



Organon Inc.

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November 14, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUBJECT: Docket No. 2003D-0382
Comments on Draft Guidance for Industry: Sterile Drug Products Produced by
Aseptic Processing – Current Good Manufacturing Practice
Public Release

Dear Sir/Madam:

Reference is made to our correspondence, dated November 5, 2003, which provided our comments regarding the FDA Draft Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice.

We were informed that the referenced correspondence had been stamped CONFIDENTIAL. Please be advised that it was not our intent for this document to be confidential; therefore, please disregard that designation.

Should you have questions or require additional information, please do not hesitate to contact the undersigned by phone at 973-325-4830.

Sincerely,

Thomas L. Pituk, PhD, RPh, RAC
Senior Director, Regulatory Affairs

Submitted in duplicate
via Certified Mail RRR # 7001-1940-0004-3744-0008



03D-0382

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