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March 17, 2006

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

RE: Docket No. 2005D-0286, Draft Guidance for Industry on Investigational New Drugs;  
Approaches to Complying with Current Good Manufacturing Practice During Phase 1

Dear Sir or Madam:

Cambrex Corporation appreciates the opportunity to comment on the draft FDA Guidance for Industry on Investigational New Drugs; Approaches to Complying with Current Good Manufacturing Practice During Phase 1. Cambrex is a global, diversified life science company dedicated to providing high quality products and services to accelerate drug discovery, development, and manufacturing processes for customers focused on health and the prevention of disease.

Provided below is a comment on the draft Guidance for Industry on Investigational New Drugs; Approaches to Complying with Current Good Manufacturing Practice During Phase 1.

- Lines 248 - 250. Please revise the sentence to require an independent quality review and release of batches.
  - Even in these circumstances, we recommend that another qualified individual not involved in the production operation perform an independent review of production records and release of the batch.

Thank you for consideration of the comment. Please call me if you have any questions.

Sincerely,

Barbara B. Zinck  
Senior Director  
Corporate Compliance  
Cambrex Corporation

2005D-0286

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