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December 12, 1973



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

Gentlemen:

As a manufacturer of parenteral products, specifically allergenic extracts, we wish to comment on the proposed amendment to CFR, Title 21, Part 133.8.

(j) "Use of Asbestos-containing filters"

Although we use the non-asbestos-containing membrane filter as the final sterilizing filter for our products, we do use asbestos-containing depth filters up-stream. We have not found a substitute for the asbestos-containing filters which will adequately clarify many of our extracts to the degree needed for the efficient use of a membrane type final filter. Therefore, we feel that we must be able to use the asbestos type filter as a pre-sterilizing or in-process filter system. We understand that this would be acceptable as the proposed regulations are now written, however it appears that we would be required to show "evidence for reduction" of asbestos fibers using methods described in "CRITERIA FOR A RECOMMENDED STANDARD - OCCUPATIONAL EXPOSURE TO ASBESTOS." We question why such "evidence" should be required when we are using a sterilizing grade (0.22 micron pore size) membrane filter as the final filter, especially in view of the fact that the sampling methods referred to in the above mentioned report specify use of a membrane filter with a pore size of 0.80 microns (Millipore filter type AA).

We would, therefore, propose that no evidence for reduction be required where the final filter in the process is the membrane type with a pore size of 0.45 microns or less.

Sincerely,

HOLLISTER-STIER LABORATORIES


L. D. Hamlin
Director of Manufacturing

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LDH/lm
Enclosures/5 copies of letter

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