CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-780

CORRESPONDENCE

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February 16, 2001

NEW CORRESPONDENCE

NDA 50-780, Cefuroxime for Injection USP and Dextrose Injection USP in the Duplex™ Container

Ms. Elizabeth Duvall-Miller, Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV, HFD-520
9201 Corporate Boulevard, Room 309
Rockville, Maryland 20852

Reference is made to pending New Drug Application, NDA 50-780 for Cefuroxime for Injection USP and Dextrose Injection USP in the Duplex™ Container, submitted April 17, 2000, and amended on December 21, 2000. Further reference is made to Dr. Pagay's fax dated February 16, 2001 outlining the draft regulatory specifications for the drug substance and drug product.

We have reviewed the draft regulatory specifications as outlined in the fax. They are consistent with the specifications and methods presented in the original application and subsequent amendments, and will be used as the regulatory specifications for the commercialized product.

Sincerely,

John Spoden
Associate Director, Regulatory Affairs

Desk copy: Dr. Shrikant Pagay