asbestos. The product samples mentioned in the New York Times article were manufactured prior to 1973 and do not reflect current production of cosmetic powder products.

We trust this information will be helpful to your constituent. If we can be of further assistance, please let us know.

Sincerely yours,

Robert C. Wetherell, Jr., Director
Office of Legislative Services

Enclosure
New York Times article

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Schaffner

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SUMMARY AND COMMENTS ON ANALYSES FOR
ASBESTOS IN COSMETIC TALC. PRODUCTS

This summary contains the analytical results for asbestos in cosmetic talc preparations, comments on these analyses, and other pertinent information on the work carried out by the following investigators:

1. Seymour Z. Lewin, Ph.D., Professor of Chemistry, New York University. Dr. Lewin was commissioned by FDA in 1971 to analyze commercial cosmetic talc products. He purchased and analyzed 195 samples by x-ray powder diffraction. Dr. Lewin was chosen because he is an internationally recognized expert on mineralogical chemistry.
2. Arnold E. Schulze, Microanalytical Branch, Division of Microbiology (BF-216), FDA. Mr. Schulze investigated 32 of the 195 samples by means of polarizing microscopy.
3. Minerals, Pigments and Metals Division, Pfizer, Inc, Easton, Pa. This investigator employed the techniques of x-ray powder diffraction and reported on 7 of the 195 samples. This work was complimentary.
4. Columbia Scientific Industries, Austin, Texas. This firm checked samples for chrysotile by means of differential thermal analysis. This work was complimentary.

There is poor correlation between Dr. Lewin's results and the findings of the other investigators. Dr. Lewin found definite indications of chrysotile in 17 of the samples (many of these also had tremolite) and definite indications of tremolite but not chrysotile in 23 samples. The chrysotile content could not be confirmed with certainty by the other investigators, and tremolite was detected by the others only in a few instances.

The reason for these discrepancies may be found in Dr. Lewin's own notes of July 10, 1973, in which he stated: "The chrysotile that I found in commercial talcs is generally different in significant respects from the chrysotile that occurs as massive, fibrous growth in veins in serpentine rocks. That is, the former has diffraction peaks that may differ from the latter by as much as 0.2 Å (at 7.3 Å); it is more reactive toward dilute acids; it shows a different appearance under the microscope; and its DTA endotherms and exotherms are shifted relative to those of the latter (and apparently diminished)." He further states that "the analytical method (x-ray diffraction) gives a reproducibility of $\pm 2\%$ to 3% average deviation in replicate determinations on the same sample, but different samples from the same bulk container are found to vary as much as 200%."

In the light of these discrepancies and because the inhalation of certain asbestiform minerals is a potential health hazard, the FDA has engaged in an intensive research project to develop one or several methods of sufficient sensitivity and reliability which will permit the determination of asbestos in talc-containing products with the necessary degree of accuracy and at concentrations at which this contaminant presents the health hazard.

Heinz J. Eiermann: 10-1-73