DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-693/S-014
NDA 50-730/S-021

Pfizer, Inc.
Attention: Beatrice Curran
Associate Director, Regulatory Affairs
235 East 42nd Street, 685/18/16
New York, NY 10017

Dear Ms. Curran:

Please refer to your supplemental new drug applications dated February 6, 2009, received February 6, 2009 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA 50-693/S-014 Zithromax® (azithromycin) Single Dose Packet
NDA 50-730/S-021 Zithromax® (azithromycin) 600 mg Tablet.

These applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These supplemental new drug applications provide for revisions to the **WARNINGS**, **PRECAUTIONS-General,** and **PRECAUTIONS-Drug Interactions** sections of the labeling.

We have completed the review of these applications. These applications are approved effective on the date of this letter, for use as recommended in the agreed-upon labeling text submitted on February 6, 2009.

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(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling submitted on February 6, 2009. Upon receipt, we will transmit this version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved supplemental applications NDA 50-693/S-014 and NDA 50-730/S-021. Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about these drug products (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
Suite 12B05
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 Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure:

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Sumathi Nambiar

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