DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-821/S-011
NDA 21-821/S-014
NDA 21-821/S-019

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

Dear Dr.Tatis:

Please refer to your supplemental new drug applications

Supplemental Application: S-011 dated March 27, 2007 received March 27, 2007
Supplemental Application: S-014 dated August 8, 2007 received August 8, 2007
Supplemental Application: S-019 dated September 4, 2008 received September 4, 2008

submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tygacil (tigecycline).

We acknowledge receipt of your submission dated January 13, 2009 for supplemental application S-014.

These supplemental new drug applications provide the following information for Tygacil labeling.

Supplemental Application S-011 (Changes Being Effected) provides information to revise the WARNINGS and ADVERSE REACTIONS concerning anaphylaxis/anaphylactoid reactions;
Supplemental Application S-014 provides information to revise the PRECAUTIONS section concerning the safety and efficacy of Tygacil in hospital acquired pneumonia;
Supplemental Application S-019 (Changes Being Effected) provides information to revise the PRECAUTIONS and Post-Marketing Experience sections concerning liver-related toxicity.

We have completed the review of these applications. These applications are 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 January 13, 2009.

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 January 13, 2009. 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 applications NDA 21-821/S-011, NDA 21-821/S-014, and NDA 21-821/S-019. 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
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