

NAPM



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NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS

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August 4, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., Rm 1-23
Rockville, MD 20857

RE: Guidance for Industry - ANDAs: Impurities in Drug Substances
[Docket No. 98D-0514]

We are requesting a 60 day extension of the comment period for the draft guidance, *ANDAs: Impurities in Drug Substances* [Docket No. 98D-0514]

Our members are currently reviewing this document and need the additional time to provide a comment letter to your office.

NAPM is the national trade organization representing manufacturers, distributors and repackagers of generic multisource prescription drugs, OTC drugs, dietary supplements and veterinary drugs. The organization prides itself in serving the needs of its members and has been heavily involved in legislative, legal, regulatory and technical issues.

Thank you for your consideration of this request.

Yours truly,

A handwritten signature in cursive script that reads "Leon Shargel".

Leon Shargel, Ph.D.
Vice President and Technical Director

cc: Robert W. Trimmer, Ph.D

98D-0514

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