

CF

Johnson & Johnson
BABY PRODUCTS COMPANY

RARITAN, N.J. 08869

April 28, 1977

SUBJECT: Status Report - Defense of Talc Safety

TO: Mr. D. D. Johnston

Since our last report of February 7, 1977, the follow represent new status in the talc safety program:

I. J&J Talc Data Generation

1. Battelle's exploratory work is still in progress for evaluating the interaction of talc with lung macrophage. They are evaluating whether their in-vitro model can provide dose-response data.
2. The CTFA round robin analysis of seven major powder brands has indicated some discrepancies with several laboratories in their application of the methodology. -Operator inexperience appears to be the problem and it will be addressed by the CTFA Task Force.

II. FDA/OTC Panel - Talc Reviews

1. Misc. External OTC Drug Products Panel

This panel has reviewed talc and placed it in Category I (Safe & Effective). The Panel stated that "Talc, free from asbestos fibers, is safe and effective as a lubricant and absorbent" on intact skin.

We do not expect any other FDA/OTC Panels to be reviewing talc.

III. Talc Scientific Publications

The following paper was published:

"Inhalation study of talc baby powder by hamsters"
Wehner et al - Jrnl. Food & Cosmetics Tox. No. 2,
Vol. 15, p.121, April 1977.

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The following papers have been submitted for publication in the Journal of Food & Cosmetics Toxicology:

"Pulmonary deposition, translocation and clearance of inhaled neutron-activated talc in hamsters"
Wehner, et al

"Leaching of radio nuclides from neutron-activated talc in serum and dilute HCL", Wehner, et al

"Gastro intestinal absorption of talc in the Syrian Golden hamster", Wehner, et al

IV. Non J&J Talc Studies

1. Lovelace Foundation

This laboratory reported that their animal study showed no treatment-related pathology had been observed after 6 months' inhalation exposure to aerosolized talc.

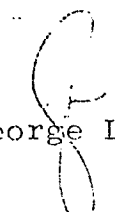
2. NIOSH Vermont Talc Workers Morbidity and Mortality

An expert consultant has confirmed that there is strong basis for questioning the validity of their mortality study and their preliminary conclusions. The final report has not been made available to us.

The NIOSH survey of current occupational environment has confirmed the absence of asbestos and negligible quartz. Their environmental study report will be presented May 26th at the conference of the American Industrial Hygiene Association. The morbidity data is still being analyzed by Harvard.

V. BPC Product Strategy

1. Additional product tests are being conducted with aged PEG-treated JBP to reduce the "respirable" concentration.
2. Single mold samples of new shaker tops were reviewed and the living hinge cap was selected for advanced prototype fabrication. Fall product testing is anticipated.


George Lee

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