DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

2736 '04 MAR 11 12:27

March 8, 2004

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:

This letter responds to your citizen petition, dated June 10, 2003, requesting that the Food and Drug Administration (FDA) determine whether approval of the new drug application (NDA) for LOVENOX (enoxaparin sodium) 90 milligrams (mg)/0.6 milliliter (mL) (NDA 20-164), was voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

The FDA has reviewed its records and determined that LOVENOX 90mg/0.6 mL was not withdrawn from sale for reasons of safety or effectiveness. Thus, the FDA will maintain LOVENOX (enoxaparin sodium) 90 mg/0.6 mL, in the *Discontinued Drug Product List* of *Approved Drugs With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 594-5638.

Sincerely,

Brian Pendleton for

Nikki Mueller
Division of Regulatory Policy I
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

2003P-0266 LET 2

PLEASE REPLACE ATTACHED RESPONSE DATED MARCH 8, 2004 WITH RESPONSE YOU WERE RECENTLY SENT. PREVIOUS RESPONSE WAS ERRONEOUSLY DATED MARCH 8, 2003. Thank you.

and 806 of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b, 2991b–3 and 2991d–1)

19. (c) Panel Reviews and Funding Decisions

ANA values the knowledge and expertise of individual reviewers. Applications for funding are randomly assigned to panel review teams. Each panel reviewer is responsible for reading the program announcement **Federal Register** and scoring each application in accordance with the published review criteria. Each application is reviewed and scored independently by a panel reviewer. After the panel review process, ANA conducts due diligence on each application in the funding range. The ANA Commissioner determines the final action on each grant application received under ANA program announcements. The Commissioner's funding decision is based on an analysis of the application by each peer review panel, the review and recommendations of ANA staff, panel review scores, comments of State and Federal agencies having contract and grant performance related information, and other interested parties. The Commissioner makes grant awards consistent with the purpose of the Native American Programs Act (NAPA), all relevant statutory and regulatory requirements, this program announcement, and the availability of appropriated funds. *(Legal authority: Sections 803(a) and (d), 803C and 806 of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b, 2991b–3 and 2991d–1)*

19. (d) Award Notification Information

Successful applicants are notified through an official Financial Assistance Award (FAA) document. The FAA will state the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the grant award, the effective date of the award, the project period, the budget period, and the amount of the non-ACF matching share requirement. Unsuccessful applicants should expect notification within 90 days after the closing deadline date. *(Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b–3)*

20. Web Site Information

In FY 2004, ANA may make public on its web site information associated with successfully funded applications. Such information will include the name of the grant recipient, type of award such as SEDS, Language, Environmental amount, the duration of the project, and a synopsis of the project. Posting this information will provide prospective applicants with examples of successfully funded projects, inform the public how and where ANA is expending its funds, and share information with other HHS, ACF, federal and state agencies. The ANA website will also include profiles of successful ANA community projects, and it will provide links to other funding sources, information on special HHS, ACF and ANA initiatives, and provide an opportunity for ANA applicants to tract the review and approval process of submitted applications for funding. *(Legal authority: Sections 803(a) and (d) and 803C of the Native Americans Programs Act of 1974, as amended, 42 U.S.C. 2991b and 2991b–3)*

21. New OMB Format Requirements

The Office of Management and Budget has changed the format for program announcements published in the **Federal Register**. ANA has modified its normal program announcement format to comply with these changes.

Additional Information

Reporting Requirements

Correction: The Social and Economic Development Strategies program announcement included in the November **Federal Register** Notice has a typographical error in one of the references to the Reporting Requirements. The Financial Status reports (SF269) will be submitted on a quarterly basis and not semi-annually as incorrectly stated on 68 FR 64685, 64707 (November 14, 2003). Under 45 CFR 74.52(a)(1)(iii) and 45 CFR 92.41(b)(3), HHS awarding agencies are authorized to require grantees to submit Form 269s as frequently as quarterly.

Dated: February 12, 2004.

Quanah Crossland Stamps,

Commissioner, Administration for Native Americans.

[FR Doc. 04–5043 Filed 3–5–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003P–0266]

Determination That LOVENOX (Enoxaparin Sodium) 90 Milligrams/0.6 Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that LOVENOX (enoxaparin sodium) 90 milligrams (mg)/0.6 milliliter (mL) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for enoxaparin sodium 90 mg/0.6 mL.

FOR FURTHER INFORMATION CONTACT: Nicole Mueller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval

of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

LOVENOX (enoxaparin sodium) 90 mg/0.6 mL, is the subject of approved NDA 20–164 held by Aventis Pharmaceuticals, Inc. (Aventis). LOVENOX (enoxaparin sodium) 90 mg/0.6 mL, approved June 2, 2000, is an anticoagulant indicated for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism. Aventis never marketed the 90mg/0.6 mL presentation of LOVENOX. On June 10, 2003, Olsson, Frank and Weeda, P.C. submitted a citizen petition (Docket No. 2003P–0266) under § 314.161 and 21 CFR 10.21(a) and 10.30, requesting that the agency determine whether LOVENOX (enoxaparin sodium) 90 mg/0.6 mL was withdrawn from sale for reasons of safety or effectiveness. The agency has determined that, for purposes of § 314.161(a) and (c), never marketing an approved drug product is equivalent to withdrawing the drug from sale.

The agency has determined that Aventis' LOVENOX (enoxaparin sodium) 90 mg/0.6 mL was not withdrawn from sale for reasons of safety or effectiveness. In support of this finding, we note that Aventis continues to market other presentations of LOVENOX that are the same concentration as LOVENOX 90 mg/0.6 mL. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, Aventis' LOVENOX (enoxaparin sodium) 90 mg/0.6 mL was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list LOVENOX (enoxaparin sodium) 90 mg/0.6 mL in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to LOVENOX (enoxaparin sodium) 90 mg/0.6 mL may be approved by the agency.

Dated: February 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–5106 Filed 3–5–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1997D–0530]

Food and Drug Adminstration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 009

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled "Modifications of the List of Recognized Standards, Recognition List Number: 009" (Recognition List Number: 009), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of "Modification to the List of Recognized Standards, Recognition List Number: 009" to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. Submit written comments concerning this document or to recommend additional standards for recognition to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by e-mail: *standards@cdrh.fda.gov*. This document may also be accessed on FDA's Internet site at *http://www.fda.gov/cdrh/fedregin.html*. See section VI of this document for electronic access to the searchable database for the current list of "FDA Recognized Consensus Standards," including Recognition List Number: 009 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health (CDRH) (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4766, ext.156.

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards, developed by international and national organizations, for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of guidance entitled "Recognition and Use of Consensus Standards." This notice described how FDA will implement its standard recognition program and provided the initial list of recognized standards.

In **Federal Register** notices published on October 16, 1998 (63 FR 55617), July 12, 1999 (64 FR 37546), November 15, 2000 (65 FR 69022), May 7, 2001 (66 FR 23032), January 14, 2002 (67 FR 1774), October 2, 2002 (67 FR 61893), and April 28, 2003 (68 FR 22391), FDA modified its initial list of recognized standards. These notices described the addition, withdrawal, and revision of certain standards recognized by FDA. The agency maintains "hypertext markup language (HTML)" and "portable document format (PDF)" versions of the list of "FDA Recognized Consensus Standards." Both versions are publicly accessible at the agency's Internet site. See section VI of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 009

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency will recognize for use in satisfying premarket reviews and other requirements for devices. FDA will