



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

May 18, 2005

**FILE COPY**

Anthony Celeste  
Senior, Vice President  
7361 Calhoun Place, Suite 500  
Rockville, MD 20855-2765

Dear Mr. Celeste:

Your petition requesting the Food and Drug Administration to make a determination that Pantoprazole sodium injection 40 mg per vial is suitable for submission as an Abbreviated New Drug Application was received by this office on 05/18/2005. It was assigned docket number 2005P-0196/CP1 and it was filed on 05/18/2005. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script, appearing to read "Lyle D. Jaffe".

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2005P-0196

ACK 1