DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 15 2003

Peter O. Safir, Esq.
Scott L. Cunningham, Esq.
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2401

Re: Docket No. 03P-0064/CP1

Dear Mr. Safir and Mr. Cunningham:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on February 19, 2003, on behalf of Aventis Pharmaceuticals Inc. Your petition requests that FDA withhold approval of any abbreviated new drug application (ANDA) for a generic version of Aventis's Lovenox (enoxaparin sodium injection (enoxaparin)) until enoxaparin has been fully characterized, unless (1) the manufacturing process used to create the generic drug is determined to be equivalent to Aventis's manufacturing process for Lovenox or (2) the ANDA is supported by proof of equivalent safety and effectiveness demonstrated in clinical trials. Your petition also requests that FDA not approve any ANDA for a generic version of Lovenox unless the generic product contains a 1,6 anhydro ring structure at the reducing ends of between 15 percent and 25 percent of its polysaccharide chains.

FDA has been unable to reach a decision on your requests because they raise complex issues requiring extensive review by Agency officials. 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 requests.

Sincerely,

Jane A. Axelrad

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

03P-0064

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