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CHARLES L. KROLL, Sc.D., director
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March 11, 1976

Department of Health, Education and Welfare
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Attention: Bureau of Drugs

Gentlemen:

Reference is made to the regulations published on March 14, 1975, concerning the use of asbestos-containing or other fiber-releasing filters and particularly the requirements under 21 CFR 133.3(j)(3) for reporting progress in the replacement of fiber-releasing filters if such replacement has not been completed by March 14, 1976.

We use a filter system for the terminal sterilization of technetium 99m eluates in our MINITEC (Technetium 99m) Generator, the subject of our New Drug Application 17-339. This system employs a membrane filter preceded by a fiber glass prefilter. We are currently evaluating a number of potential replacements for the fiber glass filter but so far have found none which do not either impede the flow, thus increasing the elution time excessively, or permit the passage of additional alumina particles which could potentially clog the membrane filter.

Sincerely,


C. L. Kroll

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