

COLUMBIA

• FILTER COMPANY •

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December 20, 1973

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

SUBJECT: 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, Vol. 38, No. 188
Friday, September 28, 1973

Gentlemen:

We wish to submit our comments to you on the proposed rule making on ASBESTOS PARTICLES IN FOODS AND DRUGS, as printed in the Federal Register, Volume 38, No. 188, Friday, September 28, 1973. We intend to comment on both the petition submitted to the FDA by the Center for Science in the Public Interest and the Environmental Defense Fund, as well as the FDA's proposed regulations with reference to asbestos containing filters. We do not intend to comment on the talc situation, since we are manufacturers of only the cellulose-asbestos filter media for liquid filtration.

It is inconceivable to us that in the United States of America, the greatest country in the World, with its wealth of technology and scientifically oriented talent, that the regulatory powers can be forced to acquiesce to so called DEFENDERS OF THE ENVIRONMENT who state that since asbestos in the lungs is a serious hazard, so also, asbestos ingested or injected must be equally hazardous, and hence must be banned from contact with foods and beverages. In point of fact, such inferential reasoning could equally be utilized in a declaration "Since WATER IN THE LUNGS is known to cause death, water should be banned from all foods and beverages taken into the human stomach." Such syllogistic reasoning is asinine. One unifying characteristic about such activist groups is that having embarked upon some crusade, whether real or imagined, they invariably add to the burden without ever acting in a positive sense to contribute to a solution. Calling oneself "Scientist" or "Research Group" is impressive to the Press and to the man on the street. However, we can see no indication that the Center for Science in the Public Interest is scientifically funded by a well meaning technically or medically oriented group with a specific sound reason for existence. The time has come to demand something more than denunciatory and disruptive statements in the Press from these people. If a real hazard appears to exist let that hazard be factualized, not merely fantasized. Then let demonstrably safer alternatives be offered for evaluation, and not lip service to such alternatives.

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The Center for Science in the Public Interest has equated occupational and respiratory hazards of asbestos to all other possible contacts with asbestos. Their only valid bibliographical reference to the purpose of their petition, specifically the banning of asbestos containing filters, is Nicholson, et al. All other references, in or out of context, deal primarily with inhalation of asbestos and its inherent hazards and problems. They further speak of "absence of known safe level"... What about absence of known unsafe level?

At this point, Nicholson, Maggiore and Selikoff's paper entitled "Asbestos Contamination of Parenteral Drugs" published in the July 1972 issue of Science should be discussed, because of the importance it plays in the petition, as well as in many Press articles written concerning same.

We had an advanced copy of this paper prior to its publication in Science Magazine, and we found what we believed to be errors in the paper. Our then president, John Tuit, wrote to Dr. Irving Selikoff on March 15, 1972 as per attached photostat of Mr. Tuit's letter. Dr. Selikoff did not answer immediately and Mr. Tuit followed up with another letter. Dr. Selikoff did answer finally in his letter of May 9, 1972, and we are also enclosing a copy of Dr. Selikoff's letter.

It is interesting to note that the original petition on the part of the Center for Science in the Public Interest, in referring to Nicholson's paper, states "a safe level of exposure below which there is no increased risk to health has not been established" is more or less in direct contrast to Dr. Selikoff's comments indicated in the last paragraph of his letter to Mr. Tuit. Since that time, we also understand, that when Nicholson's tests were conducted, there was the possibility that they were not under totally controlled conditions, with some associates entering the test area from field survey trips to construction sites, still wearing their possibly contaminated overgarments.

Dr. Selikoff's comments in paragraph 3 of his letter of May 9, 1972 to the effect that there is no need to study further whether asbestos in parenteral drugs can cause cancer in humans, and that it should simply be an abandoned method of purifying drugs seems, to us, to lack all the marks of a scientific approach. He doesn't take into account the benefits of this type of filtration procedure and evaluate them against what might be real or imagined hazards.

Following Dr. Selikoff's letter of May 9, 1972, a luncheon meeting was held at the Chemists' Club in New York City on July 25, 1972 with Dr. Carl J. Maggiore, one of the co-authors of the paper, Mr. John Tuit and Mr. George Vogel of Ertel Engineering Company. Primarily the contents of the paper as well as the two letters in question were discussed with Dr. Maggiore. Dr. Maggiore implied that Dr. Selikoff was quite often quoted out of context by the Press, and there was very little that Dr. Selikoff could do about it.

One of the most interesting dialogues was when Dr. Maggiore indicated that their group had been advised by a college professor that there were plenty of adequate substitutes for asbestos-cellulose filter media. When questioned as to what the alternates or substitutes would be, Dr. Maggiore replied to the effect that he did not know. Dr. Maggiore was questioned as to whether the Mt. Sinai group had considered doing an investigation of diatomaceous earth, activated carbon, or the polymers found in

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membranes used for filtration. On each of these points Dr. Maggiore stated that they had interesting characteristics and deserved consideration for an investigation and that some investigation had already been done on polymers with reference to stoppers, closures and tubing. Obviously, the comments were all pure conjecture.

Finally, we cannot equate paragraph two of the paper "Asbestos in Parenteral Drugs" in which it is stated "We have found that these filters unfortunately add contamination of their own", with the statement made in the last paragraph of Dr. Selikoff's letter of May 9, 1972 which reads "Indeed, we cannot even guarantee that the asbestos we have found in the particular drug samples tested by us came from asbestos filters in the production lines concerned".

The bibliography that the FDA has assembled is quite impressive and shows that a great deal of work has been done on the part of the technicians involved. Unfortunately, most of these articles again apply to inhalation or occupational problems.

It has been constantly indicated that there is a considerable lag period between the exposure to asbestos and the attended problems of ill health. Asbestos fibers have been used in filter media since 1887 or a period of approximately 85 years. The first asbestos-cellulose pads were produced in 1917 and there is no doubt that almost every bottle of wine, beer and European spirits have gone through asbestos since that time. Interestingly enough, the incidence of gastric cancer (neoplasm of the stomach) has been steadily declining in Europe for many years. For example, in the United Kingdom, there has been a reduction in the number of cases of over 10% (1952: 16,665 cases - 1965: 14,930 cases) over 13 years. It is worth noting that over the 20 years before 1952 the figures for the United Kingdom annual beer production rose by 20%, and between 1952 and 1965 by another 10%. Diabetics have been taking insulin subcutaneously daily, and twice daily, for over 40 years without any adverse effects from the asbestos containing filters, with no use of after-filters in the manufacture of insulin.

Frankly, methodology is the hang-up. Are we really interested in detecting one molecule of a so called harmful substance in one trillion parts of, for example, food? Are we interested in the ultimate count on all asbestos or are we only interested in a certain size, shape, or type, in conjunction with a specific pre-determined quantity?

Even the choice of the proper laboratory animal would have a great bearing on the ultimate results of any clinical tests. What we cannot understand is why a laboratory animal has to be jammed full of unknown grades of asbestos, and we hang or fall as a result of such tests. Why not jam them full of salt, caffeine, rhubarb leaves, household cleaners, aspirins, etc.

Obviously, reason has to enter the picture, along with common sense; in order to lay the matter to rest, hopefully once and for all. It is obvious that the FDA is heading in that direction as evidenced by the FDA news release of September 28, 1973 concerning this matter, as well as Dr. Schaffner's comments in the paper he delivered on January 11, 1973 to the Master Brewer's Association of America and the FDA's denial to a charge leveled by a Mr. Jack Anderson, newspaper columnist. The FDA is to be commended for these actions and should take more positive action along these lines.

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Mr. Philip McGrath, Director, Electron Microscopy Branch, presented a notable memorandum to Dr. Armand Casola dated July 10, 1973 concerning the filtration of an asbestos contaminated solution through an asbestos filter pad. There is no doubt that asbestos-cellulose depth filtration is extremely useful, and this is the reason for its survival for such a length of time. In line with this type of evaluation, we are presenting also a copy of a letter from Ortho Diagnostics concerning their reason for the continued use of asbestos-cellulose filter pads.

Dr. J. Richard Crout's preliminary report dated August 20, 1973 to Commissioner Schmidt, entitled "Special Survey on Asbestos Particles in Parenteral Drugs" is also most interesting by virtue of the fact that his survey would seem to indicate that there is no direct relationship with asbestos contamination in the final products, and the use of any specific filter material. In fact, it might be concluded that the use of asbestos filters might be the superior technique. In line with Dr. Crout's report, we are taking the liberty of also enclosing a copy of a report by Mr. J.P. Leineweber, entitled "Summary of Asbestos Fiber Content in Commercial Beers". Here again, in no case can there be established a correlation between the type of filter media used and the fiber content.

We would like to see more in-house evaluation on the part of the FDA along these lines, also evaluating more pharmaceuticals that would have no contact with asbestos filters. We realize the facilities of the FDA can be greatly strained and that a memo of need might be indicated for outside participation. If so, the choice of an evaluating independent house should be chosen carefully and not under the direction of Mt. Sinai or the American Cancer Society.

Finally, we return to Commissioner Schmidt's proposal listed under section 133.8. Whatever regulation is promulgated, it will have international repercussions. The necessary policing action would be formidable, if not impossible, taking into consideration the vast quantity of imported goods which normally are filtered through an asbestos-cellulose filter material.

The FDA's position in not placing any restrictions on the use of asbestos filters in food and beverage areas is proper and in our opinion should not be altered.

We do not like that portion of the proposed regulations concerning the use of asbestos filters which prohibits such use "unless it is not possible to manufacture that drug or drug ingredient without the use of such a filter". We are suffering from the terminology of the Delaney Amendment and we could have a like problem from the wording which you have used in this particular case, if not immediately, certainly at sometime in the future. Who decides whether it is possible or not possible to manufacture a drug with or without the use of such a filter? Individuals come and go but the regulation stays and can be subject to different interpretation at different times.

We do not have any objections to and we do support the requirement for an after-filter whenever an asbestos filter is used for filtering parenteral drugs; although we do not admit that it is necessary either from the public health or drug purity standpoint. Frankly, if we were recommending the proper point of use of an after-filter, it would not be right after the first filtration point but preferably at the bottling station. It is amazing what other items can go into a final product within tubing, pipelines, etc. To sum it up, the idea of an after-filter is not foreign to our thinking and in

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this particular segment of the drug industry, specifically parenterals, we have always recommended it, prior to the existence of the Center for Science in the Public Interest or the FDA.

With reference to your requirement for proof of reduction according to the NIOSH document indicated, we assume that the proof of reduction applies to the lack of visible fibers in a solution by light microscopy at approximately 430-450 magnification. Since the NIOSH document deals specifically with air and occupational problems, we believe this point needs more clarification. If this 400+ magnification for reduction is correct, then a membrane is not necessarily required. We believe you would be doing the FDA as well as pharmaceutical industry an injustice by so specifying a particular type of after-filter rather than stating that a suitable non-asbestos-containing after-filter should be utilized.

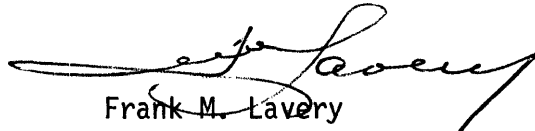
In addition to providing the public with health protection, if possible, it would be best to keep any regulations as simple and unincumbered as possible, in order to ease the necessary administrative enforcement on the part of the FDA Office of Compliance. In addition, any regulations hopefully will be such that there would be no confusion to the general public and not subject to differing interpretations at some time in the future.

In conclusion, varying industries, in addition to the drug industry, are experiencing trepidation with reference to the use of our type of media. This alarm is caused by the lack of a positive position taken by the FDA concerning such a matter. We have received countless phone calls or letters concerning this matter from these industries, and we have attempted to tell them as much as we possibly could. However, we have been kept in the dark almost as much as they have. We fully realize that it has taken a great deal of time for the FDA to become conversant with the subject. Have you considered the publicity value, at this point in time, to any company who so indicated in his national advertising "that no asbestos was used in his particular products manufactured". Although, in fact, the asbestos count might be higher conceivably than that of a competitive product which had passed through an asbestos containing filter.

We hope that our comments will be taken in good faith by the FDA in their final analysis of the standards on the use of asbestos-containing filters.

Very truly yours,

COLUMBIA FILTER COMPANY



Frank M. Lavery

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