ANDA 078281

# *OFFICE OF GENERIC DRUGS*

Office of Generic Drugs (HFD–600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North VII
7620 Standish Place
Rockville,MD 20855
Fax: 240-276-9327

## FAX TRANSMISSION COVER SHEET

APPLICANT: KUDCO Ireland Limited  TEL: 812-523-5539

ATTN: Elaine Siefert  FAX: 812-523-1887

FROM: Frank J. Nice  FDA CONTACT PHONE: (240) 276-8555

Dear Madam:

This facsimile is in reference to your abbreviated new drug application dated April 25, 2006, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Pantoprazole Sodium Delayed-release Tablets, 20 and 40 mg.

We are pleased to inform you that this application is APPROVED!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078281

Kremers Urban Pharmaceuticals, Inc.
U.S. Agent for Kudco Ireland Limited
Attention: Elaine Siefert
Director, Regulatory Affairs
1101 "C" Avenue West
Seymour, IN 47274

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated April 25, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Pantoprazole Sodium Delayed-release Tablets USP, 20 mg (base) and 40 mg (base).

Reference is also made to the letters from our office dated March 17, 2009, and August 18, 2010, and your amendments dated January 18, February 6, and April 24, 2007; October 13, October 31, and November 21, 2008; January 7, May 21, July 7, and October 16, 2009; January 15, January 15, April 15, April 20, April 20, April 29, May 4, June 17, July 16, July 30, August 13, August 23, August 23, September 13, September 29, October 1, October 13, November 19, December 3, December 14, and December 20, 2010; and January 3, January 10, and January 18, 2011.

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 Delayed-release Tablets USP, 20 mg (base) and 40 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Protonix Delayed-release Tablets of Wyeth Pharmaceuticals (Wyeth).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA and as presented in our letter dated March 17, 2009.

The RLD upon which you have based your ANDA, Wyeth's Protonix Delayed-release Tablets, is subject to a period of patent protection. As noted in the agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") U.S. Patent No. 5,997,903 (the '903 patent) will expire on June 7, 2017 (with pediatric exclusivity added).

Your ANDA contains a certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '903 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Pantoprazole Sodium Delayed-release Tablets USP, 20 mg (base) and 40 mg (base). You have notified the agency that Kudco Ireland Ltd. (Kudco) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '903 patent was brought against Kudco.

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
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 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/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

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

/s/

ROBERT L WEST
01/20/2011
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.