DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-670/S-022
NDA 50-693/S-009
NDA 50-730/S-012

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 October 24, 2003, received October 27, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for

NDA 50-670, Zithromax® (azithromycin) 250 mg Capsules
NDA 50-693, Zithromax® (azithromycin), Single-Dose Package
NDA 50-730, Zithromax® (azithromycin), 600 mg Tablets

These applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These supplemental new drug applications provide for revisions to the **PRECAUTIONS** and **ADVERSE REACTIONS** sections of the package insert to include updated wording on QT prolongation and *Torsades de Pointes.*

We have completed our review of these applications and they are approved effective on the date of this letter.

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements NDA 50-670/S-022, NDA 50-693/S-009, and NDA 50-730/S-012." Approval of this submission 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

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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