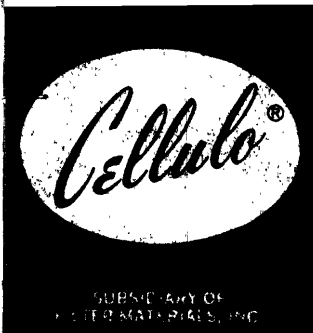




CELLULO COMPANY

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December 21, 1973

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

Ref: Department of Health, Education and Welfare
Food and Drug Administration
21 CFR Parts 121, 128, 133
Proposed Rule Making on Asbestos Particles in
Foods and Drugs As Printed in Federal Register
Volume 38, No.188, Friday, September 28, 1973

Gentlemen:

We would like to make comments with regard to the proposed rule making in view of our company's long range involvement with chrysotile asbestos fiber for filtration purposes.

We assume that other interested parties will submit comment to you perhaps with more emphasis on areas of their particular expertise. We would like to comment on the overall filtration practices in the chemical, food, beverage, and pharmaceutical industries which we serve.

We are aware of FDA's interest in assessing the extent of the use of asbestos by such industries and we were privileged to attend such a meeting in January of 1972 in Washington. That particular meeting did in fact indicate that asbestos was considered a vital filter ingredient by a large number of companies in a wide variety of industries.

Asbestos fiber when used in industrial filtration is considered a depth type filter media, whether it is used in the form of an asbestos/cellulose pad or in the form of loose fibrous product slurried in a liquid to form a filter mat on the leaves of large pressure filters.

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Large precoat filter installations and pad filters presently installed in these diverse industries represent a staggering total of capital investment. Procedures have long been established for filtering this enormous national capacity of various liquids to provide the consumer with a cleaner product than previously available prior to the large scale use of asbestos in combination with such other materials as wood cellulose, cotton linters, diatomaceous earth, perlite, etc.

The chrysotile asbestos which we supply for these various uses has many of the unique advantages that are not characteristic of substitute fibers. Primarily unique are the small fiber diameter characteristics and the Zeta potential exhibited. Consequently, such depth filters offer finer filtration due to the smaller diameter fibers in the filter matrix and the adsorption characteristics due to Zeta potential enabling particles smaller than the filter interstices to be retained.

Some measure of the economics of such depth filtration are graphically illustrated on page 11 of Millipore Corporation Bulletin MB404 attached herewith. Too often people have suggested alternate methods of filtration for specific products without full knowledge of the practicality of these suggestions. Screen or membrane filters retain contaminants on the surface with resulting limited particle holding capacity and consequent short filtration cycles resulting in cost factors being raised as high as a thousand-fold when depths filters are not employed prior to such membranes.

The mass production of certain drugs may never have been possible without the use of various asbestos bearing depth filters. The retention of asbestos fibers in the filter housing have long been a consideration of pharmaceutical manufacturers and they do an excellent job in protecting contamination of the final filtrate, not only from asbestos fibers, but other depth filter media ingredients vital to the practical production of the drug. The exclusion of asbestos fibers from the final filtrate is not limited to membranes, but is accomplished also by a number of other septums classified as non-fiber releasing. We would therefore suggest that under Paragraph 133.8 be amended to allow the use of such asbestos containing filters with a suitable screen-type after filter properly employed.

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Some of the proponents of the banning of asbestos for all and sundry purposes may fall into the category of what have been referred to as the good guys in the so-called Age of the Antagonist.

"The Age of the Antagonist" was the title of an address given by Daniel C. Searle, Chief Executive Officer of G. D. Searle Company on October 25th at the Chicago Section of the American Chemical Society. In it, he had made some worthwhile remarks with regard to this overall problem.

Permit me to quote from this speech: "My company and others in the pharmaceutical industry make medicines that restore or preserve health for millions of people, but the state of science and technology does not now and never will enable us to make medicines entirely safe and effective for all people under all conditions. Thus, in the Age of the Antagonist, we are bad guys."

Unfortunately, it has become fashionable to form instant expert consumer protection groups who are automatically put in the category of the good guy. Any society, regardless of its purpose or tactics, which espouses ecological causes is usually likewise labeled "good guys". Presently, scientists who caution us about being careful in cleaning up environmental situations for fear that we may precipitate more biological and ecological damage by removing so-called "pollutants" below a critical level, are also cast as "bad guys". However, the scientific community points out that while large concentrations of certain elements can be injurious, trace concentrations are absolutely necessary for life.

We have had the opportunity to talk with some of our customers who have made attempts to convert from asbestos bearing filter media to non-asbestos substitutes. Results have been unsatisfactory from a total efficiency standpoint. In such cases where industry has attempted to move in this direction, they had indicated the move has not been considered for fear of any medical hazard, but rather concern for reaction in the marketplace. Certain zealous self-appointed protection groups have indicated that boycotts should be placed on foods and beverages processed through asbestos-bearing filters without giving a scientific conclusion as the reason, but rather appealing to the general public on a total emotional approach to the matter.

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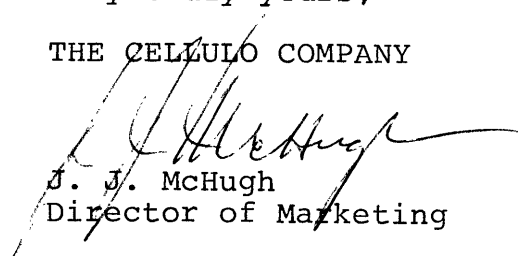
Unfortunately, many industrialists are reluctant to come forward and publicly be counted on the side of those advocating the use of asbestos filters due to possible future economic considerations in the market place.

We assume that with all of the information input that we and other companies have made to FDA, you are fully aware of the international trade implications in banning the use of asbestos in this country for filtration purposes. Considerable economic damage to this country is a possibility.

We appreciate the cooperation that has been shown over these past months in sharing information on the subject and have faith that you will come to the proper conclusion in this matter.

Very truly yours,

THE CELLULOSE COMPANY



J. J. McHugh
Director of Marketing

JJMCH:kk
Encl.