

R. T. VANDERBILT COMPANY, INC.
33 WINFIELD STREET
EAST NORWALK, CONNECTICUT 06855

CABLE ADDRESS
BILTVAN NEW YORK

December 21, 1973

Hearing Clerk
Food and Drug Administration
Room 6-86
5600 Fishers Lane
Rockville, Maryland 20852

Dear Sir:

Reference is made to the Department of Health, Education and Welfare, Food and Drug Administration "Notice of Proposed Rulemaking (21 CFR Parts 121, 128, 133) Asbestos Particles in Food and Drugs", published in the Federal Register of Friday, September 28, 1973, pages 27076 to 27081 inclusive, FR Doc 73-20711.

Reference is also made to the comments submitted on October 5, 1972 to the Hearing Clerk by the firm of Davis, Gilbert, Levine & Swartz on behalf of R. T. Vanderbilt Company, Inc., and International Talc Company, Inc. in response to the "Proposal Regarding Regulation of Prior-Sanctioned Food Ingredients" (21 CFR Part 121), published in the Federal Register of August 12, 1972 (37 F.R. 16407).

Reference is also made to additional comments on the August 12, 1972 proposal made by the R. T. Vanderbilt Company, Inc. in their supplemental letter of April 17, 1973 addressed to Mr. Allen T. Spiher, Jr. of the Bureau of Foods.

The R. T. Vanderbilt Company would like to direct its comments of the latest proposals mainly to the definition of "asbestos" on page 27076 of the Federal Register, and the criteria of a fiber in which a length to width ratio of 3 is used.

Inclusion of tremolite per se as an asbestos mineral and use of the proposed fiber ratio criteria places the majority of the tremolite containing industrial talcs used in the United States in the category of asbestos, whereas there exists no up-to-date evidence in the literature of a greater hazard involved than that attributed to the mineral talc itself. Certainly, the latest epidemiological studies by Dr. Morris Kleinfeld (Environmental Research 6, 132-143 (1973)) have proven that commercial talcs containing tremolite are not in the same category of hazard as crocidolite, amosite and chrysotile, the true asbestos minerals.

Hundreds of thousands of tons of New York State talcs containing an average of 50% tremolite and California talcs with a tremolite content varying from 5 to 30% are mined and used industrially in the United States each year. None of the tremolite in this talc is asbestiform in shape, i.e., in a form useful as asbestos. Although tremolite can occur in an asbestiform configuration, its occurrence is rare,

754-D261

The recommendations for use of our materials are based upon tests believed to be reliable. However we do not guarantee the results to be obtained

C25

Hearing Clerk

- 2 -

December 21, 1973

and its use as asbestos in commerce does not amount to more than one-tenth of one percent of all the asbestos used in this country. Nevertheless, its occurrence, compounded with the lack of a distinctive name for the asbestos form of the mineral, has resulted in its inclusion in many mineralogical text books as a variety of asbestos, although quite often a footnote stipulates that it is only "asbestos" when it occurs in the asbestiform shape.

The photomicrographs accompanying our presentation of April 17, 1973 to Mr. Spiher show distinctly and conclusively that tremolite in talcs containing 50% of this mineral do not "separate into flexible fibers made up of fibrils" when crushed or processed. It is undoubtedly for this reason that no instances of malignancy have occurred among the talc workers studied by Dr. Kleinfeld, since the particles to which the workers were exposed in no way resemble those of true asbestos minerals.

For the above reasons we respectfully request that the Food and Drug Administration's proposed legislation include in its definition of asbestos the following designations:

Chrysotile
Crocidolite
Amosite
Anthophyllite Asbestos
Tremolite Asbestos
Actinolite Asbestos

In addition, it is requested that the criteria of a fiber be changed to stipulate a length to width ratio of 10 or greater, in accordance with the accepted definition of asbestos fiber developed by The American Society for Testing and Materials (Designation D 2946-71T). Although mineralogists and geologists may take issue with the use of an aspect ratio to define a fiber, the use of the ASTM definition would seem appropriate for purposes of an OSHA Standard. A 10:1 ratio mineral particle resulting from the fracture of a shorter particle rather than from the shortening of a long fiber might rightfully be considered not a fiber. It can be argued that a fiber can be shortened until its aspect ratio is 3:1 and it is still a fiber, but a true fiber cannot be formed by the fracturing of a mineral particle that was not a fiber to begin with. In other words, a fiber may have to be defined by its peculiar property to "separate into fibrils" when crushed or processed.

Very truly yours,

R. T. VANDERBILT COMPANY, INC.

Allan M. Harvey

Allan M. Harvey, Manager
Legal and Product Application

AMH:slb