DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 13 2007

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

Re: Docket No. 2006P-0520/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 petition dated December 15, 2006. Your petition requests that the FDA determine whether methotrexate injection, USP, preservative free, equivalent to (Eq.) 500 milligrams (mg) base/20 milliliters (mL) (25 mg/mL)(new drug application No. 11-719 held by Mayne Pharma USA) was withdrawn from sale for reasons of safety or effectiveness.

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-0520

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