

Johnson & Johnson

DOMESTIC OPERATING COMPANY

NEW BRUNSWICK, N. J.

November 28, 1977

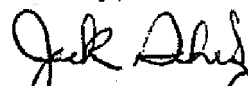
Mr. Ray Krammes
Whittaker, Clark & Daniels, Inc.
1000 Coolidge Street
South Plainfield, N.J. 07080

Dear Task Force Member:

The results for the CTFA round robin retest of coded talc samples have now been received from all participating laboratories. We should like to urge you to attend a meeting of our Task Force on December 6, 1977, beginning at 5:30 p.m. in the CTFA Conference Room. This meeting has been scheduled so as not to conflict with technical sessions being presented at the conference of The Society for Occupational and Environmental Health. This conference, "Occupational Exposures to Fibrous and Particulate Dust and Their Extension into the Environment", is being held at the Mayflower Hotel in Washington, December 4-7, 1977.

The main purpose of the Task Force meeting, as outlined in the attached agenda, will be to discuss in some detail an inter-laboratory comparison of data and to determine whether or not we have met our objectives. Hopefully, our meeting will conclude by 7 p.m. Please contact me (201/524-5518) if you cannot be present. Thank you for your continued support.

Sincerely,



John P. Schelz, Chairman
CTFA Task Force on
Round Robin Testing of
Consumer Talcum Products
Central Analytical Laboratories
Johnson & Johnson Research Center
New Brunswick, N. J. 08903

JPS/gm
Enclosure

cc: Dr. N. F. Estrin
Vice President-Science, CTFA
Mr. G. Sandland
Bristol-Myers Products

PLAINTIFF'S
EXHIBIT
WCD-419

**CTFA Talc Subcommittee
Task Force on Round Robin Testing of Major Consumer
Talcum Products for Asbestiform Amphibole Minerals**

Meeting Date: Tuesday, December 6, 1977
Time: 5:30 p.m.
Place: CTFA Offices
1133 15th Street, N.W.
Washington, D.C.

AGENDA

- I. Discussion of Partial Round Robin Retest data.
- II. Refinement of CTFA Method J4-1
 - A. Part I
 - 1. Specific sensitivity for fibrous vs. massive tremolite.
 - 2. Specific sensitivity for anthophyllite.
 - B. Part II, Tentative Revision
- III. Interaction with Mt. Sinai Environmental Sciences Laboratory
- IV. Possible CTFA Response to NIOSH Request for Establishing Safe and Healthful Criteria Relative to Occupational Exposure to Talc.

* Distributed (1) CTFA, SAC Committee on 3/18/76
(2) CTFA Talc Sub-Committee on 3/31/76

SUMMARY REPORT OF
CTFA TALC SUB-COMMITTEE

CTFA Talc Sub-Committee met on March 11, 1976 to review recent press report pertaining to analysis of talcum powder products.

As a result of information collated from the attending company representatives, the following facts were ascertained:

1. The samples were analyzed by Sinai in 1973.
2. Samples were confirmed as pre-1971 production with one product which has not been manufactured since the end of World War II.
3. The asbestos analytical results of Sinai are in conflict with those determined on the same samples by Dr. Pooley, a Cardiff scientist of world renown. Mt. Sinai reported ten samples as containing up to 20% asbestos, whereas Pooley detected asbestiform mineral in only five samples and at considerably lower levels.

Based on the above situation the committee felt that it would be important to put this situation in proper perspective by:

1. Presenting summary data to FDA to affirm the responsible action which has been pursued by our industry since 1972 when the asbestos concern first surfaced - Plan "A"
2. Considering a sampling of current industry production and submitting this to analysis by FDA, Mt. Sinai and independent analytical laboratories - Plan "B" - to be carried out only if Plan "A" were found to be insufficient.

Action taken to date has been the following:

1. Plan "A" was executed immediately over the weekend and on March 15, letters were received from the following companies and critically reviewed:

Avon
Chesebrough Ponds
Colgate Palmolive
Coty
Cyprus Minerals
Faberge
Johnson & Johnson
Walter McCrone Associates
Sterling Drug
Whittaker, Clark & Daniels

Approximately 4,000 analyses have been reviewed covering the period as early as 1971.

2. The talc sub-committee met with Dr. Schaffner and his staff on the afternoon of March 15 to summarize and present these documents. FDA was suitably impressed but urged consideration for the inclusion of a sampling plan in the CTFA Talc Standard. In consideration of the voiced practical difficulties, due to individual situations, Dr. Schaffner, as an alternative, suggested the voluntary submission of periodic reports on talc analyses. We were advised that the FDA has analyzed seventy six samples of talc products in 1975 and has not detected asbestos, according to their methods of analysis, "DTA and Optical Microscopy". Samples of these products implicated by Sinai have been offered by the FDA to Mt. Sinai laboratories for their analysis.

The Revised Talc Standard was submitted to the CTFA headquarters on March 18, 1976 for publication.

Another meeting of the Talc Sub-Committee has been scheduled for March 31, 1976 to discuss the following:

1. Discussion of further CTFA strategy, vis a vis, Mt. Sinai e.g. - data exchange, methodology of analysis.
2. CTFA analysis of FDA pick-up samples from their 1975 survey.



G. Sandland, Chairman
Talc Sub-Committee

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

COPY:

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.

Coded Sample	<u>Investigator and Results</u>		
	<u>Lucy & Walter McCrone McCrone Associates</u>	<u>H. Stanley Pfizer</u>	<u>D. Hamer Johnson & Johnson</u>
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, anthophyllite 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.



G. W. Sandland

Chairman, CTFA Talc Subcommittee