DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-693/S-019
NDA 50-710/S-034
NDA 50-711/S-032
NDA 50-730/S-027
NDA 50-784/S-019

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Anna Maria Gambino
Senior Manager, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Gambino:

Please refer to your Supplemental New Drug Applications (sNDAs) dated February 15, 2011, received February 16, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 50-693/S-019 Zithromax (azithromycin) Single-Dose Packet
NDA 50-710/S-034 Zithromax (azithromycin) for Oral Suspension
NDA 50-711/S-032 Zithromax (azithromycin) 250 mg Tablet
NDA 50-730/S-027 Zithromax (azithromycin) 600 mg Tablet
NDA 50-784/S-019 Zithromax (azithromycin) 500 mg Tablet

We acknowledge receipt of your amendments dated June 6, and October 23, 2012.

The October 23, 2012, submissions constituted a complete response to our June 9, 2012, action letter.

These "Prior Approval" supplemental new drug applications provide an update to the interpretive criteria in the **Microbiology** subsection of the package insert.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We note that your October 23, 2012, submissions include final printed labeling (FPL) for the package inserts. We have not reviewed this FPL. You are responsible for assuring that the wording in these printed labelings are identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package inserts, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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
11/02/2012