FILE NAME: Talc (TALC)

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Food and Drug Administration
Bureau of Drugs
OTC Drugs Products Evaluation Staff (BD-109)
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OTC Drug Review Information--Contraceptives and Other Vaginal Drug Products:

IV. Human Safety Data on Talc

A. Individual Active Components

5. Pertinent Medical and Scientific Literature.

a. Henderson, W.J. et al, "Talc and Carcinoma of the Ovary and Cervix," J. Obstet. Gyn. Brit. Comm., 78: 266, 1971

b. Blejer, H.P. and Arlon, R., "Talc: a Possible Occupational and Environmental Carcinogen," J. Occup. Med., 15: 92, 1973.

VI. Summary Statement--Talc is commonly used in the manufacture and packaging of condoms and diaphragms. Henderson's study revealed the presence of talc deeply imbedded in the majority of primary malignant ovarian and cervical tumors examined. The fact that these researchers could not find talc in thorough studies of a secondary tumor, and the fact that no asbestos was found in any of the tissue studied support the hypothesis that talc per se had a role in causing malignancies to develop.

Blejer and Arlon develop the hypothesis of talc carcinogenicity in their recent literature review, citing the strong chemical similarity between talc and certain asbestiform minerals (which have been proven to be carcinogenic agents). One problem in trying to isolate the effects of pure talc is the fact that most talc deposits and talc products contain traces to large fractions of tremolite asbestos. On August 12, 1972 the FDA proposed to ban the use of asbestos-containing talcs in the preparation and packaging of foods (Federal Register v. 37, no. 157). It would

certainly be appropriate to ban the use of asbestos-contaminated talcs in contraceptives, other vaginal drug products, and cosmetics immediately.

In view of Henderson's report and some points made by Blejer and Arlon there is clearly reason to consider that talc per se is a "possible carcinogen." In view of this it would be prudent to minimize the introduction of talc-bearing contraceptives into the vagina, where the talc may easily find its way to prime cancer sites.

As talcum cosmetic powders (when used by females and males) and vaginal sprays are additional sources of talc insult to the female genital tract, it is obvious that FDA's findings and actions on talc (both pure talc and asbestos-contaminated talc) in contraceptives will have direct implications for talc in cosmetics.

Sincerely yours,

Barry Castleman /MJ

Barry Castleman

Michael Jacobson

Michael Jacobson