DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-710/S-008
NDA 50-710/S-009

Pfizer Global Research and Development
Attention: Ronald Trust, Ph.D., MBA
Senior Associate Director
Regulatory Strategy and Registration
Worldwide Regulatory Affairs
50 Pequot Avenue
New London, CT 06320

Dear Dr. Trust:

Please refer to your supplemental new drug applications dated February 16, 2001, received February 16, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zithromax (azithromycin) for Oral Suspension. We note that 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 submissions dated March 15 (2); April 3, 4 and 16 (2); May 4; June 7; July 5, 17, 18 (2), 25 and 27; August 3 and 27; October 9; November 13 (2), 20 and 30; and December 7 and 12, 2001.

These supplemental new drug applications provide for the use of Zithromax (azithromycin) for Oral Suspension for:

NDA 50-710/S-008 – acute otitis media with a 1-day dosing regimen.
NDA 50-710/S-009 – acute otitis media with a 3-day dosing regimen.

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 attached final printed labeling. Accordingly, these supplemental applications are approved effective on the date of this letter.

We remind you of your postmarketing study commitments in your submission dated December 12, 2001. This commitment is as follows:

> "We commit to perform a pharmacokinetic study of azithromycin for the treatment of otitis media, to be conducted in pediatric patients ≥6 months of age. A sufficient number of patients under two years of age will be enrolled to evaluate the effect of dosing regimen on the pharmacokinetics of azithromycin."

Protocol Submission:	Within six months of the date of this letter
Study Start:	Within eleven months of the date of this letter
Final Report Submission:	Within three years of the date of this letter

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **"Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

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). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27). We are deferring submission of your pediatric studies until December 14, 2004. However, in the interim, please submit your pediatric drug development plans within 120 days from the date of this letter unless you believe a waiver is appropriate. Within approximately 120 days of receipt of your pediatric drug development plan, we will review your plan and notify you of its adequacy.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will notify you within 120 days of receipt of your response whether a waiver is granted. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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

Please submit one market package of the drug product when it is available.

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 Jose R. Cintron, R.Ph., M.A., Sr. Regulatory Management Officer/Project Manager, at (301) 827-2125.

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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