DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-226

Teva Parenteral Medicines, Inc.
Attention: Susan O'Brien, Director, Regulatory Affairs
19 Hughes
Irvine, CA 92618

Dear Ms. O'Brien:

Please refer to your new drug application dated December 20, 2007, received December 20, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Pantoprazole Sodium for Injection, 40mg.

We acknowledge receipt of your submissions dated December 20 2007; April 11, 2008; April 25, 2008; April 28, 2008; May 7, 2008; May 9, 2008; June 27, 2008; July 11, 2008; August 20, 2008; September 11, 2008; September 12, 2008; September 23, 2008; September 26, 2008; October 8, 2008; October 16, 2008; and October 20, 2008.

This NDA provides for the use of Pantoprazole Sodium for Injection for the short term treatment (7-10 days) of patients with gastroesophageal reflux disease (GERD) and a history of erosive esophagitis and treatment of pathological hypersecretory conditions associated with Zollinger-Ellison syndrome or other neoplastic conditions.

We completed our review of this application. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed upon labeling, and with the agreed upon editorial revisions (as per email correspondence dated October 20, 2008) listed below**.** This determination is contingent upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in manufacturing and testing of the drug product) and is, therefore, subject to change on the basis of any new information that may come to our attention.

(b) (4)

(b)(4) [redacted]

The listed drug referenced in your application, Protonix I.V.® of Wyeth Pharmaceuticals, Inc., are subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
4758579	July 19, 2010
6780881	November 17, 2021
7351723	November 17, 2021

Your application contains certifications to each of the patents under section 505(b)(2)(A)(iv) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of, this drug product under this application ("Paragraph IV certifications"). Section 505(c)(3)(C) of the Act provides that approval of a new drug application submitted pursuant to section 505(b)(2) of the Act shall be made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of the paragraph IV certifications. This action must be taken prior to the expiration of forty-five days from the date the notice provided under section 505(b)(3) is received by the patent owner/approved application holder. You notified us that you complied with the requirements of section 505(b)(3) of the Act. In addition, you have notified the Agency that the patent owner and/or approved application holder has initiated a patent infringement suit against you with respect to patent 4758579 in the United States District Court for the District of New Jersey (Civil Action No. 2:08-cv-02877-JLL-CCC).

Therefore, final approval cannot be granted until:
1. a. expiration of the 30-month period provided for in Section 505(c)(3)(C) beginning on the date of receipt of the 45-day notice required under Section 505(b)(3), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or
b. the date the court decides[1] that the patent(s) is/are invalid or not infringed as described in section 505(c)(3)(C)(i), (ii), (iii,) or (iv) of the Act, or,
c. the listed patent(s) has/have expired, and
2. we are 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.

Not more than 60 days prior to when approval can be granted, or when requested, submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. This information should include updated labeling, chemistry, manufacturing and controls data, and a safety update.

Failure to submit this amendment will prompt a review of the application that may result in rescission of the tentative approval letter.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

Any significant change in the conditions outlined in this NDA requires our review before final approval may be granted.

Before we issue a final approval letter, this NDA is not deemed approved. If you believe that there are grounds for issuing the final approval letters before the conditions outlined above, you should amend your application accordingly.

This product may be considered misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed with this change before final approval.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

If you have any questions, call Elizabeth Ford, Regulatory Project Manager, at (301) 796-0193**.**

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Director, Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert Label

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

/s/

Donna Griebel

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