



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

**NDA 50-733/S-018**

Pfizer, Inc.  
Attention: Mr. Priso H. Epale  
Regulatory Manager  
Worldwide Regulatory Strategy  
235 East 42<sup>nd</sup> Street 685/18/15  
New York, NY 10017

Dear Mr. Epale:

Please refer to your supplemental new drug application dated April 27, 2006, received April 28, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NDA 50-733 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.

We acknowledge receipt of your submissions dated July 31, and August 30, 2007.

This "Changes Being Effected" supplemental new drug application provides for changes to the **ADVERSE REACTIONS**, **CONTRAINDICATIONS** and **DOSAGE AND ADMINISTRATION** sections of the labeling.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/data.council/spl.html> that is identical to the enclosed labeling package insert dated August 30, 2007. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved NDA 50-733.

We note that your August 30, 2007 submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

Marketing this product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved drug.

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  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

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 Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

*{See appended electronic signature page}*

Wiley A.Chambers, M.D.  
Acting Director  
Division of Anti-Infective and Ophthalmology Products  
Office Antimicrobial Products  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Wiley Chambers

10/25/2007 09:24:07 AM