DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-281/S-003
NDA 21-281/S-004

Wyeth Pharmaceuticals
Attention: Randall B. Brenner
Director, Worldwide Regulatory Affairs
P. O. Box 8299
Philadelphia, PA 19101-8299

Dear Mr. Brenner:

Please refer to your supplemental new drug applications dated December 8, 2005 and March 3, 2006, received December 9, 2005 and March 6, 2006 submitted under 505 (b) of the Federal Food, Drug, and Cosmetic Act for Tygacil (tigecycline).

We also acknowledge your amendment May 9, 2006 (supplement S-004).

Changes Being Effected (CBE) supplemental application S-003 provides an update of safety information under the **ADVERSE REACTIONS s**ection of the labeling.

Prior Approval supplemental application S-004 provides for a formulation change and labeling that is influenced by the new formulation.

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

Under the **PRECAUTIONS - General** subsection:

Glycylcycline class antibiotics are structurally similar to tetracycline class antibiotics and may have similar adverse effects. Such effects may include: photosensitivity, pseudotumor cerebri, and anti-anabolic action (which has lead to increased BUN, azotemia, acidosis, and hyperphosphatemia). As with tetracyclines, pancreatitis has been reported with the use of TYGACIL.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the text for the package insert. These revisions are terms of the approval of these applications.

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 supplements NDA 21-281/S-003 and NDA 21-821/S-004**." Approval of these submissions 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, HFD-410
FDA
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}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

Janice Soreth
7/12/2006 04:41:10 PM