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Division of Pharmacy
1-8020401 - Unit 90

January 31, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5653 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2005N-0285

Dear Sirs:

I would like to make two suggestions to the draft document "Guidance for Industry INDs – Approaches to complying with CGMP During Phase 1" that is an accompaniment to the Federal Register Notice entitled "current Good Manufacturing Practice Regulation and Investigational New Drugs".

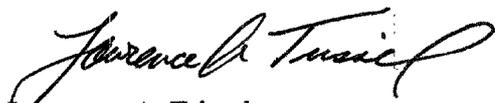
There can be no doubt that this is a positive move for encouraging clinical trials of new drugs and thereby helping patients who have little offered to them from conventional marketed medications. Please consider including the following points within the final document.

I. Introduction – The document notes that it applies to Phase 1 development. I suspect you intend this document also to apply to Phase 0 and to Pre-Phase 1 study materials as well. I think explicitly stating this would be of value.

V. Recommendations for Complying with the Statute - I think the guidance would benefit from having a general statement that all of the investigational products should comply with relevant compendial (USP) standards for drug quality. On page 13 under Sterile Products, compliance with the USP <71> sterility test is specifically cited, but another more general statement that would include other relevant compendial quality standards (e.g. bacterial endotoxin <85>, dissolution <711>, environmental quality of the production facility <797>, etc.) would be appropriate and helpful guidance. I do not believe a complete listing of all relevant standards is needed, but a more general statement that is inclusive should be added. The compendial standards should be considered the minimum quality standard unless FDA specifically gives permission for a different standard to be used.

Thank you for this opportunity to comment on the draft guidance document.

Sincerely yours,



Lawrence A. Trissel
Director Clinical Pharmaceuticals Research

2005N-0285

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located in the Texas Medical Center

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