



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305
Public Health Service

JAN 22 2007

Food and Drug Administration
Rockville MD 20857

Ms. Tania Hoffman
Project Specialist, Regulatory Affairs
SICOR Pharmaceuticals, Inc.
19 Hughes
Irvine, CA 92618-1902

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Re: Docket No. 2006P-0291/CP1

Dear Ms. Hoffman:

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 25, 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(oxaliplatin for injection), 50 milligrams (mg)/vial and 100 mg/vial, sterile lyophilized powder, was voluntarily withdrawn or withheld from sale for safety or efficacy reasons.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
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0291

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