MEMORANDUM OF MEETING
August 11, 1972

Between: FDA Representatives:

Robert M. Schaffner, Ph.D., Director, Off. Prod. Tech. BF-400
Benjamin M. Gutterman, Asst. Dir. for Coord, OPT, BF-402
Alfred Weissler, Ph.D., Actg. Director, DCCT, BF-430
John M. Gowdy, M.D., Asst. Dir. for Med. Aff., DCCT, BF-432
John A. Wenninger, Actg. Chief, Cosmetics Branch, DCCT BF-433
Howard N. Pippin, Chief, Guidelines & Compliance Res., BF-312

and

James H. Merritt, President, CTFA
John Warley, Counsel for CTFA
W. Nashed, Ph.D., Johnson & Johnson
R. Rolle, Johnson & Johnson
David H. Hamer, Johnson & Johnson
A. J. Goudie, Ph.D., Johnson & Johnson
Ian Stewart, Ph.D., McCrone Assoc. - Johnson & Johnson
Robert Giovacchini, Ph.D., Gillette Med. Eval. Lab.
Frederick Roesch, Whittaker, Clark & Daniels, Inc.
G.A. Sprott, Avon Products
Harold Schwartz, Ph.D., The Mennen Company
Murray Berdick, Ph.D., Chesebrough-Pond's Inc.
Seymour Z. Lewin, New York University

Subject: Asbestos in Cosmetics Containing Talc, Such as Dusting Powders and Face Powders.

The meeting was held at FDA, 200 "C" Street, S.W., Washington, D.C., Dr. Schaffner indicated that the meeting was requested by several individual companies as well as the Cosmetic Toiletry and Fragrance Association. The purpose of the meeting was to discuss preliminary results of the analysis of over 100 talc containing cosmetic products for asbestos contamination. The results indicated that over 40% of the samples may contain asbestiform minerals such as chrysotile or tremolite. The analyses were carried out by Dr. Lewin of New York University under contract to FDA.

Dr. Schaffner reported that FDA was preparing a "Proposed Statement of Policy" on "Asbestos in Cosmetics Containing Talc, Such As Dusting Powders and Face Powders." Dr. Schaffner indicated that when Dr. Lewin's final report is accepted by FDA it will be put on file with

The Hearing Clerk at the time the "Proposed Statement of Policy" is published in the Federal Register.

Mr. Merritt strongly objected to the possibility that FDA would make the analytical results public in such a way as to give brand names and manufacturers. Mr. Merritt indicated that such a disclosure of randomly selected samples in the market place would result in a great economic hardship for the companies involved and their employees. Dr. Schaffner said that he was advised that the final report would have to be released to the public. Mr. Merritt said that in his opinion that it is not legally the case and attempts by FDA to make the report public may cause CTFA to take legal action to prevent public disclosure. Mr. Merritt said the report, if released, should not disclose product and company names. Mr. Merritt continued by stating the FDA has traditionally operated with as great a reliance on voluntary industry compliance as possible. Dr. Schaffner indicated that public disclosure of such a report was official FDA policy. Mr. Merritt indicated that such policy had not been established since the final order on "Freedom of Information" has not yet been published in the Federal Register.

Dr. Berdick, serving as scientific spokesman for the industry group, asked if they could have Dr. Lewin outline the analytical methodology used to analyze for asbestos in talc containing cosmetic products.

Dr. Lewin reported that he used X-ray diffraction as a means of detecting chrysotile and tremolite (two species of asbestos) in the talc samples analyzed. The other mineral species he detected in the samples would not interfere with the analysis. The method has an apparent sensitivity of approximately 1 or 2%. The principal source of ambiguity by X-ray diffraction was the overlap of chrysotile and chlorite peaks in the diffraction pattern. No problems were noted with detection of tremolite. Chrysotile and chlorite could be differentiated by an independent analytical technique known as "differential thermal analysis" (DTA). Dr. Lewin then proceeded to review for the group the graphs obtained from analyses of talc by X-ray diffraction and DTA.

The industry group indicated that tremolite can occur in a non-fibrous form and therefore may not present a safety hazard. Dr. Lewin reported that optical microscopy could be used to differentiate massive form from fiber from for a particular species. It was agreed by all present that the massive form of tremolite should not be considered as asbestos. A discussion of the merits of the use of electron micrographs for the detection of asbestos in talc products took place at this point in the meeting.

Dr. Berdick asked if all the cosmetic samples analyzed by Dr. Lewin were analyzed by more than one method, namely, x-ray diffraction. Dr. Lewin indicated only a few of the x-ray diffraction results were confirmed by other methods.

Dr. Nashed of Johnson and Johnson (J&J) reported work they had done on a J&J product which Dr. Lewin reported as having chrysotile. Dr. Nashed reported that J&J scientists (Dr. Stewart and Mr. Rolle supervised the analyses) had examined a portion of the very same sample that Dr. Lewin had analyzed and found no detectable chrysotile. They reportedly used the following techniques, petrographic analysis, electron microscopy, electron diffraction, powder camera x-ray, scanning x-ray and step scanning x-ray. J&J scientists were confident that had their sample contained chrysotile they would have found it. From the code on the sample analyzed by Dr. Lewin they were able to isolate one sample from reserved stocks for each month that the product was manufactured from February 1970 to August 1971. Each sample was analyzed for chrysotile and no detectable amount was found. A technical discussion on the reliability of the various analytical methods used to detect chrysolite was carried out at this point in the meeting.

Dr. Berdick suggested that Dr. Lewin's results should be verified before any public disclosure of the results is contemplated by FDA. He suggested that Dr. Lewin report as it stands is incomplete. Dr. Berdick echoed Mr. Merritt's earlier statement that publication of the results (which he felt needed confirmation) at the present time would do great harm to any company. If the results should be in error there is virtually no way to undo the harm.

Dr. Nashed said that J&J would make all analytical data on the analyses of their talc sample available to FDA on a non-confidential basis in the very near future.

Dr. Schaffner asked Dr. Lewin how long it would take to confirm his findings. Dr. Lewin thought that if the confirmation were carried out by optical microscopy it would take about four weeks. Dr. Schaffner indicated that a final report on these samples (about 40) would be expected before October 1, 1972.

There was no disagreement between FDA and industry scientists present at this meeting about the potential safety hazard that the presence of asbestos in talc containing cosmetic product poses to the consumer.

John A. Wenninger

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