DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 2 2 2007

1635 7 JAN 25 A9:38

Mr. Steven Lieberman
Rothwell, Figg, Ernst & Manbeck
1425 K Street, N.W., Suite 800
Washington, DC 20005

Re: Docket No. 2006P-0299/CP1

Dear Mr. Lieberman:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on July 24, 2006. Your petition requests that the Agency determine whether Eloxatin (oxaliplatin for injection), 50 milligrams (mg)/vial and 100 mg/vial, sterile lyophilized powder, was voluntarily withdrawn from sale for safety or efficacy reasons.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0299

LET 1