

MEMORANDUM OF TELEPHONE CONVERSATIONS

January 22 and February 1, 1973

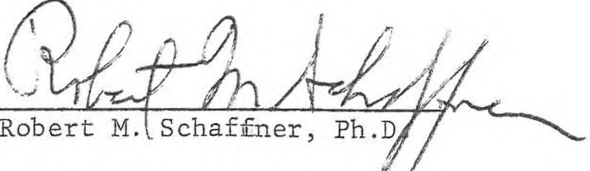
Between: Mr. John Spivak, Wall Street Journal. 783-0164

Robert M. Schaffner, Ph.D., Director, OPT

Subject: Asbestos in Talcum Powder

I provided Mr. Spivak basic information on the status of our asbestos survey on talcum powder and told him that we had not as yet received the confidential report from Dr. Lewin. I told him I understood that over 190 samples have now been examined by him and there are still a few matters to be resolved regarding methodology.

I told him that in about two months the Agency will issue some type of proposed regulation which would be to the effect that the Food and Drug Administration would consider a cosmetic adulterated if it contained talc that had asbestos present which would be determined by specific analytical techniques, probably calling for a sensitivity of 1%. I said that based on preliminary reports it appeared that manufacturers had been raising their specifications on talc; and although some of them had products on the market a year or so ago that had appreciable amounts of asbestos in the talc most of them were relatively free of asbestos at the present time. He wanted me to speculate on the percentage of cosmetics that contained talc that might be contaminated and would be recalled or seized when the regulations went into effect. I told him that I could not make any kind of estimate on this, but that I thought the percentage would be extremely small because we have been bringing this problem to the attention of the cosmetic industry for well over a year now and they were taking corrective measures.


Robert M. Schaffner, Ph.D.

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March 2, 1973

Dr. Lucile Adamson, Staff Scientist
Mr. Scott Lang, Washington Counsel
Environmental Defense Fund
1712 N Street, N.W.
Washington, D.C. 20036

Dear Dr. Adamson and Mr. Lang:

I regret the long delay in replying to your letter about asbestos in talc. Part of the delay was due to a heavy load of other responsibilities, and part was due to a hope that events might have proceeded to the point of resolution of the various questions involved. Even though this hope has not yet been realized, the lapse of time has been great enough to impel me to write as follows in response to your specific questions.

Your remarks on the health hazards of asbestos are of course well-founded; this has been of concern to us for some time. In August 1971 I organized a discussion session at FDA on asbestos in talc, which was attended by almost fifty representatives of industry, universities, and government. A major topic at the meeting was the analytical methodology for detecting small amounts of asbestos in talc. This was recognized as a difficult problem which is best attacked by a battery of four methods (optical microscopy, X-ray diffraction, electron microscopy, and electron diffraction) and possibly a fifth method, elemental analysis by electron microprobe. However, it was noted that the combined use of all the methods would be almost prohibitively expensive.

One of those in attendance at the meeting was Prof. Seymour Z. Lewin of New York University, a recognized expert on mineralogical chemistry and analysis. Some time after the meeting, I asked Dr. Lewin to undertake the analysis of samples of commercial talcum powder products for asbestos (particularly the chrysotile and tremolite varieties) by means of the X-ray diffraction technique primarily, with additional work by optical microscopy as needed. He carried out most of this work during 1972; to date he has examined 195 samples of talcum powders plus some miscellaneous samples for others at FDA.

Dr. Lewin has given us reports on his results from time to time, but we do not yet have a truly final report from him. Until we receive it, we cannot publicize the incomplete information in our possession. Dr. Lewin has written that the final report will be ready "within a few weeks" but he is a very busy man and our past experience suggests that it may not arrive until a few months from now.

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3-6-73

I hold a high regard for Dr. Lewin and the scientific quality of his work; of course, it is always necessary to maintain a critical attitude towards the results obtained by sophisticated analytical techniques. This has been particularly true in the present case, where the small amounts of asbestos involved, and the presence of transitional and altered mineralogical species, led to ambiguities in the data. In his eagerness to protect the public interest to the fullest extent, Dr. Lewin in certain cases interpreted borderline results as showing the presence of asbestos, in his earlier reports, but he later used a more conservative interpretation. He has spent a lot of time and energy in creative scientific work aimed at resolving the ambiguities (for which the public and FDA owe him a debt of gratitude) and he has succeeded for the most part. As you may know, some discussion of Dr. Lewin's earlier interpretation of the data was included in an article on asbestos in the Wall Street Journal of February 26, 1973.

Inasmuch as Dr. Lewin's results are judged acceptable, subject to the above comments, we have not undertaken a repeat survey. Because of the possibility that optical microscopy alone may constitute an acceptable technique for the detection of asbestos in talc (and is more generally available than X-ray diffraction) we are currently making a comparison between Dr. Lewin's results on selected samples and the results obtained by in-house FDA microscopists. After this comparison work is completed, a decision will be made as to the preferred procedure for detection of asbestos in talc. Details of the analytical procedure are needed for the official statement which FDA plans to issue on asbestos contamination of talc.

One more point should be noted, that FDA activities have already led to a substantial upgrading of the quality of talc used in cosmetic products. This is evident both from the results obtained by Dr. Lewin upon re-analyses of a given product where repeat purchases were made at retail over a period of time, and also from discussions with a principal supplier of talc who indicates that he now sells only asbestos-free grades of talc to the cosmetics industry.

With reference to your last question, FDA has undertaken extensive literature surveys on the carcinogenicity of asbestos and of talc, but the results thus far do not establish that talc itself is carcinogenic. We also have had discussions with members of the National Cancer Institute, where work is currently underway on carcinogenesis by fibers and minerals as well as other chemicals. As you probably realize, the mission and facilities of the National Cancer Institute are more appropriate than those of FDA for resolving the question of the possible carcinogenicity of pure talc; also, a period of many years will be needed to obtain the answer.

Page 3 - Dr. Lucile Adamson and Mr. Scott Lang

I trust that the above information satisfies your needs, and again express regret for the delay.

Sincerely yours,

Alfred Weissler, Ph.D.
Acting Director
Division of Colors and Cosmetics Technology
Office of Product Technology