# Attachment B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-821

Wyeth Pharmaceuticals, Inc.
Attention: Randall Brenner
Associate Director, Worldwide Regulatory Affairs
P. O. Box 8299
Philadelphia, PA 19202-8299

Dear Mr. Brenner:

Please refer to your new drug application (NDA) dated and received December 15, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tygacil™ (tigecycline) for Injection, 50 mg vials.

We acknowledge receipt of your submissions dated:

| | | |
|---|---|---|
| September 27, 2004 (pre-submission) | October 22, 2004 (pre-submission) | January 21, 2005 |
| February 4, 2005 | February 28, 2005 (2) | March 4, 2005 |
| March 10, 2005 | March 14, 2005 | March 16, 2005 |
| March 18, 2005 | March 22, 2005 | March 23, 2005 |
| April 12, 2005 | April 27, 2005 | April 29, 2005 |
| May 4, 2005 | May 5, 2005 | May 16, 2005 |
| May 19, 2005 | May 27, 2005 (2) | June 2, 2005 |
| June 10, 2005 (3) | June 13, 2005 (2) | June 14, 2005 (2) |

This new drug application provides for the use of Tygacil™ (tigecycline) for Injection, for the treatment of Complicated Skin and Skin Structure Infections (cSSSI) and Complicated Intra-abdominal Infections (cIAI).

We completed our review of this application as amended and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, and immediate container and carton labels). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-821.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for ages birth to less than 8 years of age and deferring pediatric studies for ages 8 to 18 years of age for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of Complicated Skin and Skin Structure Infections and Intra-Abdominal Infections in pediatric patients ages 8 to 18 years of age.

   Final Report Submission: June 15, 2008

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated **"Required Pediatric Study Commitments"**.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **"Postmarketing Study Commitment Protocol"**, **"Postmarketing Study Commitment Final Report"**, or **"Postmarketing Study Commitment Correspondence."**

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Judit Milstein, Regulatory Project Manager at 301-827-2207.

Sincerely,

*{See appended electronic signature page}*

Mark J. Goldberger, MD, MPH
Director
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: Package Insert
Carton and Container Labels

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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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Edward Cox
6/15/05 06:46:33 PM
for Mark J. Goldberger, MD, MPH