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October 13, 2003

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

Ref: Docket No. 2003D–0386

Dear Sir or Madam:

The purpose of this letter is to submit comments regarding FDA's Draft Guidance for Industry on "Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP."

The draft guidance provides an excellent framework for resolving scientific and technical issues resulting from an FDA inspection; however the tier-one requirement for a manufacturer to seek clarification of a disputed issue within 10 business days is overly restrictive. Large, multinational companies might find compliance with this provision difficult. I suggest that 20 business days (or 30 days) would be more appropriate, while preserving the necessary sense of urgency for resolving these issues.

Hopefully, these comments will prove useful to FDA as it refines and finalizes the draft guidance.

Sincerely,

Russell E. Madsen
President
The Williamsburg Group

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