DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

September 5, 1973

Norman F. Estrin, Ph.D.
Vice President, Science
Cosmetic, Toiletry & Fragrance Assoc.
1625 Eye Street, N.W.
Washington, D.C. 20006

Dear Norman:

This will confirm the discussion Dr. Schaffner, Mr. Wenninger and I had with you last Friday, August 31, 1973, concerning methods of determination of asbestos in cosmetic talc products.

There is considerable controversy among investigators with regard to the accurate determination of asbestos at concentrations of less than 2 percent. Apparently, conventional methods employing x-ray diffraction or differential thermal analysis are not sufficiently reliable to produce quantitative results of the desired precision. The Food and Drug Administration, therefore, has been exploring refractory optical microscopy as a means of measuring asbestos in talc. A copy of this method was handed to you on Friday.

You were urged to contact the scientific experts in the cosmetic industry and have them analyze samples of cosmetic talcs by this method. The results of their findings and their comments on this analytical procedure should greatly assist FDA in the assessment of the asbestos problem.

The second request submitted to you concerned a statistical measurement of the amount of airborne talc that might be inhaled by an infant per day under average conditions of use of a baby talc product. This information should be helpful in estimating the potential exposure of a child to asbestos.

The data provided by industry will supplement the efforts initiated by FDA in this matter and hopefully resolve the asbestos question in a scientifically sound manner.

Sincerely yours,

Heinz J. Eiermann, Acting Director
Division of Cosmetics Technology
Office of Technology

The Cosmetic, Toiletry and Fragrance Association, Inc.

1625 EYE STREET, N.W., WASHINGTON, D. C. 20006 202/393-2070

James H. Merritt
President

Norman F. Estrin, Ph.D.
Vice President—Science

FRED ROESCH

Mr. C.U. Driscoll
President
Whittaker, Clark & Daniels, Inc.
1000 Collidge Street
South Plainfield, New Jersey 07080

The FDA, Mr. Driscoll --

-- has informed us that they are about to publish limits for asbestos in foods and will utilize an optical microscopy method for the determination.

Their problem is that the Bureau of Foods has been considering an X-ray diffraction method for cosmetic analysis of asbestos that has a sensitivity of one to two percent, as opposed to the claimed sensitivity microscopic method of 0.001 to 0.1 percent. FDA does not feel it can publish two different methods of differing sensitivities and has asked our cooperation in testing their optical method.

FDA proposes that cosmetic manufacturers test and submit coded data for various cosmetic grade talcs, so that they can check on the validity of the method and get a feel for the type of results which can be expected.

I have attached a copy of the method for your review and a copy of a letter from Heinz J. Eiermann (FDA) requesting assistance from the Cosmetic Industry.

If you would like to participate by testing talcs, please drop a note to me or to Mr. George Sandland (Bristol-Myers) who is chairing a subcommittee which will test this and other methods.

Thank you for your cooperation.

Cordially,

Norman F. Estrin, Ph.D.
Vice President - Science

NFE:jj
September 13th, 1973
Attachments - 2

10/4

MEMBERSHIP LIST - CTFA TALC SUBCOMMITTEE

G. W. Sandland, Chairman (SAC)
Bristol-Myers Products

Dr. Murray Berdick (SAC)
Chesebrough-Ponds, Inc.

Dr. George Cohen
Bristol-Myers Products

Dr. Christopher Costello (SAC)
Colgate-Palmolive Company

Mr. Salvatore DiBianca
The Mennen Company

Mr. John Facq
Colgate-Palmolive Company

Mr. David Hamer
Johnson & Johnson Research Center

Mr. Alan M. Harvey
R. T. Vanderbilt, Inc.

Mr. Ray R. Krammes
Whittaker, Clark and Daniels

Mr. Adolph Maruszewski (SAC)
Kolmar Laboratories, Inc.

Mr. Louis D. Murino
United Sierra

Dr. DeWitt Petterson
Johnson & Johnson Research Center

Dr. Robert Rolle
Johnson & Johnson Research Center

Mr. Fred Roesch
Whittaker, Clark and Daniels

Dr. Charles Rowland (SAC)
Avon Products, Inc.

Dr. Harold Schwartz (SAC)
The Mennen Company

Dr. Joseph Simko
Colgate-Palmolive Company

Mr. Harold D. Stanley, Jr.
Pfizer

Mr. Wallace Steinberg (SAC)
Johnson & Johnson

Dr. John Travers
Avon Products, Inc.

Dr. C. S. Thompson
R. T. Vanderbilt, Inc.

Mr. Ronald Yakupcin
Kolmar Laboratories

Dr. Tryggve Baak
United Sierra

December 11, 1973

December 10, 1973

TO: MEMBERS OF THE CTFA TALC SUBCOMMITTEE & SCIENTIFIC ADVISORY COMMITTEE:

Mr. Lucas Ramirez

Attached herewith and submitted for your reading and comments is a finalized submission of the report of the CTFA Talc Subcommittee which we wish to submit to the Food & Drug Administration.

Please read at once and, likewise, call me at once if you disagree with any of the content matter.

In view of the very short time left to process this submission, your immediate attention is of paramount importance.

Thank you,

George W. Sandland

George W. Sandland
Chairman CTFA Talc Subcommittee

REPORT OF CTFA TALC SUBCOMMITTEE ON METHOD TO DETECT CHRYSOTILE AND TREMOLITE IN TALC.

December 10, 1973

The Scientific Advisory Committee of the Cosmetic, Toiletry & Fragrance Association, 1625 Eye Street, N.W., Washington, D.C. 20006 at a meeting held on September 2, 1973, designated that a subcommittee be set up to study the optical microscopic method proposed by the Food and Drug Administration. This method was published in the Federal Register of September 28, 1973. The present membership of the CTFA Talc Subcommittee is shown on an attached sheet.

At the first meeting of the Subcommittee, it was agreed to submit several samples of talc to members who volunteered to apply the FDA proposed optical microscopic method. The following talc samples were distributed without identification - except for randomly applied and non-duplicated code numbers:

Italian Talc	Grade #1615
Montana Talc	Source P
Montana Talc	Source F
Vermont Talc	Grade #66
Alabama Talc	
No. Carolina Talc	Grade 643

In addition, a sample of Italian Talc spiked w/w with 1% chrysotile and 0.15% tremolite was sent to each participant. The participants were aware that the sample was spiked, but did not know the percentage of spiking.

The attached table summarizes all reports submitted:

Sample	No. of Fibers With R.I. Greater Than 1590	No. of Fibers With R.I. Less Than 1574	Status With Regard to Proposed FDA Method
Mrs. Lucy McCrone, McCrone Associates for Chesebrough			
Spiked	320	16	Passes
Italian	120	0	Passes
Montana-Pfizer	0	0	Passes
Alabama	0	0	Passes
Vermont	0	0	Passes
No.Carolina	0	0	Passes
Montana-Ferry	0	0	Passes
Mr. Harold Stanley of Pfizer			
Italian	$\sim$ 100	$>$ 100	Fails Chrysotile Passes tremolite
Montana-Pfizer	$\sim$ 100	$>$ 100	Fails Chrysotile Passes tremolite
Montana-Ferry	$\sim$ 100	$>$ 100	Fails Chrysotile Passes tremolite
Alabama	$\sim$ 100	$>$ 100	Fails Chrysotile Passes tremolite
Vermont	$\sim$ 100	$>$ 100	Fails Chrysotile Passes tremolite
No. Carolina	$\sim$ 100	$>$ 100	Fails Chrysotile Passes tremolite
Mr. David Hamer of Johnson & Johnson			
Italian	0	0	Passes
Montana-Pfizer	1	0	Passes
Montana-Ferry	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

Sample	No. of Fibers With R.I. Greater Than 1590	No. of Fibers With R.I. Less Than 1574	Status With Regard to Proposed FDA Method
Dr. John A. Reffner (U. of Conn.) for Avon Cont'd			
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 Proposed FDA Method
	Mrs. Lucy McCrone of McCrone Associates for Kolmar		
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

The table reveals strong inconsistency between results obtained by the different scientists applying the method to the same group of coded talc samples. This inconsistency is the result of problems encountered in the methodology.

1. The alpha refractive index of talc - one of the two indices exhibited by talc plates standing on edge - varies in value between 1.539 and 1.550[1]. This in combination with item 2, below, may easily result in the mis-classification of such plates as "fibrous, less than 1.574" and therefore chrysotile.

   Dr. Reffner of the University of Connecticut, in his report to Avon, admits that this factor is paramount - "counts for chrysotile are high since (talc) edges will often be mistaken for fibrous particles".

2. The immersion method for the determination of relative refractive index becomes unreliable when applied to extremely small (ca. 1 μm) particles. This is due in part to the fact that particles around 1 μm in width approach the limit of resolution of the human eye when both size and contrast are considered, especially when applying the Becke line technique prescribed. This will

2. cause eye fatigue and resulting errors. Thus, a fine talc shard or plate on edge may be easily mistaken for an asbestos fiber. This applies to both the chrysotile and amphibole portions of the test.

3. It is quite likely that chlorite - a mineral of varied composition commonly found in pharmaceutical grade talc - would be incorrectly identified as tremolite. Refractive indices for chlorite vary in the range 1.57-1.66[2].

4. The examination of a sample of one milligram dispersed on a single microscope slide presents the investigator with a preparation which is too dense for a petrographic study.

5. The method is laborious and time consuming. Dr. Reffner quotes an analysis time of about five hours per sample and at JOHNSON & JOHNSON the investigator (D. H. Hamer) estimated at least two or three hours.

6. Dr. Walter C. McCrone in an earlier letter to the FDA suggested that there were relatively few scientists in the country who could use the method effectively. Scientists at Bristol-Myers, The Mennen Company, Liberty Mutual and Colgate-Palmolive had great difficulty in following the method to conclusion.

7. The proposed FDA method implies that all fibrous particles in talc having optical properties similar to those of asbestos minerals are in fact asbestos. This is probably an unwarranted assumption.

REFERENCES:

1. Deer, W.A., Howie, R.A., and Zussman, J., Rock-Forming Minerals, Vol. 3, p. 121 (1962).

2. Ibid, p. 131.

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We have concluded that the method published in the Federal Register does not provide a truly reliable means for the detection of asbestos in talc. It results in both false-positive and false-negative findings. It is also tedious and may consume as much as one half day per sample.

The subcommittee urges that the Food and Drug Administration defer finalizing the proposed optical microscopic method and proceed into a Phase II program which would combine FDA and Industry in a strong effort to develop a truly reliable method for measuring chrysotile content in talc. We are confident that the detection and estimation of fibrous tremolite can also be done, if necessary, as a fringe benefit, at the same time.

We estimate that a satisfactory method will take at least six months to a year to develop. We suggest a close liaison between FDA and industry in this all-out effort with updating reviews to take place as frequently as necessary.

Review of Alternate Methods

The CTFA Talc Subcommittee has reviewed several methods to detect chrysotile and tremolite in talc, including modifications of the optical microscopic method. These are listed with comments.

1. Optical Microscopic Method - may be used with some modification. Possibly better selection of R.I. liquids and reduction of sample size per slide.

2. X-ray Step Scanning - A good method for detecting tremolite if we could accept about 0.2% as the threshold of detection. It does not distinguish fibrous from non-fibrous tremolite. The simultaneous detection of chlorite makes method impractical for chrysotile.

3. X-Ray Step Scanning + Optical Microscopy - Acceptable as in #2 above but the optical method continues to present the dilemma in reliable identification of chrysotile. However, this does not rule out a major revision of the optical method to do the chrysotile identification and counting.

4. X-Ray Scanning - The problem of chlorite interference in the detection of chrysotile is present in all x-ray procedures thus far available. It is reliable for the detection of 1% tremolite (both fibrous and non-fibrous).

5. Differential Thermal Analysis - This procedure is capable of detecting chrysotile at the 1% level, however, it will not detect tremolite.

6. Scanning Election Microscopy - This procedure is not capable of identifying asbestos. Even with energy dispersive analysis, completely satisfactory identification is not possible.

7. Transmission Electron Microscopy + Electron Diffraction - This appears to offer the best, most reliable method and is probably capable of detecting chrysotile and tremolite (fibrous), both at a level of 0.1%. It is estimated that an installation would cost about $130M +, and is obviously prohibitive for the small manufacturer who uses talc. The amount of talc sample examined by this procedure is miniscule.

Summary

The CTFA Talc Subcommittee has completed its review of the Optical Microscopic Method for the Estimation of Chrysotile and Fibrous Tremolite in Talc, which appeared in the Federal Register, vol. 38 (No. 188),(p. 27076, September 28, 1973). It recommends postponement of the finalization of the proposed regulation on talc. In addition, a collaborative effort between FDA & industry to resolve a satisfactory method of estimating chrysotile and tremolite in talc, is recommended, with periodic liaison reviews to monitor the project status. A task force of industry experts has been designated to pursue alternate methods. We invite FDA to participate in collaboration with the task force.

George W. Sandland
Chairman CTFA Talc Subcommittee

GWS:dd

Jack Travers reported that NIOSH has proposed a revised (lower) TLV of 50 mcg/cubic meter for crystalline silica.

Bob Rolle described the latest results of Round Robin #3 using the CTFA Proposed Optical Microscope Procedure For Detection of Chrysotile in Talc. This is the method intended to be used as a back-up to the DTA method, since DTA can give a false positive for chrysotile when non fibrous antigorite is present. Unfortunately, there was disagreement among 3 very capable investigators, McCrone Associates, Harold Stanley of Pfizer and Dave Hamer of Johnson & Johnson.

It was agreed, however, that chrysotile is never found in cosmetic talcs, based on numerous analyses by several investigators. The only discoverer of chrysotile in cosmetic talcs has been Professor Lewin, and his results have been refuted in a repeat testing of the same samples by John Stuart at FDA.

The committee concurred, therefore, that our only courses of action are either to rely only on DTA by itself (without a back-up procedure), or else, based on the wealth of data available, eliminate the need for a chrysotile specification in cosmetic talc. Either way, we are confident at this point, that chrysotile won't be found and simply is not present in cosmetic talc.

We are still awaiting additional DTA results on talc samples (some spiked) which were sent to Colgate-Palmolive, Mennen, Pfizer, and Whittaker Clark & Daniels. In addition, Jack Travers has submitted a set of samples to John Reffner (V. of Comm) for DTA analysis.

Jack Schelz described an inexpensive DTA unit sold by Columbia Scientific Industries costing $3350 without a recorder and about $4600 with a recorder. This instrument was evaluated by Dr. Schelz and was found to be capable of detecting serpentine minerals above the 0.5% w/w level in talc, when used according to the proposed CTFA test method.

It was agreed that we include in the procedure for chrysotile, the latest definition of a fiber as published by OSHA in Field Information Memorandum #74-92, which was sent to OSHA Assistant Regional Directors and Area Directors. This memorandum states that:

"In order to be considered asbestiform or fibrous the following criteria will be used by the Salt Lake City Laboratory of OSHA.

A. Particles must appear to be fibrous, rather than as crystals or slivers.

B. The maximum diameter of a fiber to be counted is 3 microns.

C. The maximum length of a fiber to be counted is 30 microns.

D. The length to width ratio must be 5 or more to 1, that is, 5 times or more longer than wide.

E. The separate or individual fibers must contain fibrils or the "bundle of sticks" effect, unless they are at a non-divisible stage. A fibril cannot be subdivided and would be counted, if it meets the other criteria. The electron microscope may be used to prove the fibrous nature of the particles. The length to width ratios of 5 or more to 1 is not meant to imply that other particles are not hazardous."

The directive states at the end that the above guidance is temporary and may change as a result of findings from an on-going NIOSH study on this subject.

A CTFA Talc Task Force comprised of Dr. Berdick, Dr. Estrin (CTFA), Mr. Lee, Dr. Rolle and Mr. Sandland will meet with Dr. Robert Schaffner, Mr. Eiermann and their designated personnel at FDA on Friday, February 7, 1975. It is planned to propose the 0.5 to 1.0% limit for each fibrous tremolite and chrysotile in cosmetic talc. Our CTFA Task Force developed methodology will be submitted in latest form as part of the proposal. A preliminary meeting at CTFA Headquarters will be held in the morning and the meeting with FDA is scheduled at 1:00 P.M.

A report of this meeting will be submitted to the members of the CTFA Talc Subcommittee.

Allan Harvey reported that he will attend a meeting on Tuesday, February 11, 1975 which has been called by Dr. Raymond E. Shapiro of FDA who is heading up a Subcommittee on Asbestos Protocols. This subcommittee was assigned the job of reviewing all existing data with respect to the biological effects of orally administered asbestos, with particular reference to carcinogenesis, and if necessary of

developing appropriate protocols for studies to elaborate on any data deficiencies in this area.

At the meeting of February 11th, the subcommittee members will discuss a working draft which has been furnished to them to provide a basis for comment and discussion.

A paper entitled "Is Short-Fibered Asbestos Dust a Biological Hazard?" by Paul Gross, M.D., Charleston, S. C. was discussed. Here Gross states there is evidence that asbestos particles which are submicroscopic in size (<5 microns)elicit only a macrophage reaction in the lungs of monkeys. Similar results resulted in several other animals including rats and hamsters when submicroscopic asbestos was injected intratracheally and intra-abdominally.

There being no further business, the meeting was adjourned.

George W. Sandland

G. W. Sandland
Chairman, CTFA Talc Subcommittee

Members of Talc Subcommittee. 2/26/75
Any comments on this? Please
bring to meeting. TALC BJ 3/11/75
George Sandbank

CTFA Specification
TALC
(Formerly TGA Spec No. 10)
Issued: 6-1-42
Revised: 3-23-62
5-20-71

DEFINITION: Talc is a white, odorless or very slightly earthy, finely powdered, native, hydrous, magnesium silicate, sometimes containing a small portion of aluminum silicate.

TEST	SPECIFICATION	METHOD
Color	As specified by the buyer and showing no change after heating	Heat 1 to 2 g at 200°C for 5 minutes
Odorless	As specified by the buyer	
Identification	Positive: Close match to CTFA Spectrum—IR with no indication of foreign materials	CTFA G 3-1
Slip	As specified by the buyer	
Lustre	Do.	
Carbonates	No effervescence	USP XVIII, page 708 Observe reaction for effervescence during digestion in Test for Acid-Soluble Substances
Water-Soluble Iron	Passes test	USP XVIII, page 708
Screen Test	100% through 100 mesh 98% minimum through 200 mesh Finer grades: as specified by the buyer	CTFA C 6-1
Alkalis and Acids	Neutral to litmus paper	USP XVIII, page 708 See Test for Reaction and Soluble Substances.
Water Soluble Substances	0.1% maximum	Do.
Acid-Soluble Substances	2.0% maximum	USP XVIII, page 708
Loss on Ignition	5.0% maximum	Do.
Arsenic (as As)	3 ppm maximum	CTFA F 1-1, Parts I-A and II
Lead (as Pb)	20 ppm maximum	CTFA F 2-1, Parts I-A and II
→ Tremolite (fibrous)	none detected	CTFA

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Note

The Cosmetic, Toiletry and Fragrance Association, Inc.

1133 15th STREET, N.W., WASHINGTON, D.C. 20005 • 202/331-1770 • TELEX 89-2673

James H. Merritt
President

Norman F. Estrin, Ph.D.
Vice President—Science

TALC TASK FORCE

M I N U T E S

A meeting of the Talc Task Force was held on February 7th, 1975. After a pre-meeting at the CTFA Offices, the Task Force reconvened at the office of Dr. Robert Schaffner at the Food and Drug Administration, 200 C Street, SW, Washington, DC. Those in attendance were:

Mr. George Sandland, Bristol-Myers (Chairman)
Dr. Murray Berdick, Chesebrough-Pond's
Mr. George Lee, Johnson & Johnson
Dr. Robert Rolle, Johnson & Johnson
Dr. Norman Estrin, CTFA

Those in attendance from the Food and Drug Administration were:

Dr. Robert Schaffner
Mr. Henry Davis
Mr. Heinz Fitzmann
Dr. William Horwitz
Mr. Ronald Yates

Mr. Sandland opened the meeting stating that the objective of the Task Force meeting was to give a status report on its activities and at the same time ascertain the status of work at FDA in this area. Dr. Schaffner responded FDA was still interested in development of satisfactory methodology and Dr. Horwitz noted briefly his work in this area.

Mr. Sandland called upon Dr. Rolle to give a report on CTFA progress. Dr. Rolle reported on the development of a Differential Thermal Analysis procedure for serpentine followed by an optical microscopy procedure, with detection limits between 0.5 and 1%. For amphiboles like tremolite, an x-ray diffraction method, followed by dispersion staining optical microscopy has been developed; this procedure allows determination of whether the

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material is fibrous or not. Dr. Rolle noted successful completion of round robin tests with detection levels between 0.5 and 1%. Dr. Rolle observed that he has been unable to obtain a single naturally occurring sample containing chrysotile.

Dr. Berdick questioned the need for a regulation on chrysotile since no sample has yet to be confirmed as containing this material.

Mr. Eiremann responded that he sees no problem with a regulation covering both amphiboles and chrysotile, since "if chrysotile is not there, you should have no problems."

Dr. Estrin and Dr. Berdick objected, stating that Mr. Eiremann was proposing regulations for the sake of regulation, and has not considered the wasteful tax on resources that would arise from inclusion of a standard for chrysotile. Dr. Berdick and Dr. Estrin concluded that if a regulation is not necessary, it should not be proposed.

Dr. Schaffner responded with a suggestion that CTFA send in a letter with documentation, showing the extent of tests and results which would support a recommendation about the inappropriateness of a regulation for chrysotile.

It was noted that Professor Lewin was the only scientist to ever have mentioned chrysotile in his report and the lack of confirmation of his results by other scientists.

Dr. Schaffner asked for a progress report on Professor Lewin's activities, and stated that [illegible] will speak to Dr. Lewin shortly concerning his progress.

Mr. Sandland noted that CTFA specifications for Talc published as part of the CTFA Standards, are up for revision. He reported that the new specifications will add a tremolite specification and the methodology for continuous scanning x-ray diffraction, but added that CTFA would not expect to include a specification for chrysotile. He added that chrysotile has never been found in cosmetic talcs from either European or dosmetic sources.

FDA was asked for its present timetable, and responded, it is ~~are~~ awaiting results from the Franklin Institute and have arrived at no definite time schedule for either a food or a cosmetic regulation.

Mr. Sandland proposed limits of 1% for tremolite, stating that based on the OSHA limit of 2 fibers per cc in an 8-hour day proposed for 1976, one would arrive at a safety factor of 48,000 if such a limit were adopted.

Mr. Eiermann questioned this calculation on the basis of his understanding of the OSHA limits for short and long-term exposures.

Dr. Schaffner added the political inadvisability of citing mine-worker standards for cosmetic talcs, and advised that it would be more meaningful to have animal studies with talc than statistical estimates.

Mr. Lee responded by noting animal work in progress.

Mr. Eiremann then proposed "non-detectable" terminology rather than numerical limits.

Mr. Yates noted briefly that there was no progress yet on enrichment for chrysotile and that he was pessimistic about the possibilities in this area.

Mr. Lee offered participation of the CTFA Talc Subcommittee in evaluating any methods developed by FDA.

There being no further business, the meeting adjourned.

Norman F. Estrin, Ph.D.
Vice President - Science

NFE:mp
2/17/75