DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-693/S-017
NDA 50-710/S-033
NDA 50-711/S-031
NDA 50-730/S-026
NDA 50-733/S-030
NDA 50-784/S-018

SUPPLEMENT APPROVAL

Pfizer Global Research and Development
Attention: Priso H. Epale
Regulatory Manager, Worldwide Regulatory Strategy
235 East 42nd Street 685/18/15
New York, NY 10017

Dear Mr. Epale:

Please refer to your Supplemental New Drug Applications (sNDAs) dated December 22, 2010, received December 22, 2010, submitted under section (505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

NDA 50-693/S-017	Zithromax (azithromycin) Single Dose Packet
NDA 50-710/S-033	Zithromax (azithromycin) for Oral Suspension
NDA 50-711/S-031	Zithromax (azithromycin) 200 mg Tablet
NDA 50-730/S-026	Zithromax (azithromycin) 600 mg Tablet
NDA 50-733/S030	Zithromax IV (azithromycin for injection)
NDA 50-784/S-018	Zithromax (azithromycin) 500 mg Tablet

These Prior Approval supplemental new drug applications provide for changes to the **CONTRAINDICATIONS, WARNINGS, and ADVERSE REACTIONS** sections of the labeling.

We also refer to our letter dated October 15, 2010, notifying you to update the above sections with regard to hepatotoxicity. These supplemental new drug applications provide for revisions to the labeling for azithromycin, consistent with our October 15, 2010 letter.

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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 December 22, 2010, 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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling text for package insert and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements and any 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 this NDA, 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.

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If sending via USPS, please send to:

Carmen DeBellas
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6154
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

If sending via any carrier other than USPS (e.g., UPS, DHL), please send to:

Carmen DeBellas
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6154
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about these drugs (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE
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
01/28/2011