



NDA 50-710/S-019

Pfizer, Inc.
Attention: Robert Clark
Vice President, US Regulatory Affairs
235 East 42nd Street
New York, New York 10017

Dear Mr. Clark:

Please refer to your supplemental new drug application dated October 23, 2003, received October 27, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zithromax (azithromycin for oral suspension), 100 mg/5 mL and 200 mg/5 mL. 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 December 15, 2003 and February 12, 2004.

This "Changes Being Effected" supplemental new drug application provides for revised labeling to include deletion of labeling statements pertaining to dosing devices in the **DOSAGE AND ADMINISTRATION** and **HOW SUPPLIED** section of the Zithromax USPI to reflect removal of dosing devices with Zithromax oral suspension packaging.

We have completed our review of this supplemental application and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the package insert submitted October 23, 2003. 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 50-710/S-019". 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

NDA 50-710/S-019

Page 2

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Susmita Samanta, M.D., Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Chemistry Team Leader for the
Division of Anti-Infective Drug Products (HFD-520)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Jim Vidra

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