September 16, 1976

Theodore H. Meltzer, Ph.D.
Senior Filtration Specialist
Gelman Instrument Company
13101 Elsdale Court
Rockville, Maryland 20851

Dear Dr. Meltzer:

This is in reference to your letter of September 14, 1976, concerning your Company's remarks on filters relative to the pending FDA proposal on CGMP for LVPs, and the extension of these to SVPs.

This is to advise you that we are forwarding copies of your letter and enclosures to the Hearing Clerk as comments under Docket Numbers 76N-0099 (Large Volume Parenterals) and 76N-0100 (Small Volume Parenterals).

Sincerely yours,

T. E. Byers
Associate Director
for Compliance
Bureau of Drugs

cc:
HFD-320 (Mr. Loftus)
HFC-20 (Hearing Clerk)
HFD-300 R/F
HFA-226
dc

76N-0099

ANS 5