DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-821/S-016

Wyeth Pharmaceuticals, Inc.
Attention: Nia Tatsis, Ph.D.
Senior Manager, Global Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr.Tatsis:

Please refer to your supplemental new drug application dated February 11, 2008, received February 11, 2008 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tygacil (tigecycline).

This supplemental new drug application provided revisions to the **DOSAGE AND ADMINISTRATION** and **HOW SUPPLIED** sections of the labeling to add compatibility information for Lactated Ringer's Injection, USP and extend storage time to 48 hours for reconstituted solution.

We have completed the review of this application. This application is approved effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on February 11, 2008.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling submitted on February 11, 2008. Upon receipt, we will transmit this version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved supplemental application NDA 21-821/S-016. Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
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).

If you have any questions, call Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, M.D.
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure:

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

/s/

Kathrine Laessig
2/10/2009 09:37:18 AM