DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-821/S-022

Wyeth Pharmaceuticals Inc.
Attention: Roger A. Wilson
Sr. Manager, Global Regulatory Affairs-CMC
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Mr. Wilson:

Please refer to your supplemental new drug application dated February 27, 2009, received February 27, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tygacil® (tigecycline) for Injection.

This supplemental new drug application provides for the use of an alternate 10 mL/20 mm container closure system for the drug product.

We completed our review of this application. This application 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 submitted labeling (package insert submitted February 27, 2009, immediate container and carton labels submitted February 27, 2009). Please submit the electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-821/S-022**". Approval of this submission by FDA is not required before the labeling is used

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 Althea Cuff, Regulatory Project Manager, at (301) 796-4061.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
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/

Hasmukh Patel

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