DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-710/S-017 and S-021
NDA 50-711/S-015 and S-017

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 submitted under section 505(b) for:

Drug Name	NDA #	Supplement	Dated	Received
Zithromax® (azithromycin) for oral suspension	50-710	017	March 17, 2003	March 17, 2003
Zithromax® (azithromycin) 250 mg Tablets	50-711	015	March 17, 2003	March 17, 2003
Zithromax® (azithromycin) for oral suspension	50-710	021	October 24, 2003	October 27, 2003
Zithromax® (azithromycin) 250 mg Tablets	50-711	017	October 24, 2003	October 27, 2003

These applications are 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 your submissions dated December 15, 2003, for NDA 50-710/S-021 and 50-711/S-017.

These supplemental new drug applications provide for:

> Treatment of acute bacterial sinusitis using a 3-day regimen of Zithromax® (azithromycin) Tablets, 500 mg (NDA 50-710/S-017 and NDA 50-711/S-015) and
>
> Revisions to the PRECAUTIONS and ADVERSE REACTIONS sections of the package insert (NDA 50-710/S-021 and NDA 50-711/S-017) to include updated wording on QT prolongation and *Torsade de Pointes*.

We completed our review of these applications 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 50-710/S-017 and S-021, and NDA 50-711/S-015 and S-017." Approval of these submissions by FDA is not required before the labeling is used.

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,

{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 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/

Janice Soreth

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