



MINERALS, PIGMENTS & METALS DIVISION
RESEARCH CENTER • EASTON, PENNA.

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AUG 13 1971

EASTON, PA.

MEMORANDUM

Subject Asbestos in Talc "Analytical Methodology" **Date** August 10, 1971
Conference at FDA, Washington, D.C., 3 August 1971"

The writers attended the above conference as representatives for Pfizer. The purpose of the conference was to discuss in detail analytical methods for the determination of minor amounts of "asbestos like" material in talc with particular reference to cosmetic grade talcs.

The agenda and the list of people attending are enclosed. Individual topics were discussed by people knowledgeable in the discussion topics listed.

1. Asbestos and talc mineral deposits were discussed by Dr. Malcolm Ross of U.S. Geological Survey. The important points of his discussion were that:
 - a. There are two classes of asbestos type minerals which are commonly called chrysotile and "ampiboles". Under the class of ampiboles are included minerals such as tremolite and anthophyllite.
 - b. During Dr. Ross's discussion, a basic description of asbestos as it applies to this discussion was offered. "Asbestos is a fibrous fine grain mineral of the ampibole or chrysotile groups."
 - c. Chemical mineralogy of common talc deposits was discussed with particular reference to the New York talcs. It was rather disappointing that in no part of Dr. Ross's discussion did he mention Montana type talcs.
2. Fiber content of cosmetic talcum products was presented by Dr. L. J. Cralley. Dr. Cralley's discussion dealt with a publication he co-authored in 1968 involving the nature and extent of respirable fibers in typical samples of talc. Sources of fibers in talc according to Dr. Cralley are two fold (the ore itself and additives used in formulation of the final product). Dr. Cralley stated that of the 22 samples he examined the majority of them contained 9 to 30% fibers. Dr. Cralley defined a fiber as having a ratio of length and to width 3 to 1 or greater.

When questioned by those assembled at the meeting, it became apparent that the 9 to 30% fibrous fractions were essentially 100% talc as determined by Dr. Cralley's x-ray diffraction experiments.

**PLAINTIFF'S
EXHIBIT
WCD-253**

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Dr. Cralley presented some data concerning trace metal content of some typical commercial talcs. Again, it was rather interesting that no Montana talcs were considered in the study. He discussed New York, Georgia, North Carolina, French and Italian talcs.

The purpose for the trace metals analysis information at this meeting was not clear, since the objective was to discuss the methods for the determination of asbestos in talc. Several of the attendees made this point to Dr. Weissler, the moderator from FDA.

3. Biological-Medical Significance of Asbestos and Other Fibers.

- a. Dr. Selikoff, Mt. Sinai School of Medicine, presented data showing the affects of asbestos in the formation of certain types of rare lung cancer. A great deal of work has been done by the Mt. Sinai group involving the collection of biological medical data from a controlled group of asbestos workers dating back over the last 30 years. The results of this study give very good evidence that indeed asbestos causes certain types of lung cancer. The reason for the present emphasis being placed upon the detrimental affect of asbestos is that prior to about 1968 it was thought, as a result of clincial studies, that asbestos only caused irritation to the lung. The results of Mt. Sinai studies published in 1968, shows hard evidence for presence of lung cancer directly traceable to asbestos.
- b. Dr. G. Hildick-Smith from Johnson & Johnson discussed his experience in the biological medical investigation of asbestos and other fibers. Dr. Hildick-Smith's main argument was that in order to properly assess the asbestos in talc problem, one must determine the total lifetime exposure from talc for the average individual. In this context he has estimated that from birth to age 70 a person would have about two month's constant exposure to cosmetic talcum powder. In addition, Dr. Hildick-Smith presented complete results from a study involving the occurence of cancer in hamsters. The conclusions from this study were that tremolite and/or platy talc caused no case of cancer in any of the above mentioned subjects.

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Dr. Hildick-Smith was the first to point out that this information was only obtained on animals and did not necessary extrapolate to humans. However, he was very adamant in his opinion that specific work has not been completed to date to clearly demonstrate affects of fiber materials on the human system. He made particular comment to Dr. Selikoff's work at Mt. Sinai Hospital.

- c. Dr. Gross of the Medical University of South Carolina, discussed rather briefly, certain aspects of asbestos and other fibrous materials. Dr. Gross's main question to the assembly was how long do the fiber particles have to be in order to be harmful. The threshold limit value (TLV) regulation on asbestos requires that only those particles greater than 5 microns in length be counted.

Dr. Gross pointed out that this TLV was set up as a expedient to testing laboratories in that 5 microns is the smallest length that can easily be measured with a light microscope. He did admit that perhaps electron microscopy counting of particles would be a much better approach for the determination of the TLV for asbestos.

4. Current FDA Interest in Asbestos.

Dr. Barzilai of the FDA Bureau of Drugs, spoke very briefly on the results of a rather complete literature survey recently completed on the affects of asbestos and talc on humans. The main conclusions from this study were:

- a. There was no positive animal data showing asbestos and/or talc as the cause of cancer.
- b. There was no positive evidence for talc causing cancer even by the direct addition to certain body organs. In fact, talc is sometimes used as a fibrating agent in some types of complicated heart surgery.
- c. Inadequate physical and chemical data was collected on any of the materials reported in the literature up to 1968. Because of this it is very difficult for us to know precisely the individual minerals examined.

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5. Consumer Interest in Asbestos.

Mr. Morris Kaplan, representating The Consumers Union, made a very brief statement stressing the fact that any specification or requirements resulting from this meeting should be determined in such a manner that they eliminate any question of danger from the consumer standpoint.

6. Cosmetic Industry Interest in Asbestos.

Dr. Norman Estrin, representative from CTFA, gave a very brief statement expressing industry's concern in developing and supplying safe products. At this point of the proceeds, we had progressed through 2 1/2 hours of discussion which had not touched upon its true purpose, the description of methodology for the determination of asbestos in talc. Dr. Estrin stated this and indicated that we get down to the business at hand.

7. Analytical Methods for Asbestos.

- a. Mr. Wm. Eisenberg, from FDA, discussed the basic methods proposed by FDA for asbestos and talc. He based his complete determination on optical microscopy and refractive index measurements. Most of those attending pointed out that many of the particles we wish to examine are smaller in size than are resolvable by light microscopy.

It was felt that this determination could be used as a rough screening test on relatively coarse materials.

- b. Dr. Speil, from Johns-Manville, in our opinion was the high light of the meeting. He was to the point and brief. He recommended the following procedures for the determination of asbestos in talc:

1. X-ray diffraction--the amphiboles will give a 8.4 angstrom peak which is characteristic for all of these materials. Serpentine and chrysotile give peaks at 7.0 angstrom which are again very characteristic.

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2. He suggested petrographic microscope observation for the determination of the fibrous nature of the specimen. Exception was taken to this idea, as indicated in Section 7a, with electron microscopy observation being a more practical approach.

3. A complete bulk chemical analysis

The one really interesting point that Dr. Speil brought up was that instead of worrying about the bulk properties of talcum shouldn't we really be interested in air born analysis of talcs and the dusting properties of talc as determined in simulated test?

c. Mr. S. R. Mountsier, Jr., from Whittaker, Clark & Daniels, deferred his part of the discussion to Dr. Lewin, a consultant from New York University. Dr. Lewin's recommendations were that we consider x-ray diffraction as a primary test for the determination under discussion. Dr. Lewin had measured some of the same samples that we had previously measured for Whittaker, Clark & Daniels and our results were the same. Of particular interest is the absence of fibrous minerals in MP 399 (BX-106).

d. Dr. A. M. Langer, from Mt Sinai Hospital, discussed the procedures used by them for the determination of asbestos in talc. They were:

1. Light microscope.
2. X-ray diffraction.
3. Electron microscopy.

While discussing the aspects of the electron microscopy determination, Dr. Langer indicated that they had done a great deal of work by electron diffraction. However, when subsequently questioned on other points concerning electron diffraction, Dr. Langer was not clear thus raising some doubts in the minds of those attending as to the validity of their determinations

e. The writers representing PFIZER INC, indicated that they essentially agreed with the comments made by Dr. Speil and Dr. Lewin. We indicated that PFIZER:

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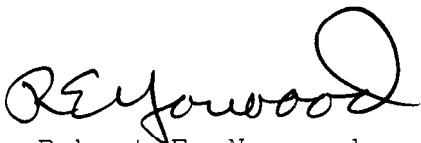
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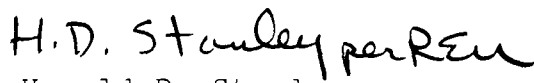
1. Determines mineralogy of the talcs by x-ray diffraction and that no amphiboles or chrysotile are detected in our Montana talcs.
 2. Determines bulk chemical properties on many of the talcs used for cosmetic purposes.
 3. Determines the morphology of talcs by detailed electron microscopy determinations. We demonstrated to the meeting typical electron micrographs of BX-106 Montana talc. Additionally, we showed electron micrographs of the same talc after doping with 1% fine grain asbestos. The results of this experiment were rather dramatic and showed conclusively that at least at this level it was possible to determine asbestos accurately. It is of interest to note that none of those attending this meeting had tried an experiment as direct and as obvious as this.
- f. Johnson and Johnson arrived with a rather impressive group as can be seen by the list of attendees. Professor Pooley was from an environmental control agency in Wales dealing with lung diseases in miners. Dr. Gene Grieger and Dr. Ian Stuart were from McCrone Institute and are considered experts in electron microscopy techniques. Dr. Caneer was from U.S.G.S. and is considered expert in optical microscopy and x-ray diffraction techniques. Each of the persons listed from Johnson and Johnson and their consultants described individual aspects of the asbestos in talc problem and dealt mainly with standard products from Johnson and Johnson. The methods recommended by Johnson and Johnson were x-ray diffraction coupled with electron microscopy.
8. As a result of this meeting, the following action will be taken.
 1. FDA will prepare a recommended procedure for the determination of asbestos in talc based upon the above discussion. The proposed procedure will include:

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- a. X-ray diffraction.
 - b. Electron microscopy.
 - c. Electron diffraction.
2. FDA will circulate copies of the proposed procedure to the attendees for comments and revisions.


Robert E. Norwood


Harold D. Stanley

REN:HDS:bls
Enclosures

cc: H. R. Bailey
J. P. Bartels
A. T. Gronet
S. M. Grossmann
C. F. Hagan
M. Hoffman/K. R. Hancock
J. W. Jenkins
W. E. McCoy
E. G. Ratcliffe
W. M. Stephenson
G. A. Wells✓
R. Linnett

DIVISION OF COLORS AND COSMETICS TECHNOLOGY
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C.

ASBESTOS AND TALC

Discussion Session, August 3, 1971, Room 1409, 200 C Street, S.W.
Moderator: Dr. Alfred Weissler

Discussion Topics

1. Asbestos and Talc Mineral Deposits - Dr. Malcolm Ross
U.S. Geological Survey
2. Fibrous Content of Cosmetic Talcum Products - Dr. L. J. Cralley
NIOSH
3. Biological-Medical Significance of Asbestos and Other Fibers -
Dr. I. J. Selikoff, Mt. Sinai School of Medicine
Dr. G. Hildick-Smith, Johnson and Johnson
Dr. Paul Gross, Medical University of S.C.
4. Current FDA Interests in Asbestos - Dr. R. E. Barzilai, Bureau of Drugs
Dr. J. K. Lamar, Bureau of Drugs
Dr. H. F. Kraybill, Bureau of Foods
5. Consumer Interest in Asbestos - Morris Kaplan
Consumers Union
6. Cosmetics Industry Interest in Asbestos - Dr. Norman Estrin
CTFA
7. Analytical Methods for Asbestos - William Eisenberg, FDA
Dr. S. Speil, Johns-Manville
S. R. Mountsier, Jr., Whittaker,
Clark & Daniels
Dr. A. M. Langer, Mt. Sinai
R. E. Norwood, Chas. Pfizer & Co.
Dr. W. Nashed et al., Johnson and
Johnson

DIVISION OF COLORS AND COSMETICS TECHNOLOGY
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C.

DISCUSSION SESSION ON "ASBESTOS AND TALC"

Tuesday, August 3, 1971 - 9:30 A.M.
Room 1409, Federal Building #8
200 "C" Street, S.W.

Purpose: To specify a laboratory procedure for the determination of asbestos in cosmetic talcum powders which will give consistent, meaningful results. This may require answers to such questions as:

1. Is there a need to count not only "asbestos fibers" but also "non-asbestos fibers" or "fibrous talc"?
2. Is there a need to specify the variety of asbestos: tremolite, chrysotile, anthophyllite, etc.?
3. What particle size ranges should be reported, on the basis on biological effects?
4. Should the analytical results reported for "% asbestos" be based on number of particles counted or on percent by weight as estimated from particle areas?
5. Can a similar procedure be used for determining the asbestos content of a variety of foods, drugs, and other products?

Format: Brief presentations (about 10 minutes each) on current work and judgments related to the problem. Emphasis on informal discussion and full exchange of information to provide a sound basis for the analytical procedure to be used.

Prospective Participants:

Lewis J. Cralley, Ph.D.,	-	National Institute of Occupational Safety and Health, Cincinnati, Ohio
Irving J. Selikoff, M.D.	-	Mt. Sinai School of Medicine
Arthur M. Langer, Ph.D.	-	"
William J. Nicholson, Ph.D.	-	"
L. J. Maggiori	-	"
Malcolm Ross, Ph.D.	-	U.S. Geological Survey

Continued on Next Page

Wilson Nashed, Ph.D.	-	Johnson & Johnson
Gavin Hildick-Smith, M.D.	-	"
R. F. Rolle, Ph.D.	-	"
T. H. Shelley, Ph.D.	-	"
A. Goudie, Ph.D.	-	"
Consultants: Prof. Fooley	-	"
W. T. Caneer	-	"
Ian Stuart, Ph.D.	-	"
Dr. Grieger	-	"
S. R. Mountsier, Jr.	-	Whittaker, Clark & Daniels
Prof. Lewin (consultant)	-	"
Paul Gross, M.D.	-	Medical University of South Carolina
Sidney Speil, Ph.D.	-	Johns-Manville
Morris Kaplan	-	Consumers Union
Norman Estrin, Ph.D.	-	Cosmetic, Toiletry, & Fragrance Association
Murray Berdick, Ph.D.	-	"
Herman F. Kraybill, Ph.D.	-	Food and Drug Administration
Robert M. Schaffner, Ph.D.	-	"
Alfred Weissler, Ph.D.	-	"
John M. Gowdy, M.D.	-	"
Sylvan H. Newburger, Ph.D.	-	"
John A. Wenninger	-	"
Francis N. Marzulli, Ph.D.	-	"
Charles J. Kokoski, Ph.D.	-	"
George Thompson, Ph.D.	-	"
Denis J. McGrath, M.D.	-	"
Hyman R. Gittes	-	"
William V. Eisenberg	-	"
Richard A. Anderson	-	"
Raymond E. Barzilai, M.D.	-	"
Jule K. Lamar, M.D.	-	"
Mrs. Manjeet Singh	-	"
Armand R. Casola, Ph.D.	-	"
William Cook	-	"
R. E. Norwood	-	Chas. Pfizer & Company
H. D. Stanley	-	"
Commr. Harold Romer	-	N.Y.C. Dept. of Air Resources