DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-797/S-001

Pfizer, Inc.
Attention: Mr. Priso H. Epale
Regulatory Manager
Worldwide Regulatory Strategy
235 East 42nd Street 685/18/15
New York, NY 10017

Dear Mr. Epale:

Please refer to your supplemental new drug application dated April 27, 2006, received April 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NDA 50-797 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 submissions dated July 31, and August 30, 2007.

This "Changes Being Effected" supplemental new drug application provides for changes to the **ADVERSE REACTIONS and** CONTRAINDICATIONS section of the labeling.

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 enclosed agreed-upon labeling text.

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.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling package insert dated August 30, 2007. 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 NDA 50-797.

We note that your August 30, 2007 submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

Marketing these products with FPL that is not identical to the approved labeling text may render the products misbranded and an unapproved drug.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, M.D.
Acting Director
Division of Anti-Infective and Ophthalmology Products
Office 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/

Wiley Chambers

10/25/2007 09:31:54 AM