DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-797/S-008

Pfizer, Inc.
Attention: Donald R. Jaffe, Ph.D.
Director, Worldwide Regulatory Affairs and Quality Assurance
50 Pequot Avenue
New London, CT 06320

Dear Dr. Jaffe:

Please refer to your supplemental new drug application dated October 19, 2007, received October 22, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zmax® (azithromycin extended release) for oral suspension. This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submission dated May 22, September 15 and 19, 2008. This supplemental new drug application provides for the use of Zmax® (azithromycin extended release) for oral suspension, 2 g in pediatric patients with community acquired pneumonia.

We have completed the review of this application, as amended. This application is approved effective on the date of this letter, for use as recommended in the content of labeling submitted on September 19, 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 May 22, 2008. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved supplemental NDA 50-797/S-008. Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for community- acquired pneumonia for ages 0 to 6 months. We note that you have fulfilled the pediatric requirement for community-acquired pneumonia for pediatric patients 6 months to 18 years of age.

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 Fisher 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}

Wiley A. Chambers, MD
Acting Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

Wiley Chambers

10/7/2008 11:12:15 PM