



NDA 050733/S-033

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Anna Maria Gambino
Manager, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017-5755

Dear Ms. Gambino:

Please refer to your supplemental New Drug Application (sNDA) dated November 1, 2011, received November 1, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zithromax (azithromycin for injection) IV.

This “Prior Approval” supplement provides for revisions to the **CLINICAL PHARMACOLOGY** section, **Microbiology** subsection, regarding the *in vitro* susceptibility test interpretive criteria (breakpoints) and the quality control parameters for *in vitro* susceptibility testing listed in the package insert as requested in our letter of January 6, 2008, and communication of October 17, 2011.

Specifically, our communication of October 17, 2011, requested the following revisions:

1. Change “Streptococci including *Streptococcus pneumoniae*” in Table 3 to *Streptococcus pneumoniae* since this is the only streptococcus listed in the “INDICATIONS AND USAGE” section of the package insert.
2. Change *Haemophilus* spp. in Table 3 to *Haemophilus influenzae* since this is the only *Haemophilus* listed for any of the indications in the “INDICATIONS AND USAGE” section of the package insert.
3. Update the Clinical and Laboratory Standards Institute (CLSI) references to the most recent versions of the documents.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text, submitted on November 1, 2011 [LAB-0024-10.0 dated October 2011].

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 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 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, R.Ph., Pharm.D., Senior Regulatory Project Manager, at (301) 796-1203.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective 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
11/16/2011