DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-797

Pfizer, Inc,
Attention: Donald R. Jaffe, PhD
Director, Worldwide Regulatory Strategy
50 Pequot Avenue
New London, CT 06320

Dear Dr. Jaffe:

Please refer to your new drug application (NDA) dated and received August 12, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zmax™ (azithromycin extended release) for oral suspension), 2 g.

This application is subject to the exemption provisions in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated:

September 22, 2004
October 15, 2004
December 14, 2004
January 18, 2005
February 22, 2005
March 7, 2005
May 4, 2005
May 27, 2005
June 10, 2005
September 29, 2004
December 1, 2004
December 17, 2004
February 4, 2005
February 25, 2005
March 14, 2005
May 11, 2005
June 3, 2005
October 8, 2004
December 9, 2004
January 13, 2005
February 9, 2005
March 3, 2005
April 21, 2005
May 25, 2005
June 7, 2005

This new drug application provides for the use of Zmax (azithromycin extended release) for oral suspension for the treatment of Community Acquired Pneumonia (CAP) and Acute Bacterial Maxillary Sinusitis (ABS).

We have completed our review of this application, as amended, and it 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 enclosed labeling (text for the package insert, immediate container and carton labels, and patient package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 deferring submission of your pediatric studies for ages 6 months to 18 years until December 31, 2005.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA in pediatric patients ages 6 months to 18 years of age.

   Final Report Submission: December 31, 2005

Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments**".

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
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 Judit Milstein, Regulatory Project Manager at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package insert
Immediate carton and container label
Patient 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/

Janice Soreth

6/10/05 05:07:41 PM