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***APPLICATION NUMBER:***

**ANDA 079197**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

ANDA 079197

Akorn Inc.  
Attention: Sam Boddapati, Ph.D.  
Sr. Vice President, Regulatory Affairs  
1925 West Field Court, Suite 300  
Lake Forest, IL 60045

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 27, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Pantoprazole Sodium for Injection, 40 mg (base)/Single-dose Vial.

Reference is also made to your amendments dated January 9, June 18 and 20, August 22 and 27, October 1 and 17, 2008; November 17, 2009; March 31, April 26, June 15, and September 1, 2010; January 11 and 28, February 28, March 1 and 28, April 8, August 1 and 19, 2011; and January 11, June 6, June 7, September 19, and September 24, 2012.

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 Division of Bioequivalence has determined your Pantoprazole Sodium for Injection, 40 mg (base)/Single-dose Vial, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Protonix I.V. for Injection, 40 mg (base)/Single-dose Vial, of Wyeth Pharmaceuticals Inc. (Wyeth).

The RLD upon which you have based your ANDA, Wyeth's Protonix I.V. for Injection, 40 mg (base)/Single-dose Vial, 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. 6,780,881 (the '881 patent) and 7,351,723 (the '723 patent) are

scheduled to expire on May 17, 2022 (with pediatric exclusivity extensions added).

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Pantoprazole Sodium for Injection, 40 mg (base)/Single-dose Vial, under this ANDA. You have notified the agency that Apotex Inc. (Apotex), the former holder of this ANDA, complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '881 patent was brought against Apotex within the statutory 45-day period in the United States District Court for the Northern District of Illinois, Eastern Division [Nycomed GmbH and Wyeth v. Apotex, Inc. and Apotex Corp., Civil Action No. 1:08-00827]. You have also notified the agency that the litigation was dismissed.

As of October 1, 2012, Akorn Inc. (Akorn) must pay fees in accordance with the Generic Drug User Fee Amendments of 2012 (Public Law 112-144, Title III). Because your ANDA was pending on October 1, 2012, your ANDA is now subject to a backlog fee. However, you will not be penalized until the backlog fee payment is overdue. As indicated in the Federal Register (FR) notice (77 FR 65199), published on October 25, 2012, the backlog fee is due no later than 30 days after publication of the notice. If you do not pay the fee by the due date, statutory penalties take effect. At that time, FDA cannot receive any further ANDAs or supplements from Akorn Inc. or its affiliates, and Akorn will be placed on a publicly available arrears list until the fee is paid.

In addition, your ANDA is now subject to facility fees. As noted above with regard to the backlog fee, you will not be penalized for nonpayment of the facility fee until the fee payment is overdue. The fee must be paid within 45 days after publication of the FR notice announcing the amount of the facility fee. If you do not pay the facility fee by the due date, statutory penalties take effect. At that time, FDA will deem misbranded this ANDA product and all products from facilities that have not paid the appropriate fee. In addition, facilities that have not paid the fee will be placed on a publicly available arrears list, until the fee is paid or the facilities are removed from the ANDA.

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.

Please 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.

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.

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  
Office of Prescription Drug Promotion  
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 Office of Prescription Drug Promotion 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 in content 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/UCM072392.pdf>. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

*{See appended electronic signature page}*

Gregory P. Geba, M.D., M.P.H.  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ROBERT L WEST

11/08/2012

Deputy Director, Office of Generic Drugs, for  
Gregory P. Geba, M.D., M.P.H.