

W.L. HOCKERSMITH
D.R. HOLMES
W.M. STEPHENSON
G.A. WELLS
(201) 561-6100



WHITTAKER, CLARK & DANIELS, INC.

1000 COOLIDGE STREET • SOUTH PLAINFIELD, N.J. 07080

April 18, 1973

Mr. J. Callaghan
Pfizer, Inc.
230 Brighton Road
Clifton, New Jersey 07012

RECEIVED - CLIFTON

APR 23 1973

MPM DIV.

Dear Jack:

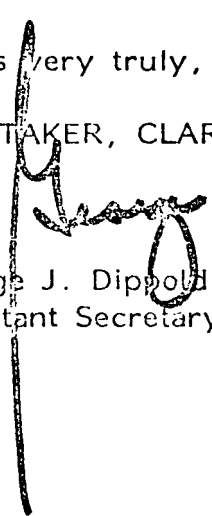
We are enclosing two copies of the notes taken by our Mr. Rex Smith during the recent meeting of the Talc Group.

This information is for your disposal and should be treated as confidential.

We will continue to keep you apprised of the substance of these meetings in the future.

Yours very truly,

WHITTAKER, CLARK & DANIELS, INC.


George J. Dippold
Assistant Secretary

GJD/aam
Enclosure

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CLIFTON, PA.

IMPORTERS • MANUFACTURERS • EXPORTERS
MINERALS, COLORS, PIGMENTS

Meeting of Talc Group

March 21, 1973

Attending: C. S. Thompson, Allan Harvey, Robert Bacon (R. T. Vanderbilt Company); Dr. W. H. Ashton (Johnson & Johnson); Dr. William Smith (Pathologist, Fairleigh Dickinson University); Fred Kuehl, Peter McCarthy (International Talc Company), W. Reitze (Johns Manville); Fred F. Roesch, Rex S. Smith (WHITTAKER, CLARK & DANIELS, INC.); Duncan Ogden (Vermont Talc); Art Neilson (self); Alan Dankworth (Engelhard Minerals).

1. Dr. Smith opened the meeting with a discussion and slides of his experiments, using hamsters as a human model to test the effect of various mineral dusts, including tremolitic talc, supplied by WC&D, on these animals. They were treated through the life cycle with various dosages and analyzed for emphysema (large air sacs on lungs), fibrosis (scars-solid fibrous tissues) and tumors.

Hamsters were chosen because of their short life cycle and they showed a proper balance of sensitivity/insensitivity to lung irritants so as to provide good screening. Fifty animals were used in each experiment. The attached tables show details of numbers of tumors (Mesotheliomas) from various causes. It was found that a combination of irritants (total environment) is more active, causing cancer at lower levels than required by either alone. Thus, small doses of cigarette smoke and soft chrysotile together might be carcinogenous due to the irritating effect of chrysotile causing a delayed clearance of smoke from the lungs.

Short fibers caused less tumor growth than long, even though fibers were lying directly on the surface of the lung. Crocidolite, used in Table 2, was the most active.

Table 3 indicates that thicker spun glass fibers are less active than thin Silica fibers even though, theoretically, they have the same chemical composition.

Based on his screening tests, Dr. Smith said he could make a statement that tremolite or chrysotile has very little, if any, carcinogenic effect on animals.

Dr. Selikoff's publications were discussed; consensus was that they lacked background and were extremely dangerous.

2. Dr. W. H. Ashton (J & J) began discussion of Methodology for determining "asbestos" or "fibers" by reviewing J & J experience with different instruments. Least sensitive is optical microscope; next in order of increasing sensitivity (and cost and difficulty to run) are X-ray scan, X-ray step scan, Electron scan, Electron differential scan, and DTA (Differential Thermal Analyser). The latter is sensitive to 1% chrysotile. In the FDA, the cosmetic group wants to study methods and limits in depth so as to be on firm ground when a statement is issued. They have hired Dr. Levine as consultant. The food group seems to be rushing towards a statement with little background and has little communication with cosmetic group. Optical microscopy can be very misleading because many "fibers" are actually rolled plates or plates viewed edgewise. This makes non-fibrous materials appear "fibrous".

Dr. Levine, in a survey on cosmetic talcs, found a large number containing "asbestos" by using an optical microscope. J & J took exception, and Dr. Levine is redoing the survey using X-ray Diffraction.

J & J recommends X-ray Diffraction Scanning first; if negative, the product is O. K. If there are peaks which indicate asbestos form materials, go to step scanning; if this shows peaks then it is necessary to go to electron instruments for a quantitative analysis. Dr. Selikoff prefers the electron microscope. FDA cosmetic group favors DTA, (Differential Thermal Analysis); food group may require optical microscope arbitrarily because their April 15 deadline (extended to May 1) doesn't give them much time for study. Contacts are Alan Spire, Director, (preferred) or Dr. Corbin Miles, his assistant, (GRAS Review). A lot of talc goes into food packaging so there is a large stake there; not too much goes directly into food.

A new paper by Dr. Hoenzell in the October 1972 Journal of National Cancer Institute contradicts Dr. Merrill's paper, saying that gastric cancer in Japan and Hawaii was not caused by talc in rice. Dr. Kleinfeld's paper, "Mortality among Talc Miners and Millers in New York State", has been updated in a letter to Dr. Marriner of Johns - Manville; the new information will be published in the Journal of Occupational Medicine.

3. W. Reltze (Johns - Manville) discussed their migration studies of talc-loaded papers, citing "prior precedent" that if an additive is non-migratory, it is O.K. for food packaging. These studies will be presented to the FDA. Many tests were made, involving many low and high loadings (up to 40% Talc), and showed no migration. Tests were made on paper itself and on meat wrapped in the paper. Several tests have been made by DuPont on plastics; they also say there is no migration, but won't be quoted.

FDA, OSHA, NIOSH and USBM have encouraged presentation and discussion of data on which they can base mandatory standards. It was decided that overall interest would best be served by individual corporate presentations, each attacking from their own viewpoint rather than by an industry presentation.

4. Mr. Bacon reported that his contacts in the U. S. Congress say that attitude towards FDA, OSHA, etc. is changing. Originally, whereas anything that was said by these organizations had been considered almost sacred, opinion is now swinging opposite to the point where almost anything is questioned. This should ease the burden somewhat, on industry.

USBM has announced a public symposium to study health and safety effects of talc dust; 9:00 A.M., May 8, 1973 in the auditorium, Department of Interior, 18 S C Streets Northwest, Washington, D. C. Presentations should include information relating to characterizing of airborne dust from mining and milling of minerals and medical data on disease and exposure, as detailed as possible.

Art Nielsen mentioned that FDA cosmetic group and NIOSH have started a crash study of some kind at a pharmaceutical plant in Arizona. No details were available at the moment.

Rex S. Smith

RSS/ep
Attachment

TABLE 1

TUMORS FOUND WITH VARIOUS DUSTS

<u>DOSE</u>	<u>CHRYBOTILE</u>	<u>AMOSITE</u>	<u>ANTHOPHYLLITE</u>	<u>CROCIDOLITE</u>
25 mg	9			
10	4	3	3	10
1	0	0	0	2

TABLE 2

EFFECT OF FIBER LENGTH

<u>AVERAGE LENGTH OF FIBERS</u>	<u>KIND OF CROCIDOLITE</u>	<u>NUMBER OF TUMORS</u>
6.9 Microns	Soft	8
5.3 Microns	Harsh	9
0.9 Microns	Soft	0
0.4 Microns	Harsh	0

TABLE 3

EFFECT OF FIBER COMPOSITION

<u>MATERIAL</u>	<u>DOSE</u>	<u>TUMORS</u>
Tremolitic Talc	25 mg	0
Serpentine Rock Dust (chemically like chrysotile, but not fibrous)	25 mg	1
Nemalite (Fibrous Magnesium Oxide)	25 mg	0
Silica fibers	10	4
Glass Fibers	10	0
Glass Fibers with phenolic binders	10	0