

SCHERING CORPORATION

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CABLES: SCHERING BLOOMFIELD, N. J.

December 19, 1973

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

Dear Sir:

This is in response to the publication in the Federal Register, Vol. 38, No. 188, September 28, 1973, requesting comments regarding the Commissioner's proposal to regulate the use of asbestos-containing filters for the manufacture of parenteral drug products.

Schering Corporation will make every effort to eliminate asbestos-containing filtering materials in the manufacture of parenteral drugs by July 1, 1975. However, we must point out a number of factors that could prevent completion of the substitution program by that date.

The finding and testing of replacement filters in our basic synthesis and manufacture of raw materials and bulk active substances used in the formulation of drug dosage forms is highly complex and extensive. It will require substantial research to replace some of our current asbestos-containing filtration procedures with others that are equivalent in their effectiveness. The time for completion and success of the program is not now predictable.

A membrane filter, which is usually used in the last step in many parenteral manufacturing operations, will remove most of the asbestos particles but not the smallest ones, even though it effectively removes microorganisms and particulate matter down to 0.22 microns in size.

The substitution of membrane or similar filters for the current asbestos-type filters is further complicated by the fact that membrane filters differ in mode of action from asbestos-type filters; membrane filters remove matter by mechanical sieve action, while asbestos-type filters do so by both mechanical and adsorptive action.

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An additional complicating factor is that our manufacture of raw materials and active drug substances requires the use of many organic solvents, such as chloroform, alcohol, and acetone, and of acids and alkalies, which generally attack the membrane-type filters but are compatible with the asbestos-type filters.

It is for these briefly stated reasons that ample time is requested for development of suitable replacements for asbestos-containing filters.

Sincerely,

A handwritten signature in cursive script, reading "H. I. Mitchell".

H. I. Mitchell
Director of Quality Assurance

HIM/lc

cc: Mr. C. Joseph Stetler - PMA