

Carlson-Ford Limited

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The Hearing Clerk,
Food & Drug Administration,
Room 8-86,
5600 Fishers Lane,
Rockville,
Maryland 20852,
U. S. A.

17th December, 1973.

Dear Sir,

Department of Health, Education and Welfare
Food and Drug Administration
(21 CFR Parts 121, 128, 133)
Asbestos Particles in Food & Drugs
Notice of Proposed Rule-Making.

In accordance with the provisions made therein, I wish respectfully, on behalf of Carlson-Ford Limited, to submit a number of comments on the above Notice printed in the Federal Register, Volume 38, No. 188, on Friday 28th September, 1973 as follows:-

1. We do not feel that it is appropriate for us, as specialists in the field of filtration, to comment in any detail on the various medical aspects of the possible health hazards that may arise from the ingestion of asbestos fibres. On the other hand, as this Company and its predecessor Companies, John C. Carlson Limited and T.B. Ford Limited, have been active in the supply and/or manufacture of asbestos bearing filter media since 1921 in the former case and since 1937 in the latter case, with the former Company also being able to draw on the experience of its prewar supplier of asbestos bearing filter media who have been operative in the field since about the turn of the century, we do feel competent to make comment on the usage of such filter media. We refer you to the enclosed paper which we have prepared entitled "A Brief History of the Use of Asbestos Bearing Filter Media for the Clarification and Sterilisation of Beverages and Drugs". From this you will see that various forms of asbestos bearing filter media - filter pulp, fibrous materials and filter sheets - have been in use in the beverage industries for nearly a century and in the preparation of drugs for some 50 years. In view of this relatively long history of usage of these filter media for the beverage and drug industries, we venture to suggest that if there were a serious health hazard associated with the ingestion of asbestos particles that they might contain, it would have shown itself ere now.

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2. It is an established fact that the use of asbestos bearing filter sheets has enabled producers of beers, wines, soft drinks and fruit juices to eliminate spoilage organisms and thus present to the consuming public a stable product that will not deteriorate in quality if stored for long periods.

Whilst it is agreed that it is possible to ensure microbiological stability of beverages by means of pasteurisation, it is an accepted practical fact that sterilising of beer by means of asbestos bearing filtering media is far more economic than "in bottle" pasteurisation of the packaged product. Further, not only are running costs very much lower but also capital costs for the necessary equipment and both these factors must reflect favourably on overall production costs. In the shorter term the flavour of a beverage sterilised by filtration will not show up to advantage as compared to that which has been pasteurised but, in the longer term, it does. In other words, where trading conditions are such that the particular beverage is likely to be stored for a considerable period prior to consumption then the consuming public benefits by having at its disposal a product of a better flavour.

The use of filter sheets containing special adsorptive agents can result in an improved quality of processed beverage at lower cost than other methods. Typical examples are the stabilisation of beers against chill hazes and oxidation hazes by passing them through filter sheets impregnated with Polyclar AT - Polyvinylpyrrolidone - which gives a product of such stability as could only be achieved by extended cold storage and all that that means by higher capital costs for the necessary equipment and naturally, very much higher running costs. Another example is the usage of carbon impregnated filter sheets by soft drink manufacturers that enables them to use a lower grade of sugar for the manufacture of their products than would otherwise have been the case and thereby to keep down their manufacturing costs.

3. Reference is made in the Federal Register to the question of pyrogen removal from parental drugs. May we take this opportunity of drawing your attention to a work by Wallhausser and Schmidt entitled "Sterilisation: Desinfektion Konserveirung Chemotherapie", published in 1967.

We enclose herewith a photostat copy of pages 41 and 42 of this publication together with a "without commitment" translation. You will note from this work that it is specifically stated that pyrogens can be eliminated by filtration and further that there appear to be two classes, one of which can be eliminated by membrane filtration but the other of which can only be removed by depth filtration through filter sheets which are, of course, asbestos bearing.

May we also draw your attention to certain other aspects of pyrogens and their elimination from parental drugs. It is accepted that they can be destroyed by heat but there are certain drugs which are thermostable and therefore the only possible way to free them from pyrogens is by filtration. It will be clear from what has already been stated in this respect that the ideal system is clearly that as proposed for the processing of parental drugs i.e. filtration through a depth medium such as an asbestos bearing filter sheet followed by another filtration through membranes for, in this way, one has the certainty that both types of pyrogen will be eliminated.

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Whilst water can hardly be classified as thermolabile, it is nevertheless acknowledged that it cannot be freed from pyrogens by distillation for pyrogen-like bodies which have the same temperature raising effect, can and do pass over when water is distilled. Activated carbon can certainly be used for pyrogen removal for many products and, indeed, there is a special asbestos and carbon bearing filter sheet available to the pharmaceutical industries that combines both carbon and depth filtration when used for depyrogenising filtration of pharmaceutical products.

It is gratifying to note that the Food & Drug Administration does not propose any control or prohibition of the use of asbestos bearing filters in the preparation of beverages and food and we trust that these observations serve to support their recommendation and that they will be given due consideration when the definitive rules are drawn up.

Yours faithfully,
for and on behalf of CARLSON-FORD LTD.,



G. Osgood
Deputy Chairman

Enclosed:

Brief History of use of
Asbestos Bearing Filter Media
Photostat copy pages 41/42
Desinfektion Konserveirung Chemotherapie
Without commitment translation.