DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

August 7, 2006

FILE COPY

Charles J. Raubicheck
Frommer, Lawrence & Haug, LLP
745 Fifth Avenue
New York, New York 10151

Dear Mr. Raubicheck:

Your petition requesting the Food and Drug Administration to issue a determination that the drug product ELOXATIN (oxaliplatin for injection) lyophilized powder for infusion, 50 mg and 100 mg vials was not voluntarily withdrawn from sale for safety or effectiveness reasons, was received by this office on 08/07/2006. It was assigned docket number 2006P-0309/CP 1 and it was filed on 08/07/2006. 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,

Gloria Ortega

Gloria Ortega, Deputy Director
Division of Dockets Management
Office of Management Programs
Office of Management

2006P-0309 ACK 1