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Johnson & Johnson
BABY PRODUCTS COMPANY

RARITAN, N.J. 08869

May 13, 1977

SUBJECT: TALC NEWSLETTER

TO: J & J Affiliates

The United States has served as an arena for considerable discussion and controversy over the safety of talc. To answer issues raised, J & J has dedicated concerted effort towards the sponsorship of relevant studies and the communication of relevant information to concerned regulatory and scientific groups. These on-going talc activities are coordinated by the Baby Products Company's Research Department and we hope that this newsletter will provide a useful information summary for our overseas affiliated companies.

TALC DATA SUPPORTING SAFETY FOR CONSUMER USE

1. J&J has conducted studies to measure how much talc an infant would inhale during powdering of the diapering area.
2. Long term animal inhalation studies have been completed on hamsters with exposures to JOHNSON'S Baby Powder of up to 1700 times the dose received by infants during powdering. No effects from these exposures were noted.
3. Animal studies also on hamsters show that inhaled talc is cleared from the lung and does not translocate to other body organs.
4. A study of causes of deaths amongst Italian talc workers show that, even with long duration working exposures to cosmetic grade talc, there is no evidence of increase in deaths from cancer.

TALC STANDARDS & QUALITY

1. The Cosmetics, Toiletries & Fragrance Association (CTFA) - the largest toiletry industry trade association in the U.S. - has published a revised raw material standard for

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cosmetic grade talc which specifies no detectable fibrous asbestos minerals and a typical purity level of 90% mineral talc.

2. J&J has continued to furnish to the U.S. Food & Drug Administration (FDA) relevant data to support the view that normal consumer use of JOHNSON'S Baby Powder for body powdering is free from hazard. However, the FDA has not issued regulations to cover talcs used in foods, drugs and cosmetics.
3. Four advisory panels to the FDA have completed their review of the safety and efficacy of talc as an ingredient in various "over-the-counter" product categories. They have all recommended that talcs which do not contain asbestos minerals should be regarded as "safe". These panels are:

Antiperspirant Panel - cosmetic grade talc free of asbestiform fibers in an aerosolized form in antiperspirant products was regarded as safe.

Nighttime Sleep-Aid, Daytime Sedative & Stimulant Panel - talc containing asbestos should not be permitted as an inactive ingredient in nighttime sleep-aids, daytime sedatives and stimulants.

Anti-Microbial II Panel - cosmetic grade talc free of detectable asbestos was concluded to be safe for use in fungal infections of the foot and groin as an anti-fungal powder.

Miscellaneous External OTC Drug Products Panel - talc free of asbestos fibers was judged to be safe as a lubricant and adsorbent on intact skin.

4. The U.S. Food and Drug Administration's Bureau of Foods has concluded that there is safety data supporting the continued use of talc - free of asbestos - in foods, but has delayed issuance of regulations pending acceptance of analytical methods for determining the presence of asbestos.
5. The Consumer Product Safety Commission has declared household products containing asbestos as a hazard to the public. It has banned spackling compounds, wall patching mixtures, imitation fireplace logs and ashes which contain asbestos. Talc containing tremolite was

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also banned for use in putties and spackling compounds

ONGOING REGULATORY STUDIES IN U.S.

1. The U.S. Food and Drug Administration has a sponsored animal study underway to evaluate the inhalation effects of aerosolized talc.
2. The National Institute For Occupational Safety and Health (NIOSH) has been conducting an environmental exposure, morbidity and mortality study amongst talc workers in the State of Vermont.
3. The Occupational Safety and Health Administration (OSHA) has contracted the National Bureau of Standards (NBS) to determine the presence or absence of asbestos in some 88 talc samples.

TALC SCIENTIFIC PUBLICATIONS

The following are important supporting talc scientific papers published in prominent scientific journals. Copies may be obtained on request from my office.

"Mortality Studies of Talc Miners & Millers", Rubino et al
Journal of Occupational Medicine, Vol. 18; 1976

"The Characterization of Talc & Associated Minerals",
Rolle et al
American Industrial Hygiene Association Journal, May 1976
p. 296-304

"The Biology of Talc", G.Y. Hildick-Smith
British Journal of Industrial Medicine, 1976, 33, p. 217-229

"Inhalation Study of Talc Baby Powder by Hamsters", Wehner et al
Journal Food & Cosmetics Tox., No. 2, Vol. 15, p. 121, April '77

We expect several more papers to be published in the next twelve months, and will keep you informed.

/by
cc: Distribution

George Lee, Director
Applied Research