

MEMORANDUM OF MEETING

January 7, 1975

BETWEEN: FDA Representatives

Robert M. Schaffner, Ph.D., Associate Dir. for Technology  
William Horwitz, Ph.D., Dep. Dir., Assoc. Dir. for Sciences  
Heinz J. Eiermann, Dir., Division of Cosmetics Technology  
Henry M. Davis, Actg. Branch Chief, Product Composition Br.  
Ronald L. Yates, Product Composition Branch

and

Cosmetic Industry Representatives

Dr. Murray Berdick, Chesebrough Ponds  
Mr. George Sandland, Bristol Myers  
Dr. George Lee, Johnson and Johnson  
Dr. Norman Estrin, CTFA  
Dr. Robert Rolle, Johnson and Johnson

SUBJECT: Status of Regulations(s) Regarding Asbestos in Talc

Mr. Sandland opened with a general statement concerning the purpose of the request for a meeting between industry and FDA. First, he would like to know the status of the proposed regulation concerning asbestos in talc. Mr. Sandland stated that a standard for talc in the form of a regulation was unnecessary because evidence indicates that chrysotile does not occur in talc. Dr. Schaffner replied that the FDA, in order to meet its responsibilities, was still interested in having a method for the determination of chrysotile in talc.

Dr. Horwitz then reviewed work that has been done recently on the development of methodology for determination of chrysotile. He stated that not much work was being done on the development of optical microscopic methods because it was a generally troublesome procedure. He added that the Franklin Institute, doing contract work on chrysotile methods for the FDA, had concluded that it was unable to do gross determinations of chrysotile by SEM because of problems encountered during sample preparation. Dr. Horwitz said that Franklin Institute has done no additional talc surveys since their last report.

Mr. Sandland then stated that the industry was being cooperative and responsive to this need by setting up the CTFA methods committee.

Dr. Rolle summarized the work done by the CTFA methods committee. A number of coded, spiked samples were sent to various investigators for round robin analyses. It was found that analysis for amphibole (tremolite) minerals by x-ray diffraction was a reliable method with a sensitivity of 0.5%. Dispersion staining was found to be a good method for the detection of tremolite. For the determination of chrysotile, Dr. Rolle stated that a combination of two methods were investigated. DTA was used for determination of chrysotile followed by optical microscopy for confirmation. This approach, based on results received from round robin investigators, was not reliable because DTA could not distinguish between chrysotile and antigorite and that optical microscopy was not suitable for confirmation because of the small fiber dimensions of chrysotile. He added that he has tried everywhere to obtain a natural sample of talc containing chrysotile but has so far been unsuccessful. Dr. Rolle stated that although SEM can detect chrysotile, the industry needs a more rapid method for this determination.

Dr. Murray Berdick then asked the FDA representatives if we had any evidence that chrysotile occurred in cosmetic talc.

Mr. Eiermann replied that if evidence indicates that chrysotile does not occur in talc, the cosmetic industry should not be concerned about possible regulations.

Dr. Berdick replied that industry would still have the expense of analyses as well as the problem of obtaining a representative sample from many tons of talc.

Dr. Horwitz said that the only evidence that the FDA has that indicates chrysotile is present in cosmetic talc samples is contained in Dr. S. Lewin's report.

Dr. Estrin stated that Dr. Lewin does not now believe that the samples analyzed contain chrysotile.

Dr. Horwitz replied that he did not get that impression when he last talked to Dr. Lewin.

Dr. Rolle said that Dr. Lewin told him that chrysotile is converted into forsterite during the grinding process.

Dr. Schaffner then stated that the CTFA should file a letter documenting the industry position concerning the proposed regulation and include all supporting evidence to be placed on file so that it can be evaluated by the Commissioner.

Mr. Sandland then summarized what the industry plans to do in the area of self-regulation. They plan to determine tremolite by continuous scanning x-ray diffractometry. He said he was sure there was no chrysotile present in cosmetic grade talc. Drs. Berdick, Rolle and Iee also said they could not find talc which contained chrysotile. Mr. Sandland also stated that, based on statistical data obtained from talc dusting experiments, 1% tremolite does not pose a health hazard. Using OSHA's standard for asbestos and the data obtained from the dusting experiments, Johnson and Johnson had calculated a safety factor of 48,000.

Mr. Eiermann pointed out that Johnson and Johnson's evaluation of the statistical data was partially in error because they did not consider transient concentrations of talc where the asbestos fiber count could exceed 10/cc, the upper exposure limit according to OSHA's standards.

Dr. Schaffner added, that from a public relations standpoint, exposure of infants to talc should not be equated to exposure limits established for miners.

Dr. Schaffner stated that perhaps the industry should address itself to the safety of talc per se with a series of animal studies.

*Ronald L. Yates*

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