DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-670/S-019
NDA 50-693/S-007
NDA 50-710/S-014
NDA 50-711/S-012
NDA 50-733/S-010
NDA 50-730/S-010

Pfizer Inc.
Attention: Ann Carey
Director, Worldwide Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms.Carey:

Please refer to your supplemental new drug applications dated November 20, 2001, received November 21, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA 50-670/S-019, Zithromax (azitrhomycin dihydrate) Capsules
NDA 50-693/S-007, Zithromax (azithromycin dihydrate) Single Dose Packet
NDA 50-710/S-014, Zithromax (azithtomycin dihydrate) Oral Suspension
NDA 50-711/S-012, Zithromax (azithromycin dihydrate) Tablets, 250 mg
NDA 50-730/S-010, Zithromax (axithromycin dihydrate) Tablets, 600 mg (MAC)
NDA 50-733/S-010, Zithromax (azithromycin dihydrate) IV

We note that 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 "Changes Being Effected" supplemental new drug applications provide for revisions to the **ADVERSE REACTIONS, Post-Marketing**, and **PRECAUTIONS General** sections of the package inserts.

We have completed the review of these supplemental applications, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. We also note that the proposed language for these applications had been incorporated in the label for NDA 50-710/S-008 and S-009, approved on December 14, 2001. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted November 20, 2001).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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, these submissions should be designated "FPL for approved supplement NDA 50-670/S-019, 50-693/S-007, 50-710/S-014, 50-711/S-012, 50-730/S-010, and 50-733/S-010." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 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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