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MEETING NOTES OF CTFA TALC SUBCOMMITTEE

PRESENT:

Mr. George Sandland, Chairman	Bristol Myers Products
Dr. Murray Berdick	Chesebrough Ponds
Dr. George L. Cohen	Bristol Myers Products
Mr. Sal DiBianca	Mennen Company
Mr. Ray Krammes	Whittaker, Clark & Daniels
Mr. George Lee	Johnson & Johnson
Mr. Fred Roesch	Whittaker, Clark & Daniels
Dr. Robert F. Rolle	Johnson & Johnson
Mr. Jack Sivertson	Johnson & Johnson
Dr. C. A. Thompson	R. T. Vanderbilt
Dr. John Travers	Avon Products
Mr. Thomas Wolf	Colgate Palmolive

COPY:

Dr. Tryggve Baak	United Sierra
Dr. Christopher Costello	Colgate Palmolive
Mr. Harold D. Stanley	Pfizer
Mr. Ronald Yakupcin	Kolmar Laboratories
Mr. Alan M. Harvey	R. T. Vanderbilt

Scientific Advisory Committee

Covington and Burling

0022306

CTFA [Tremolite] [Asbestos]

REPORT OF AD HOC METHODOLOGY COMMITTEE

(Dr. F.R. Rolle, Chairman)

Dr. Rolle described the status of the work of the Methodology Committee:

The following samples were submitted to members of the committee who are able to perform analyses by Differential Thermal Analysis (for serpentine) and X Ray Diffraction (for amphibole).

1.) Sample spiked with chrysotile

2.) Sample spiked with tremolite

3.) Two samples supplied by FDA

4.) Two samples from Cyprus Mines (Unperfumed)

5.) One sample from Pfizer (Unperfumed)

6.) Sample of Avon's Rapture

7.) Sample of Ammens Powder

8.) Sample of Cashmere Bouquet

9.) Sample of Johnson's Baby Powder

Items 6, 7, 8 & 9 were purchased from the market, and since they might have been recognized by odor, were masked by the addition of musk oil.

All samples were submitted with a code number as the only identification. Dr. Rolle alone, has the cross referenced identification. Methodology involves DTA for Chrysotile and X Ray diffraction for tremolite with microscopy as a follow up secondary method in the case of a positive for serpentine. IR is an alternate method for tremolite. Copies of the methods are attached.

Not all of the participants in the round robin have completed the tests, however, there is very good agreement of data among the submissions received so far. One sample from FDA showed the presence of serpentine particles.

0022307

The DTA method for serpentine has a limit of 0.5 to 1.0%. One limitation in the method occurs when a positive reading is found, requiring a follow-up using microscopy. The method requires reading an exothermal peak at 800° and an endothermal peak at 650°C.

Antigorite will be detected as serpentine, but shows up as platey by microscope. Many times chrysotile is so fine that it can't be seen by optical microscopy at 300X to 1000X, but it will be detected by SEM and still requires TEM for positive identification and determination.

A talc sample containing 0.75% tremolite failed using the x ray diffraction method. Avon was able to detect tremolite at this level also, by means of I.R. spectroscopy. One advantage in the IR method is its specificity for tremolite.

Dr. Rolle stated that FDA resurrected the optical microscopic method in May and requested samples to be run by J & J and McCrone, both of whom came up with results similar to those obtained in our "round robin" evaluation in 1973. The same criticisms of the method were likewise offered.

Dr. C. S. Thompson gave a report of discussions with the N.Y. Bureau of Mines and their consideration of proposals submitted by R.T. Vanderbilt:

1.) It has been proposed that the certification of an ore body, or mine, be required in order for it to be used to supply talc for cosmetic, food, or similar uses.

2.) Suggestions have been made to get around "aspect ratio" as the definition of a fiber. An aspect ratio of 3 to 1 and length greater than 3 to 5 M has been pushed by FDA. ASTM on the other hand is considering a 100 to 1 aspect ratio.

Dr. Thompson stated that RTV is well on the way to getting NIOSH to work on this problem along with a review of an RTV petition.

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Mr. J.N. Sivertson, Manager of Statistical and Computer Operations at J & J then presented "An Estimate of a Safe Detection Level of Asbestos Fiber in Baby Powder Talc." A copy of the report is attached. Included attached also is Reference (1) which represents the source of the data used.

0022308

The data presented by Mr. Sivertson indicate clearly that a 1% limit each for asbestos and tremolite in talc would offer significantly (48,300 times) better protection for the users of talc based products, than would be provided, using the 1976 OSHA standards for talc miners. In addition, we now have adequate, dependable analytical methodology to make the application of the specification realistic.

We recommend, therefore, that a recommendation be made by CTFA to FDA that a proposal of the 1% limits be published in the Federal Register. This recommendation should be well accepted this time since they favor the methods approach and also the very substantial safety factor based on the J & J data should lend weight to the proposal. FDA has already received the Reference (1) material and has had ample opportunity to review it.

The J & J data are based on work done by Dr. Pooley using J & J Baby Powder. The CTFA Talc Subcommittee has compiled a sedimentation rate comparison of J & J Baby Powder with several brands of talcum powders representing 80% of the total market. This comparison was described in our meeting notes of January 4, 1974 (Release date - April 4, 1974), and should justify the application of the J & J data to all talcs.

In a review of literature available on the subject of tremolite, all investigators whose work has been published appears to demonstrate that tremolite is not carcinogenic. We refer this to the Pharmacology and Toxicity Committee for an opinion regarding the need for any additional substantiation of the non-carcinogenicity of tremolite. A copy of a literature survey is appended for reference. (SAC Committee only)

If indeed, tremolite is not a carcinogen, it would appear that a specification limit of 1% may be unnecessary, and we should recommend either a higher limit, or perhaps no limit at all in our petition to FDA.

The time is particularly propitious for us to petition FDA. There is no regulation, (only a proposal which has been refuted not only by industry but also by academic experts) and unless FDA comes up with some form of regulation soon, the individual states will be making up their own. If we permit this to happen, there will be most certainly a lack of uniformity across the board.

It is requested that this subject be discussed as part of the agenda for the next meeting of the Scientific Advisory Committee on September 18, 1974.

G. W. Sandland
Chairman, CTFA Talc Subcommittee

0022309