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October 28, 2003

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

RE: Docket No. 2003D-0380, Federal Register: September 5, 2003 (Volume 68, Number 172, pp. 52781-52782)

Dear Sir or Madam:

Cambrex Corporation appreciates the opportunity to comment on the draft FDA Guidance for Industry: Process Analytical Technology, PAT – A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance. 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Provided below is a comment on the draft Guidance for Industry: Process Analytical Technology, PAT – A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance.

- Line 57 footnote and Lines 69 - 70. Please amend the guidance to include products regulated by CBER and products in CDER's Office of Biotechnology Products. There are areas where PAT could be utilized without adversely affecting biotechnology products. As examples, controls for buffer preparation or the use of NIR spectroscopy for raw materials, some of which are common to both small molecules and biotechnology products.

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

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