

3 DEC 1982

Raymond J. Russell
121 Riveredge Road
Lincoln Park, New Jersey 07035

Dear Mr. Russell:

This replies to your letter dated October 15, concerning the presence of needle-like particles in talc containing baby powder and face powder which you believe may present a hazard similar to one which exists from the inhalation of asbestos fibers. You indicated in your letter that a microscopic examination of talc revealed that approximately 5 to 10 percent of the particles have a 10 to 20 micron, needle-like structure, similar to that of asbestos.

The matter of contamination of talc with fibrous asbestos was extensively studied by both the Food and Drug Administration and industry in the mid to late 1970's. We have no knowledge of any cosmetic talc product on the market that contains fibrous asbestos. Nor do we have information or data which indicates that presently marketed cosmetic talc preparations are unsafe when used as directed. While we are well aware that talc is chemically, closely related to asbestos, we believe that the needle-like particles that you have briefly described in your letter are talc needles, not fibrous asbestos. Talc needles are not known to cause harm or to present a hazard to health when talc containing baby powder and face powder are used under customary conditions of use or as directed on their label. If you have any scientific evidence that the particles are not talc needles or that a hazard exists, we would appreciate receiving such information.

For your perusal, we are enclosing a number of documents which review the current state of our knowledge relating to the health effects of talc and asbestos. These documents are as follows:

- ✓ 1. Letter dated 1/11/79 Kennedy/Wolfe
- ✓ 2. "Safety of Consumer Cosmetic Talc Products" Journal of Toxicology and Environmental Health 2:1221-1222 1977.
- ✓ 3. "Mineralogical Characterization of Cosmetic Talc Products" Journal of Toxicology and Environmental Health 2:1223-1226, 1977.
- ✓ 4. 21 CFR 73.1550 - Talc
- ✓ 5. Federal Register document of April 4, 1975 Part 8.

We thank you for your comments since it is often through observations made by concerned citizens such as yourself that potential areas of concern are brought to our attention.

You can be assured that if any cosmetic product offered for sale in this country is found to be inherently injurious, the FDA will take appropriate regulatory action to remove such products from consumer channels.

If we can be of any further assistance, please feel free to contact us.

Sincerely yours,

Allen R. Halper
Assistant to the Director
Division of Regulatory Guidance
Bureau of Foods

Enclosures:
as stated above

cc:
HFC-1 r/f
HFF-300 r/f
HFF-314 r/f
HFF-1 with copy of control card
HFF-1 (Nightingale)
HFF-440 (Eiermann)
HFF-441 (Wenninger)
R/D Init:JAWenninger:12/3/82
ARHalper:bdh:12/3/82:245-1505

Optical Microscopy: To determine fibrous tremolite, anthophyllite, and chrysotile.

Health Hazards

Asbestos: diffuse, nonmalignant scarring of lungs.

Bronchogenic carcinoma: malignancy of interior of lungs.

Mesothelioma: malignancy of lining of chest cavity (pleural) or abdomen (peritoneal).

Cancer of stomach, colon, rectum.

5-7 fold increase in lung cancer in asbestos workers, beginning 10-14 years after first exposure and significant after 20 years.