

MEMORANDUM OF MEETING

July 8, 1971

Between: Representatives of Johnson & Johnson
Research Division, New Brunswick, N.J.

and

The Food and Drug Administration

Subject: Asbestos Particles in Talc

The meeting was held in Dr. Schaffner's office in FB-8, 200 "C" Street,
S.W., Washington, D.C. -

Dr. Nashed of Johnson & Johnson opened the meeting by briefly revealing
the recent events on the subject of asbestos particles in talc. He in-
dicated that the group present at the meeting from Johnson & Johnson

would like to review the analytical methodology on the detection and
determination of asbestos particles in talc. He indicated they would be
happy to answer any questions we had concerning methodology.

Dr. Shelly indicated that talc used in Johnson's Baby Powder was Vermont
talc obtained from their own mines. The mined talc is purified by flot-
ation. This talc is incorporated into baby powder which has the following
composition:

Talc

Calcium Carbonate (a constituent of talc)

Sodium Citrate 0.2% (a buffer)

Perfume 0.2%

Dr. Rolle showed photographs of talc obtained by use of an electron micro-

scope at 500x magnification. In these photographs, comparisons were made between Vermont talc used in Johnson's products and samples of talc containing 1, 5, 25 and 50% asbestos particles. It was their opinion that these photographs lended additional evidence that their talc contains less than 1%, if any, asbestos. Dr. Rolle was quick to point out that this technique was not very reliable analytically.

Dr Nashed provided Dr. Schaffner with three (3) copies of a report on the analyses of Johnson's Baby Powder and various samples of Vermont talc used in Johnson's Baby Powder. This report contained the following 3 parts.

1. June 24, 1971, Report on Particle Size and Shape Distributions of Grantham, Italian, and Vermont Talc Final Products for Johnson & Johnson by
~~Colorado School of Mines Research Institute.~~
2. July 7, 1971, X-ray analyses report on JOHNSON'S Baby Powder sample 344-L, and six samples of Vermont Talc by Colorado School of Mines Research Institute.
3. June 28, 1971, Report of x-ray examination of Talc Products by Dr. R. C. Reynolds, Jr., Geology Dept., Dartmouth College, Hanover, New Hampshire.

Dr. Nashed noted that the information and data submitted contains trade secrets and is confidential and that FDA may not make it public without written permission from the company.

Dr. Caneer then briefly discussed the contents of the reports submitted and described the various analytical techniques used to obtain the results. The techniques used were microscopic examination (point counts

were made at 500x) and X-ray diffraction. Dr. Caneer indicated that he would send the details of the procedures used to Dr. Schaffner in the near future.

Dr. Caneer then described the results from X-ray diffraction examination of Vermont talc. These results indicated that this talc contains essentially no anthophyllite and only minor amounts (below 1%) of tremolite and actinolite, or in other words contains less than 1%, if any, asbestos particles. Dr. Caneer was confident that X-ray diffraction would detect most mineral forms of asbestos at a level of 1%.

Dr. Shelly indicated that within the next few weeks Johnson and Johnson will have analyses of Vermont talc from an additional 3 or 4 independent laboratories.

Dr. Smith then reviewed some of the medical reports in the literature about asbestos. He indicated that the presence of asbestos to the extent of 5% by weight gave rise to medical problems in industrial workers. He then outlined the type of future testing that would be carried out by Johnson and Johnson.

Those attending from industry were:

R.F. Rolle, Ph.D. Laboratory Supervisor
 Johnson & Johnson
 Research Division
 New Brunswick, N.J. 08903

Wilson Nashed, Ph.D. Division of Science
 Information
 JJ

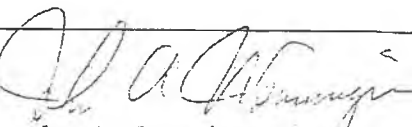
T. H. Shelley, Ph.D. Director, Research
 Dept.
 JJ

G. H. Smith, M.D. Director of Clinical
 Research
 JJ

W. T. Caneer Asst. Manger, Mining Division
(Consultant for J. and J.) Colorado School of Mines
Research Institute
Golden, Colorado 80401

From FDA:

R. N. Schaffner, Ph.D.	Director Office of Technology
C. J. Kokoski, Ph.D.	Division of Toxicology
H. R. Gittes	Division of Toxicology
S. H. Newburger, Ph.D.	Division of Colors & Cosmetics Technology
J. A. Wenninger	Division of Colors & Cosmetics Technology
W. V. Eisenberg	Division of Microbiology
R. E. Newberry	Division Case Guidance


John A. Wenninger
Assistant Chief, Cosmetics Branch
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