

**LEDERLE LABORATORIES**



A Division of AMERICAN CYANAMID COMPANY

PEARL RIVER, NEW YORK 10965

AREA CODE 914 735-5000

December 21, 1973

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

Dear Sir:

We refer to the Notice of Proposed Rulemaking on the subject of Asbestos Particles in Food and Drugs as stated in the Federal Register, Vol. 38, No. 188 -- Friday, September 28, 1973. Comments were requested on this subject and our comments relate to biological products.

Filters containing asbestos have been used in processing of biologicals for many years. This type of filter has proven satisfactory for sterile filtration of biological products and has as an additional advantage the ability to adsorb impurities from certain of these products. We have been aware of the controversy regarding the use of asbestos type filters for some time. As a result of this, a significant amount of experimentation has been undertaken. One should be made well aware that any sudden changes in filtration techniques could adversely affect the efficacy of biological products. Therefore, we have been concerned in our product study with 1) protein composition, 2) product stability, 3) product fragmentation, 4) product aggregation, 5) flow rate for viscous products, 6) pyrogenicity, 7) sterility, etc.

Our study involves more than fifteen biologicals. During some stage of their manufacture, the process requires filtration through asbestos type filters. As of this date, we have been successful in developing an asbestos-free type of filtration for only one product. Since each product is unique unto itself and therefore represents a different problem, it has not and will not be possible to arrive at an early solution for a complete change to an asbestos-free process. Furthermore, we wish to draw attention to the fact that there is no reliable and economical method of assay for detection of asbestos fibers. Therefore, until such a method is developed, it will be difficult to ascertain the degree of success in our experimentation.

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Since this program is a complex one and concerns life-saving and disease-preventing products, due consideration should be given to the promulgation of any new regulations. We expect considerable experimentation to be necessary and anticipate a minimum of two years will be required to resolve all issues.

We respectfully request that these comments be given due consideration.

Very truly yours,



R. J. Vallancourt, D.V.M.  
Manager, Biological Section

RJV-WSH:vmp