DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 24 2003

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Arthur Y. Tsien
Olsson, Frank and Weeda, P.C.
1400 Sixteenth Street, N.W.
Washington, D.C. 20036-2220

Re: Docket No. 2003P-0266/CP1

Dear Mr. Tsien:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition dated June 10, 2003, requesting that the FDA determine whether approval of the new drug application (NDA) for LOVENOX (enoxaparin sodium), 90 milligrams /0.6 milliliter (NDA 20-164), was voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the Agency. 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 we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

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

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