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April 28, 1975

Alexander M. Schmidt, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852

Dear Doctor Schmidt:

On March 14, 1975, the Food and Drug Administration published certain revisions to 21CFR133 (40FR11865-11869). These revisions addressed themselves to the elimination of fiber-releasing filters during product manufacture [21CFR133.8(j)] and to the requirement that containers for parenteral drugs, drug products or drug components be cleansed with water filtered through a non-fiber-releasing filter (21CFR133.9). The effective date of the order is given as April 14, 1975.

We note that 21CFR133.8(j)(3) provides a hopefully reasonable time period for manufacturers to achieve substitution for fiber-releasing filters that may currently be used during production.

However, the revised 21CFR133.9 had an effective date of April 14, 1975, meaning that manufacturers had only 30 days (less the time it takes for delivery of the Federal Register) to install a suitable non-fiber-releasing filter into their container wash water lines. This, in our opinion, is not a sufficient time period and fails to recognize the impact on manufacturers. If manufacturers can be allowed 18 months to eliminate fiber-releasing filters from production, we cannot see the need for requiring installation of a membrane-type filter in wash water lines within 30 days. We question what hazard exists to warrant this urgency.

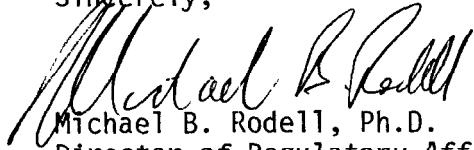
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We urgently request that you publish a notice in the Federal Register delaying the effectivity of revised 21CFR133.9 until at least September 14, 1975.

Sincerely,

A handwritten signature in cursive script, appearing to read "Michael B. Rodell".

Michael B. Rodell, Ph.D.
Director of Regulatory Affairs
and Clinical Development

lg

cc: John Adams, Ph.D.
PMA