CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-784 / S-004, S-006

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-784/S-004 and S-006

Pfizer, Inc.
Attention: Robert Clark
Vice President, US Regulatory Affairs
235 East, 42nd Street
New York, NY 10017

Dear Mr. Clark:

Please refer to your supplemental new drug applications dated March 17, 2003, received March 17, 2003 for S-004, and October 24, 2003, received October 27, 2003, for S-006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zithromax® (azithromycin) Tablets, 500 mg.

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 also acknowledge receipt of the submissions dated May 8, August 25, and September 12, 2003, (S-004), and December 15, 2003 (S-006).

These supplemental new drug applications provide for:

> Treatment of acute bacterial sinusitis using a 3-day regimen of Zithromax® (azithromycin) Tablets, 500 mg (S-004) and
>
> Revisions to the PRECAUTIONS and ADVERSE REACTIONS sections of the package insert to include updated wording on QT prolongation and *Torsades de pointes* (S-006).

We have completed our review of these applications, as amended, and they are 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).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 50-784/S-004 and S-006." Approval of these submissions 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. We are partially waiving the pediatric study requirement for ages < 6 months, considering that there are too few pediatric patients with this disease to study.

We also note that you have fulfilled the pediatric study requirement for ages ≥ 6 months, for this indication.

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, HFD-410
FDA
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,

/S/

{See appended electronic signature page}

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

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/

Janice Soreth
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