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

RE: Docket No. 2005N-0285
Current Good Manufacturing Practice Regulation and Investigational New Drugs; Direct Final Rule

Dear Sir or Madam:

Cambrex Corporation appreciates the opportunity to comment on the Current Good Manufacturing Practice Regulation and Investigational New Drugs; Direct Final Rule. 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 Current Good Manufacturing Practice Regulation and Investigational New Drugs; Direct Final Rule.

- The FDA should maintain the 1991 "Guideline on the Preparation of Investigational New Drug Products (Human and Animal)" until the Agency provides additional guidance or regulations to clarify FDA's expectations with regard to fulfilling cGMP requirements for producing investigational drugs for Phase 2 and Phase 3 clinical studies. If this guideline is withdrawn prematurely the increased regulatory and validation burden on industry will far outweigh the savings gained from the proposed Current Good Manufacturing Practice Regulation and Investigational New Drugs; Direct Final Rule without benefit to patients.
- Accurate record keeping and internal document review is an absolute must for all drugs and medical devices regardless of the stage of clinical development, as is using the best raw materials available during their production. However, manufacturing processes are often not locked-down during clinical trial material preparation, especially in complex manufacturing processes for biologics. Processes are often changed to increase efficiencies, increase yields, or as a result of scale-up to meet the requirements of larger numbers of clinical subjects in the clinical trials. Many processes are also not linearly scaleable. Additionally, assays used to release such products at this stage are often still under development as the processes evolve.
- Since most products do not make it out of the clinical trial phase of development, the burden for full GMP compliance far outweighs any perceived benefit from full cGMP compliance at this stage. The requirement for cGMP compliance should be a progressive scale all the way through clinical trials into licensure.

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

Sincerely,

Barbara B. Zinck
Senior Director, Corporate Compliance

2005N-0285

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