

Johnson & Johnson

BABY PRODUCTS COMPANY

NEW BRUNSWICK, N. J. 08903

November 15, 1974

RAF 11/22/74

Robert M. Schaffner, Ph.D.
Associate Director for Technology
Bureau of Foods
Food and Drug Administration
Department of Health, Education, and Welfare
200 "C" Street, S.W.
Washington, D.C. 20204

Dear Dr. Schaffner:

My colleagues and I at Johnson & Johnson would like to thank you and your staff for the meeting last Wednesday. I have always believed that face-to-face discussion leads to a better understanding and interpretation of different points of view.

As Dr. Hildick-Smith indicated, we have received the Italian version of the paper presented by Dr. Rubino. Currently, it is undergoing translation and we would hope to have both the Italian and the translation to you by the end of the month. We believe this study addresses the direct question of the safety of talc inhalation over long term exposure periods in humans.

Thank you again for the opportunity to meet you, and please extend our appreciation to your staff as well.

Very truly yours,

D. R. Petterson
D. R. Petterson

Johnson & Johnson

BABY PRODUCTS COMPANY

NEW BRUNSWICK, N. J. 08903
April 3, 1975

CERTIFIED MAIL

Robert M. Schaffner, PhD
HFF-400
Bureau of Food
Food and Drug Administration
200 "C" Street, S. W.
Washington, DC 20204

Dear Dr. Schaffner:

In continued cooperation with the Food and Drug Administration on informational exchange regarding the talc question, we have learned that a paper on Dr. G. F. Rubino's epidemiological study with Italian cosmetic talc miners and millers will be presented on April 15, 1975 at the San Francisco Hilton during the American Industrial Health Conference. As soon as a copy of the paper, which contains the main epidemiological data, is made available to us, we will forward it for your review.

We also note that during the same conference Dr. L. J. Fine of Harvard will be presenting a paper, "Respiratory Morbidity in Talc Workers", providing data on pulmonary function of industrial rubber workers who have been exposed to a combination of industrial grade talc and organic solvents. Discussions with the Harvard group enabled us to have a sample of the mineral powder analyzed and this was shown to contain only 42 percent talc.

Concerning these studies we point out the vast differences in the nature of material, to which the populations of each, respectively, were exposed. From the program there appear to be no other talc related papers other than the two described above. We trust this information will be useful.

Respectfully yours,

JOHNSON & JOHNSON
Baby Products Company

Wm. C. Waggoner

Wm. C. Waggoner, PhD
Administrator
Medical and Regulatory Affairs

cy 4-10

Johnson & Johnson

Certified Mail
Return Receipt Requested

BABY PRODUCTS COMPANY

NEW BRUNSWICK, N. J. 08903

July 22, 1975

Robert M. Schaffner, PhD
Hff-400
Bureau of Foods
Food and Drug Administration
200 "C" Street, S.W.
Washington, DC 20204

Dear Dr. Schaffner:

On July 9, 1975, representatives of Johnson and Johnson participated in an industry presentation under the auspices of the Cosmetic, Toiletry & Fragrance Association at an open session of the FDA OTC Antiperspirant Advisory Panel. Data attesting to the safety of cosmetic talc was presented.

In support of the presentation, the appended volume, containing relevant information on the safety of cosmetic grade talc in both dusting powder and aerosols, was given to the panel. You will note that the volume contains copies of several letters written to you on prior occasions. These letters were included because they gave appropriate explanation and identification to several of the accompanying documents and to other material previously submitted to your office. This information is forwarded in a spirit of continuing cooperation.

Respectfully yours,

JOHNSON & JOHNSON

Wm. C. Waggoner

Wm. C. Waggoner, PhD
Administrator
Medical & Regulatory Affairs

Enclosure

7-30-95

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Johnson-Johnson

HFF-440

BABY PRODUCTS COMPANY

NEW BRUNSWICK, N. J. 08903

January 8, 1976

Robert Schaffner, PhD
Bureau of Foods HFF-400
Food and Drug Administration
200 "C" Street
Washington, D.C. 20204

RA 11/14/76

Dear Dr. Schaffner:

Pursuant to the June 25, 1974, letter from Johnson & Johnson, a copy of the final report entitled, "Investigation of Effects of Inhaled Baby Powder in Hamsters", is transmitted to your office in continuing cooperation on informational exchange regarding the talc question.

Respectfully yours,

Wm. C. Waggoner

Wm. C. Waggoner, PhD
Manager
Regulatory Affairs

Report to HFF-440 w/cy ltr. 1-15-76