

Meeting Date: December 7, 1973
Release Date: December 21, 1973

MINUTES

Meeting of CTFA Talc Subcommittee

Present:

Mr. George W. Sandland (Chairman), Bristol-Myers Products
Dr. Tryggve Baak
Dr. Christopher Costello, Colgate-Palmolive Research Center
Mr. John N. Facq, Colgate-Palmolive Research Center
Mr. David H. Hamer, Johnson & Johnson Research Center
Mr. Allan M. Harvey, R. T. Vanderbilt Company
Mr. Raymond R. Krammes Whittaker, Clark and Daniels Co.
Dr. George Lee, Johnson & Johnson Research Center
Mr. Louis D. Murino, United Sierra Co.
Dr. Wilson Nashed, Johnson & Johnson Research Center
Dr. Fred Roesch, Whittaker, Clark and Daniels Co.
Dr. F. Robert Rolle, Johnson & Johnson Research Center
Dr. John P. Schelz, Johnson & Johnson Research Center
Dr. Joseph Simko Colgate Polmolive Research Center
Mr. Harold Stanley, Charles Pfizer Company
Dr. John Travers, Avon Products, Inc.
Mr. Ronald Yakupcin, Kolmar Laboratories, Inc.

The meeting was held in the Colgate-Palmolive Research Center, Piscataway, New Jersey

The results of the "round robin" analysis of seven talc samples were discussed. A summary of the data follows:

PLAINTIFF'S
EXHIBIT
WCD-399

<u>Sample</u>	<u>No. of Fibers With R.I. Greater Than 1590</u>	<u>No. of Fibers With R.I. Less Than 1574</u>	<u>Status With Regard to Pro- posed FDA Method</u>
<u>Mrs. Lucy McCrone, McCrone Associates for Chesebrough</u>			
Spiked	320	16	Passes
Italian	120	0	Passes
Montana- I	0	0	Passes
Alabama	0	0	Passes
Vermont	0	0	Passes
No. Carolina	0	0	Passes
Montana- II	0	0	Passes

Mr. Harold Stanley of Pfizer

Italian	~ 100	> 100	Fails Chrysotile Passes tremolite
Montana- I	~ 100	> 100	Fails Chrysotile Passes tremolite
Montana- II	~ 100	> 100	Fails Chrysotile Passes tremolite
Alabama	~ 100	> 100	Fails Chrysotile Passes tremolite
Vermont	~ 100	> 100	Fails Chrysotile Passes tremolite
No. Carolina	~ 100	> 100	Fails Chrysotile Passes tremolite
Spiked	< 1000	> 100	Fails Chrysotile Passes tremolite

Mr. David Hamer of Johnson & Johnson

Italian	0	0	Passes
Montana- I	1	0	Passes
Montana- II	25	0	Passes
Alabama	0	0	Passes
Vermont	0	0	Passes
No. Carolina	0	0	Passes

Dr. John A. Reffner (U. of Conn.) for Avon

Spiked	632	12,930	Fails Chrysotile Passes Tremolite
Italian	220	1,114	Fails Chrysotile Passes Tremolite

<u>Sample</u>	<u>No. of Fibers With R.I. Greater Than 1590</u>	<u>No. of Fibers With R.I. Less Than 1574</u>	<u>Status With Regard to Pro- posed FDA Method</u>
<u>Dr. John A. Reffner (U. of Conn.) for Avon Cont'd.</u>			
Montana-I	0	5,844	Fails chrysotile Passes tremolite
Montana-II	13	9,281	Fails chrysotile Passes tremolite
Alabama	26	15,125	Fails chrysotile Passes tremolite
Vermont	41	165	Fails chrysotile Passes tremolite
No. Carolina	14	11,852	Fails chrysotile Passes tremolite

Dr. Tryggve Baak of United Sierra

Spiked	3,000	2,000	Fails
Italian	1,000	0	Passes
Montana-I	0	0	Passes
Montana-II	0	0	Passes
Alabama	0	0	Passes
Vermont	0	0	Passes
No. Carolina	500	0	Passes

Richard E. Stevens of Ernest F. Fullam, Inc. for Whittaker-C&D

Italian	8,250	1,350	Fails chrysotile & tremolite
Montana-I	18,000	450	Fails chrysotile & tremolite
Montana-II	29,250	5,200	Fails chrysotile & tremolite
Alabama	21,825	6,075	Fails chrysotile & tremolite
Vermont	3,225	675	Fails chrysotile & tremolite
No. Carolina	20,850	6,000	Fails chrysotile & tremolite

Spiked sample was not run.

Sample	No. of Fibers With R.I. Greater Than 1590	No. of Fibers With R.I. Less Than 1574	Status With Regard to Pro- posed FDA Method
<u>Mrs. Lucy McCrone of McCrone Associates for Kolmar</u>			
Italian	53	0	Passes
Montana-I	0	0	Passes
Montana-II	0	0	Passes
Alabama	0	0	Passes
Vermont	0	0	Passes
*No. Carolina	0	0	Passes
Spiked Sample	488	16	Passes

*Sample noted to contain some fiber bundles which are rolled up talc plus some non-fibrous tremolite

The following participants examined their samples but were unable conscientiously to count particles with confidence, therefore, did not report numbers:

Miss Marie Jones for Dr. G. Cohen - Bristol-Myers Products Research Labs.
Mr. Salvatore DiBianca - The Mennen Company
Liberty Mutual Insurance Co., Research Center - for Kolmar Laboratories
Mr. John Facq - The Colgate Palmolive Company, Research Center

It was agreed that the strong inconsistencies among the data obtained by different scientists using the same method on duplicated sets of samples, clearly show that the optical microscopic method proposed in the Federal Register, vol. 38 (No. 188), p. 27076, September 28, 1973, requires either modification or replacement of a more dependable method.

Among the criticisms offered were:

1. Talc plates standing on edge are easily misidentified as fibers, since one of the two indices of refraction will vary between 1.539 and 1.550.
2. The determination of relative refractive index becomes unreliable when applied to extremely small (1 μ m in width) particles, since at this dimension we approach the limit of resolution and applying the Becke line technique becomes extremely difficult.
3. Chlorite, which has a refractive index range of 1.57 to 1.66, will be incorrectly identified as tremolite, in many instances.
4. The use of a one milligram sample provides a field which is too dense for good petrographic study.
5. The implication that all fibrous particles in talc, having optical properties similar to those of asbestos, are indeed asbestos is very

probably an unwarranted assumption.

6. The number of petrographic experts with sufficient depth and training in the use of the optical microscope, is very small.
7. The amount of time required for one analysis ranges from 2 to 5 hours, and a borderline sample would likely to be considerably longer.

It was agreed to urge FDA to defer finalizing the proposed optical microscopic method until it can be altered to be more reliable, or even replaced if necessary. We hope that a cooperative effort between FDA and ourselves can be launched as soon as possible toward this goal.

Dr. Costello suggested that we set up a task force to develop alternative methods, and all agreed. The following scientists volunteered to serve as members:

Dr. Tryggve Baak	Dr. John Schelz
Mr. John Facq	Dr. Joseph Simko
Mr. David Hamer	Mr. Howard Stanley
Dr. F. Robert Rolle	

Dr. Rolle agreed to serve as head of the task force.

The question was raised whether we would be able to encourage a non-industry scientist (or scientists) to serve on the task force. It was agreed that this is a good idea, however, there may be some financial considerations involved. Mr. Sandland will explore the availability of funds from CTFA if required.

Mr. Sandland will also draft an expanded version of Dr. Rolle's summary of data from the "round robin", along with our recommendations for presentation to the Food and Drug Administration. A copy of the draft will be sent to the membership of the CTFA Talc Subcommittee and Scientific Advisory Committee for review.

Addendum:

The expanded, complete report was drafted By Mr. Sandland and submitted to the Talc Subcommittee and the Scientific Advisory Committee on December 10, 1973. After receiving comments and approval from members of both committees, the report was sent to Dr. Estrin. Dr. Estrin cleared the Subcommittee Report through the CTFA Government Relations Committee on Wednesday, December 19, 1973 and indicated that it will be sent with a covering letter to FDA on Friday, December 21, 1973.

Respectfully submitted to the
Scientific Advisory Committee,


George W. Sandland, Chairman

GWS/lmw