



NORTH AMERICAN FILTRATION COMPANY

7 INDUSTRIAL AVENUE • UPPER SADDLE RIVER, N. J. 07458

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December 21, 1973

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

Dear Sir: Re: Proposed Rulemaking, Asbestos Particles
Federal Reg. Vol. 38, No. 188
Sept. 28, 1973

As called for in above Notice of Proposed Rulemaking, we respectfully submit comments for your consideration.

Just as the inhalation of many varieties of particulate matter in a normal atmosphere is admittedly injurious to man's health, it is certainly recognized and agreed that special atmospheres that may be germane to occupational activities should and must be regulated and controlled to prevent avoidable harm to individuals. Those of us engaged in manufacture of products which in the course of normal processing produce or are coincidentally associated with possibly hazardous atmospheres are obligated to provide safeguards to nullify such hazards. Thanks, in great part, to our regulatory bodies such as the Federal Food & Drug Administration, these safeguards have been promulgated and are generally in common practice. Certainly, industrial atmospheres are much healthier today than in the past.

As may be expected in an activity such as this, a certain danger of "over-reacting" or premature judgment would surely exist. I am reminded, for instance, of some unfortunate publicity a few years ago on possible hazards to be associated with our common cranberry. Similarly, more recently, we decided that one of the modern miracles of chemistry, an artificial sweetener, was suspected of being more harmful than good. In this case, the product was first summarily banned and some industrial producers literally went out of business. Quite shortly thereafter, it was decided that perhaps this material was not all bad and did have a place in man's diet. Unfortunately, like simple chemistry, not all reactions are reversible. Some of the individuals involved in the businesses concerned were in no position to pick up the loose pieces and begin, again.

The current question on asbestos as it is related to filtration of liquids would seem to possibly present a parallel case. After

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recognizing that a totally uncontrolled inhalation of heavy doses of asbestos fibres over a long period of time can possibly be directly associated with respiratory problems, it surely should not follow that an occasional exposure to an infinitely smaller quantity of fibres is necessarily harmful. This is particularly true when it is realized that the general populace has been already exposed for most of man's history due to the ubiquitous nature of asbestos.

To go further along this tack and ban or even question the use of asbestos fibres in the filtration of liquids, particularly those whose very production depends, at least in the practical case, upon clarification, separation or sterilization by means of an asbestos filter septum would, again, seem to be another unfortunate premature judgment. Most of the research work done in this field indicates that even deliberate and excessive feeding produces either non-conclusive or negative results so far as proving a direct relationship between ingestion of asbestos and the claimed mesothelioma or other tumors.

Considering the fact that asbestos has been present in our atmosphere for most of man's history and that asbestos filters have been extensively used for many, many products of common use by man extending from the exotic anti-biotics and serums to ordinary foods, drinking water and swimming-pool water, how do we explain that man is still "alive and kicking" if contact with this substance relates to fatal malignancies?

It is also very disappointing that so many times, the groups that come forward to loudly proclaim that such-and-such a substance has been found to be very dangerous to mankind and should be banned from use immediately are never asked to spend some of their effort and frequently public monies which they have spent, to provide their fellow man with a legitimate substitute. The asbestos caper is no exception in this. During the era of the second world war, we were all very grateful for the asbestos filter that allowed sterilization and thus the production of many miracle drugs without autoclaving which would have destroyed them. To this day, at least this manufacturer knows of no practical (not academic) substitute for sterilization by filtration with the tight asbestos media. Sure, we have membranes that can sterilize by virtue of a fine filtration, but these materials also have limitations and are almost always preceded by another filtration using media having depth characteristics in addition to fine porosity.



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We would submit, therefore, that along with the reports from one group who seem to have a personal interest in eliminating one of the natural minerals that has been serving mankind for much longer than they have and in a much more positive manner, that the Food & Drug Administration review the many reports and other evidence that denies any conclusiveness on claims of harmful attributes of asbestos in the quantities reportedly found in parenteral drugs, foods, and normal atmospheres.

We would further submit that the Food & Drug Administration might also serve our people by counteracting inaccurate claims, particularly when these claims are given unfortunate publicity in the popular press. In this specific instance, we would request a formal notice of refusal to rule against asbestos as a filter media until more positive data is forthcoming.

Respectfully yours,

NORTH AMERICAN FILTRATION CO.

E. F. Daly
E. F. Daly
Pres.

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