DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-784/S-002

Pfizer Inc.
Attention: Rita Wittich
Vice President, Worldwide Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms. Wittich:

Please refer to your supplemental new drug application dated June 28, 2002, received July 1, 2002, submitted under section 505(b) pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for NDA 50-784/S-002, Zithromax® (azithromycin dihydrate) 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 acknowledge receipt of your submission dated July 24, 2002.

This supplemental new drug application provides for revised Geriatric Labeling in accordance with the August 27, 1997 Federal Register Notice.

We completed our review of this application, as amended, and it is approved for use as recommended in the agreed-upon labeling, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the package insert submitted on June 28, 2002, and include the following text for the second and third paragraph in the **PRECAUTIONS, Geriatric Use** section. Inclusion of the following text is a term of the approval of these applications.

> "In multiple-dose clinical trials of oral azithromycin, 9% of patients were at least 65 years of age (458/4949) and 3% of patients (144/4949) were at least 75 years of age. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out."
>
> ZITHROMAX® 250 mg tablets contain 0.9 mg of sodium per tablet.
> ZITHROMAX® 500 mg tablets contain 1.8 mg of sodium per tablet.
> ZITHROMAX® for oral suspension 100 mg/5 mL contains 3.7 mg of sodium per 5 mL of constituted solution.
> ZITHROMAX® for oral suspension 200 mg/5 mL contains 7.4 mg of sodium per 5 mL of constituted solution."

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 supplement NDA 50-784/S-002. 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, HF-2
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, M.D.,
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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