Meeting Date: December 4, 1974
Release Date: December 19, 1974

MEETING NOTES OF CTFA TALC SUBCOMMITTEE

PRESENT:

Mr. George Sandland, Chairman	Bristol-Myers Products
Dr. George Cohen	Bristol-Myers Products
Mr. Alan M. Harvey	R. T. Vanderbilt
Mr. Ray Krammes	Whittaker, Clark & Daniels
Mr. George Lee	Johnson & Johnson
Dr. F. Robert Rolle	Johnson & Johnson
Mr. Joseph Simko	Colgate-Palmolive
Mr. Harold Stanley, Jr.	Pfizer
Dr. John Travers	Avon Products

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Dr. Murray Berdick	Chesebrough-Ponds
Dr. Christopher Costello	Colgate-Palmolive
Mr. Salvatore DiBianca	Mennen Co.
Dr. John Menkart	Clairol
Dr. Norman Estrin	CTFA
Mr. Eugene I. Lambert	Covington & Burling
Mr. Fred Roesch	Whittaker, Clark & Daniels
Dr. C. S. Thompson	R. T. Vanderbilt
Mr. Ronald Yakupcin	Kolmar Laboratories

The meeting was held in the Bristol-Myers Technical Services Conference Room at Hillside, N. J. G. Sandland presided.

The committee discussed the results of the round robin testing of talc samples to evaluate the DTA/optical microscope procedure for chrysotile and the x-ray diffraction/optical microscope procedure for amphibole, developed by the Ad Hoc Methodology Committee.

It was concluded that we can recommend x-ray diffraction with the optical microscope as back-up for the detection of amphibole at a 1% level.

Only 2 members supplied data using the DTA procedure for serpentine. The use of the optical microscope as back-up to differentiate non-fibrous serpentine (antigorite) from fibrous serpentine (chrysotile) was shown to be unreliable based on results from 3 investigators.

Investigator and Results

Coded Sample	Lucy & Walter McCrone McCrone Associates	H. Stanley Pfizer	D. Hamer Johnson & Johnson
A - Talc Sample from Pfizer containing chrysotile and Antigorite	none detected pass	chrysotile found - fail	Chrysotile found fail
B-1% Chrysotile in Talc prepared by a simulated industrial milling process	chrysotile found fail	none found pass	Chrysotile found fail
C-1.2% fibrous talc in platy talc	none found pass	none found pass	none found pass

The only other back-up procedure would be TEM which theoretically is satisfactory, but which has the following disadvantages:

1. Lack of availability to most talc users.
2. Its ultra sensitivity could be a problem.
3. A statistically significant sample size cannot be examined within a reasonable time frame.
4. Not amenable or compatible in a Quality Assurance environment.

Since we do not have a readily available back-up for DTA, it was agreed that we would have to depend solely on it, knowing that it will detect both fibrous and non-fibrous serpentine. However, since no one to our knowledge has ever detected chrysotile or antigorite by DTA in any cosmetic talc, it is our opinion that the risk involved, without a back-up method, is extremely small.

The committee concurred, though, that we should obtain additional data to confirm the reliability of DTA. Avon and Johnson & Johnson already have contributed data. The following additional sources of data will probably be available within the next few weeks:

H. Stanley (Pfizer) - expects delivery of new DTA (Mettler) this week and will do samples.

S. DiBianca(Mennen) - expects receipt of 1200° cell very soon and will do as soon as possible. Has duPont DTA.

R. Krammes (Whittaker, Clark & Daniels) - will have samples analyzed by De Bel and Richardson Testing Institute, Enfield, Conn.

J. Simko (Colgate-Palmolive) - expects to purchase DTA, but will attempt to have samples run by the instrument supplier prior to purchase. Mr. Simko feels that tests could be completed within next 2 months.

Dr. Rolle will furnish coded samples to each of the above participants as required.

One of the original aims of our Ad Hoc Methodology Committee was to work collaboratively with the technical staff at FDA, and at first, it appeared that John Stuart would be the contact. However, he has been deluged with assignments to the extent that he has been unable to be an active participant on the Methodology Committee. This is unfortunate, since such a divisive arrangement has made it virtually impossible to approach our goal on a common ground with FDA.

It was suggested that we attempt to set up a liaison meeting with Dr. Shaffner or Mr. Eiermann in order to establish a collaborative approach to the problems involved in this project.

Mr. Sandland pointed out that CTFA meets with FDA routinely by means of the Government Liaison Committee, and agreed to discuss the matter with Dr. Estrin in order to determine the best way to resolve the problem.

Mr. Harvey called the attention of the committee to an entry in the Federal Register of Monday, July 1, 1974, pertaining to Department of the Interior, Bureau of Mines and defining Health and Safety Standards in Metal and Nonmetallic Open Pit Mines. Threshold limit values are stated for "asbestos" which is defined to include only chrysotile, amosite, crocidolite, anthophylite asbestos, tremolite asbestos and actinolite asbestos. The word "asbestos" is included in naming the last 3 materials in order to differentiate them from the non-asbestiform types of these materials, such as tremolite of a non-asbestiform, which occurs in talc deposits, and is not mentioned in the definition, and, therefore, is not covered in the regulation.

The 8-hour time weighted average airborne concentration of asbestos dust to which employees are exposed shall not exceed 5 fibers per milliliter, greater than 5 microns in length. No employee shall be exposed at any time to airborne concentrations of asbestos fibers in excess of 10 fibers longer than 5 microns, per milliliter of air, as determined by the membrane filter method over a minimum sampling time of 15 minutes.

Mr. Harvey also stated that NIOSH is considering the establishment of a standard for talc which will be separate from the asbestos standard. This will require a joint overview study to determine the nature of all talcs and will probably take 2 to 3 years to complete from the time it is started.

Mr. Krammes circulated to the committee a Field Information Memorandum #74-92, to all OSHA Assistant Regional Directors and Area Directors on the subject of Tremolite and Talc. A copy of the memorandum is attached.

A significant feature which is apparent in both of the above government publications is a change in the definition of a fiber and an apparent deviation from the previous 3 to 1 aspect ratio definition.

The next meeting will be held on February 4, 1975 at 10:00 A.M. at the Bristol-Myers Technical Services Conference Room, 225 Long Avenue, Hillside, N. J.

The agenda will include:

1. Consideration of all available data on the DTA analysis for Chrysotile.

2. Finalization of our proposal for presentation to FDA.

George W. Sandland

G. W. Sandland
Chairman, CTFA Talc Subcommittee