DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 77-056

APR 19 2006

TEVA Pharmaceuticals USA
Attention: Philip Erickson, R.Ph.
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated February 2, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Pantoprazole Sodium Delayed-release Tablets, 20 mg (base) and 40 mg (base).

Reference is also made to your amendments dated July 20, and December 29, 2005; and January 25, 2006. We also acknowledge receipt of your correspondence dated June 15, 2004, addressing the patent issues noted below.

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the patent issue noted below. Therefore, the ANDA is **tentatively approved.** This determination is based upon information available to the agency at this time, (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The reference listed drug product (RLD) upon which you have based your ANDA, Protonix Delayed-release Tablets, 20 mg (base) and 40 mg (base), of Wyeth Pharmacueticals, Inc., is currently 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 4,758,579 (the '579 patent) and 5,997,903 (the '903 patent) listed for this drug product are scheduled to expire on July 19, 2010, and December 7, 2016, respectively. Your ANDA contains paragraph IV certifications to the '579 and '903 patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Pantoprazole Sodium Delayed-release Tablets, 20 mg (base) and 40 mg (base), under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately unless an action was brought against Teva Pharmaceuticals USA, (Teva) for infringement of one or both of the patents that were the subjects of the paragraph IV certifications. You have notified the Agency that Teva 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 Teva within the statutory 45-day period. However, you notified the agency that litigation for infringement of the '579 patent was brought against Teva within the statutory 45-day period in the United States District Court, District of New Jersey [Altana Pharma AG and Wyeth v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd., Civil Action No. 04-2355]. This litigation is ongoing.

Therefore, final approval of this ANDA cannot be granted until:

1. a. pursuant to sections 505(j)(5)(B)(iii) and 505(j)(5)(F)(ii) of the Act, the expiration of the 7½ year period from the date of approval of the RLD, i.e., until August 2, 2007, or

   b. the date the court decides[1] that the '579 patent is invalid or not infringed. See section 505(j)(5)(B)(iii)(I), (II), and (III), of the Act, or

   c. the '579 patent has expired, and

2. The agency is assured there is no new information that would affect whether final approval should be granted.

[1] This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

To reactivate your ANDA prior to final approval, please submit a "MINOR AMENDMENT - FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT - FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (cGMPs) are subject to agency review before final approval of the ANDA will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 501 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book."

For further information on the status of this ANDA, or prior to submitting additional amendments, please contact Yoon Kong, Project Manager, at 301-827-5849, for further instructions.

Sincerely yours,

Robert L. Lee /for

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research