CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-670/S-015

50-693/S003

50-730/S005

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 2085.

NDA 50-670/S-015
NDA 50-693/S-003
NDA 50-730/S-005

Pfizer Inc.
Attention: Ronald I. Trust, Ph.D.
Associate Director II
Eastern Point Road
Groton, CT 06340

Dear Dr. Trust:

Please refer to your supplemental new drug applications dated January 13, 2000, received January 13, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zithromax® (azithromycin) Capsules, NDA 50-670; Zithromax® (azithromycin) Single Dose Packet, NDA 50-693; and Zithromax® (azithromycin) Tablets, NDA 50-730. 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.

We acknowledge receipt of your submissions dated:

February 1, 2000	August 23, 2000	October 13, 2000
February 11, 2000	August 30, 2000	November 9, 2000.
February 16, 2000	September 8, 2000	
June 9, 2000	October 11, 2000	

These supplemental new drug applications provide for revision to the combined package insert for the use of Zithromax Tablets, 600 mg, in combination with ethambutol, for the treatment of disseminated *Mycobacterium avium* complex (MAC) infections in persons with advanced HIV infection.

We have completed the review of these supplemental applications, as amended, 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. 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 9, 2000).

Please submit 20 paper copies of the FPL as soon as they are available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, these submissions should be designated "FPL for approved

supplement NDAs 50-670/S-015, 50-693/S-003, 50-730/S-005." Approval of these submissions by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, 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 or deferred (63 *FR* 66632)(21 CFR 314.55 (or 601.27)). FDA is deferring submission of the pediatric assessments of safety and effectiveness as required under these regulations until May 13, 2002.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to these NDAs 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 Diana Willard, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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