DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 077857

Sandoz Inc.
Attention: Marcy Macdonald
Director, Regulatory Affairs
2555 West Midway Blvd.
Broomfield, CO 80020

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated August 26, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Enoxaparin Sodium Injection USP, 100 mg/mL, [packaged in 30 mg/0.3 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL, 100 mg/ 1 mL], and 150 mg/mL [packaged in 120 mg/0.8 mL and 150 mg/1 mL] (Prefilled Single-dose Syringes with Automatic Safety Device) (Preservative-Free).

Reference is made to your amendments dated July 6, August 31, September 7, October 5, November 9, November 17, November 29, December 28, 2006; January 5, February 20, February 27, March 23, March 26, June 8, September 19, October 26, 2007; February 13, February 27, June 2, June 13, September 23, September 25, November 20, November 21, December 12, 2008; January 20, February 27, March 2, March 12, March 20, April 8, May 21, June 1, June 3, June 19, June 25, July 1, August 6, September 18, September 30, October 7, October 21, December 1, and December 30, 2009; and January 13, January 18, March 15, April 28, and May 26, 2010. Reference is also made to your communications dated June 22, and September 8, 2006; multiple amendments (47 submissions) dated January 3, 2007 through March 9, 2007; and June 13, and September 16, 2008.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Office of Generic Drugs has determined that your Enoxaparin Sodium Injection USP, 100 mg/mL and 150 mg/mL, (Preservative-Free), meets the standards for

approval (including those for active ingredient sameness and bioequivalence) and, therefore, is therapeutically equivalent to the reference listed drug (RLD), Lovenox Injection, 100 mg/mL and 150 mg/mL, respectively, (Preservative-Free), of Sanofi Aventis US, LLC (Sanofi).

The reference listed drug (RLD) upon which you have based your ANDA, Sanofi's Lovenox Injection, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 5,389,618 (the '618 patent) and RE38743 (the '743 patent) expire on February 14, 2012.

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '618 and '743 patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Enoxaparin Sodium Injection, 100 mg/mL, 150 mg/mL (Prefilled Single Dose Syringes with Automatic Safety Device), under this ANDA. You have notified the agency that Sandoz, Inc. (Sandoz) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Sandoz for infringement of the '618 and '743 patents in the United States District Court for the Central District of California [Aventis Pharma S.A. and Aventis Pharmaceuticals, Inc.v. Sandoz Inc., Civil Action Nos. CV-07-2558 (previously CV-06-3671) and CV-06-4858]. As noted below, these patents were found to be unenforceable.

With respect to 180-day generic drug exclusivity for Enoxaparin Sodium Injection, 100 mg/mL and 150 mg/mL (Prefilled Single Dose Syringes with Automatic Safety Device), ANDAs containing paragraph IV certifications and referencing Lovenox were submitted to FDA before the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) (MMA). Therefore, 180-day exclusivity for drug products referencing Lovenox is governed by section 505(j)(5)(B)(iv) of the Act as in effect before passage of the MMA. See section 1102(b)(1) of the MMA. In accordance with the applicable exclusivity provisions, any 180-day exclusivity for these products was triggered on October 2, 2008, when the Federal Circuit issued the Mandate with respect to its decision in Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc. (525 F.3d. 1334; Fed. Cir. May 14, 2008) affirming the district court's finding that the '618 and '743 patents are unenforceable due to inequitable conduct. The 180-day period expired on March

31, 2009. Therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U_CM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-77857	ORIG-1	SANDOZ INC	ENOXAPARIN SODIUM

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KEITH O WEBBER
07/23/2010