DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-797/S-010
NDA 50-797/S-012
NDA 50-797/S-014

SUPPLEMENT APPROVAL

Pfizer Global Research and Development
Attention: Priso E. 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) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zmax (azithromycin extended release) for Oral Suspension, 2 g;

S-010 dated July 30, 2009 received July 30, 2009
S-012 dated July 21, 2010 received July 21, 2010
S-014 dated December 23, 2010 received December 23, 2010

We acknowledge receipt of your amendments dated April 28, 2011 and May 24, 2011.

The April 28, 2011 and May 24, 2011, submissions constituted a complete response to our February 3, 2011, action letter.

Supplemental application S-010: "Changes Being Effected" supplemental new drug application provides for artwork combination from pediatric and adult packaging into unified packaging.

Supplemental application S-012: "Prior Approval" supplemental new drug application provides for the addition of pyloric stenosis to the **ADVERSE REACTIONS** section, **Postmarketing Experience** subsection.

Supplemental application S-014: "Prior Approval" supplemental new drug application provides for changes to the **CONTRAINDICATIONS, WARNINGS** and **ADVERSE REACTIONS** sections of the labeling.

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 package insert for supplemental applications 50-797/S-012 and S-014 and carton and container labels for supplemental application 50-797/S-010.

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 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 Stantard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformatin/Guidance/UCM072392.pdf.

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, 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).

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your April 28, 2011, submission containing final printed carton and container labels.

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.

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
Carton and Container label

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
06/07/2011