DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-821/S-013
NDA 21-821/S-017
NDA 21-821/S-018

Wyeth Pharmaceuticals, Inc.
Attention: Ourania Tatsis, Ph.D.
Senior Manager, Global Regulatory Affairs
500 Arcola Road
Collegeville, PA 19426

Dear Dr. Tatsis:

Please refer to your supplemental new drug applications dated July 26, 2007, received July 27, 2007, submitted under 505(b) of the Federal Food, Drug and Cosmetic Act for Tygacil® (tigecycline) Injection.

We acknowledge your submissions dated August 12, 2008 and March 13 and March 18, 2009.

Your submission of September 22, 2008 constituted a complete response to our May 27, 2008 action letter.

These supplemental new drug applications provide information to support the use of Tygacil® (tigecycline) Injection for the indication of Community Acquired Bacterial Pneumonia (S-013), the addition of pathogens to the Complicated Skin and Skin Structure Indication (S-017), and the addition of pathogens to the Complicated Intra-abdominal Indication (S-018).

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the content of labeling submitted March 18, 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 (1)] in structured product labeling (SPL) format as described at http://www.fda.gove/oc/datacouncil/spl.hyml that is identical to the enclosed labeling submitted on March 18, 2009. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administration purposes, please designate these submissions, "SPL for approved supplemental applications NDA 21-821/S-013, NDA 21-821/S-017 and NDA 21-821/S-018. Approval of these submissions by FDA is not required before the labeling is used.

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration, and are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived or deferred or inapplicable.

We are waiving the pediatric study requirement for ages 0 to 7 years because there is evidence strongly suggesting that the drug product would be unsafe in this pediatric group. FDA has not required pediatric studies in pediatric patients less than 8 years of age because the product is a tetracycline and has the potential to stain the teeth in this age subset. Labeling for tigecycline includes a statement in the WARNING section about tooth discoloration.

We are deferring submission of your pediatric studies for ages 8 to 17 years for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug and Cosmetic Act. These deferred pediatric studies under PREA are listed below.

1.A Phase 3, Multicenter, Double-blind Study to Evaluate the Safety and Efficacy of Tigecycline Versus Clindamycin for the Treatment of Complicated Skin and Skin Structure Infections, Including Those Due to MRSA, in Pediatric Subjects Ages 8 to 17 Years Old.

Protocol Submission:	March 2009
Study Start:	May 2009
Final Report Submission:	December 15, 2014

2. A Phase 3, Multicenter, Randomized, Double-blind Study to Evaluate the Safety Versus a Ceftriaxone Regimen in the Treatment of Complicated Intra-abdominal Infections and Community-Acquired Bacterial Pneumonia in Pediatric Subjects Ages 8 to 17 Years Old.

Protocol Submission:	March 2009
Study Start:	May 2009
Final Report Submission:	December 15, 2014

Submit clinical protocols to your IND for this product. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each requirement 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 submission, including supplements, relating to these post marketing requirements should be clearly designated **"Required Pediatric Assessment".**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road

Beltsville, MD 20705-1266

As required under 21 CFR 314.81 (b) (3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

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 an electronic copy of the letter to both this NDA and 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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