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BY HAND DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

A. Action Requested

The undersigned submits this petition under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FFDCA") (21 U.S.C. § 355(j)) and 21 C.F.R. §§ 10.25(a), 10.30 and 314.161, to request the Commissioner of Food and Drugs to determine that Lovenox® (enoxaparin sodium), NDA 20-164 (90mg/0.6ml) (Product Number 006), sponsored by Aventis Pharmaceuticals Inc. ("Aventis"), was not withdrawn from sale for reasons of safety or effectiveness.

B. Statement of Grounds

The Drug Price Competition and Patent Term Restoration Act of 1984 amended the FFDCA to require, among other things, that FDA publish a list including each drug which has been approved for safety and effectiveness, along with relevant patent information. 21 U.S.C. § 355(j)(7)(A). FDA publishes this list as part of its *Approved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book"). Included in the Orange Book is a cumulative list of approved products that have never been marketed, have been discontinued from marketing, or have had their approvals withdrawn for other than safety or efficacy reasons subsequent to being discontinued from marketing. This list is known as the "Discontinued Drug Product List" (Introduction to *Approved Drug Products With Therapeutic Equivalence Evaluations*, Section 1.1 (23rd ed., 2003)).

Under its implementing regulations at 21 C.F.R. § 314.161(a)(1), FDA must make a determination whether a discontinued listed drug was withdrawn from sale for reasons of safety or effectiveness prior to approving an abbreviated new drug application ("ANDA") that refers to that discontinued drug. Upon making a determination that such a listed drug was not withdrawn from sale for reasons of safety or effectiveness, FDA is required to publish a notice of this determination in the Federal Register. 21 C.F.R. § 314.161(e).

Lovenox® (enoxaparin sodium) is an injectable drug product with numerous available concentrations, strengths, and dosage forms. The product at issue here, NDA 20-164 Product Number 006, a 90mg/0.6mL strength of enoxaparin sodium, was approved by FDA on June 2, 2000, and subsequently voluntarily withdrawn from sale by Aventis. Presently, Product Number 006 appears in the "Discontinued Drug Product List" section of the Orange Book.

Petitioner requests that FDA determine that Aventis's decision to withdraw Product Number 006 was for reasons other than safety or effectiveness. Petitioner submits that the withdrawal of the 90mg/0.6mL strength could not have been for safety or effectiveness reasons.

First, Lovenox® remains on the market in eight various strengths, with U.S. sales of $958 million in 2002 (http://www.aventispharma-us.com/main/0,1003,EN-US-28455-45933--,00.html). Lovenox® enjoys continued market success despite competition from other anticoagulants because of its acceptable risk/benefit profile. Thus, the withdrawal of one product strength from a nine product line with strong sales indicates continued safety and effectiveness acceptance for Lovenox®, both by FDA and by prescribers.

Second, the 90mg/0.6mL strength Lovenox® which was voluntarily withdrawn from the market was part of the 150mg/mL concentration product line which Aventis continues to market. *See* "How Supplied" section of Lovenox® package insert, attached and available at http://www.aventis-us.com/PIs/lovenox_TXT.html. The same 150mg/mL concentration Lovenox® remains on the market in different volume presentations, specifically both 120mg/0.8mL and 150mg/1mL strengths. Therefore, the withdrawal of the 90mg/0.6mL strength could not have been for safety or effectiveness reasons.

C. Environmental Impact

The action requested by this petition is subject to categorical exclusion pursuant to 21 C.F.R. § 25.31.

D. Economic Impact

An economic impact statement will be provided at the request of the Commissioner.

E. Certification

The undersigned certifies that, to best of his knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

Arthur Y. Tsien

AYT:jdc