



NDA 50-733/S-012

Pfizer Inc.
Attention: Robert B. Clark
Vice President, US Regulatory
235 East, 42nd Street
New York, NY 10017-5755

Dear Mr. Clark:

Please refer to your supplemental new drug application dated October 24, 2003, received October 27, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zithromax[®] IV (azithromycin for injection).

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This "Changes Being Effected" supplemental new drug application provide for revised labeling to comply with the Final Rule entitled "Labeling Requirements for Systemic Antimicrobial Drug Products Intended for Human Use" (68FR 6062, February 6, 2003).

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

The following typographical error should be corrected by the time of the Final Printed Labeling submission:

In the CLINICAL PHARMACOLOGY section, 5th paragraph, 2nd sentence, inside the parenthetical phrase, the superscript on AUC²⁴ should be changed to a subscript AUC₀₋₂₄.

The final printed labeling (FPL) must be identical to the package insert submitted October 24, 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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-733/S-012." 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, HFD-410
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, MD
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
1/15/04 11:00:51 AM