DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-693/S-022
NDA 50-710/S-038
NDA 50-711/S-035
NDA 50-730/S-030
NDA 50-733/S-034
NDA 50-784/S-022

**SUPPLEMENT APPROVAL**

Pfizer Global Research and Development
Attention: Anna Marie Gambino
Manager, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017-5755

Dear Ms. Gambino:

Please refer to your Supplemental New Drug Applications (sNDAs) dated June 4, 2012, received June 5, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

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| NDA 50-693/S-022 | Zithromax (azithromycin) Single Dose Packet |
| NDA 50-710/S-038 | Zithromax (azithromycin) for Oral Suspension |
| NDA 50-711/S-035 | Zithromax (azithromycin) 200 mg Tablet |
| NDA 50-730/S-030 | Zithromax (azithromycin) 600 mg Tablet |
| NDA 50-733/S-034 | Zithromax IV (azithromycin for injection) |
| NDA 50-784/S-022 | Zithromax (azithromycin) 500 mg Tablet |

These "Prior Approval" supplemental new drug applications were submitted in response to an Agency supplemental request letter dated May 3, 2012 to add language concerning QT prolongation to the **WARNINGS and Geriatric Use** sections of the label.

We have completed our review of these supplemental applications. 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 June 4, 2012, submissions include final printed labeling (FPL) for your package inserts. We have not reviewed this FPL. You are responsible for assuring that the wording in these printed labeling 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 test for the package insert, 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 this supplemental application, 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
Office of Antimicrobial Products
Division of Anti-Infective Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

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/s/

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SUMATHI NAMBIAR
06/06/2012