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September 23, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Ref: Docket No. 2003D-0382

Dear Sir or Madam:

Enclosed are comments regarding FDA's Draft Guidance for Industry on "Sterile Drug Products Produced by Aseptic Processing."

I believe the draft guidance significantly improves on the 1987 guidance it is intended to replace. However, its scope goes considerably beyond aseptic processing. The draft guidance could be improved and simplified if the sections on Sterilizer Qualification and Validation, Equipment Controls and Instrument Calibration, and Sterility Testing were deleted and, if necessary, were the subjects of separate guidance documents.

Hopefully, these comments will prove useful to FDA as it refines and finalizes the draft guidance.

Sincerely,

Russell E. Madsen
President
The Williamsburg Group

Enclosure

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