

Office of Clinical Pharmacology Memorandum

Date	June 6, 2008
From	Kimberly L. Bergman, Pharm.D. Primary Reviewer
Through	Charles Bonapace, Pharm.D. Team Leader
Subject	Clinical Pharmacology Memorandum
NDA/BLA #	50-797/S-008 (dated May 22, 2008)
Product	Azithromycin Sustained Release (Zmax™)
Formulation	Azithromycin Sustained Release Oral Powder for Suspension (azithromycin SR), 2.0 g per bottle to be reconstituted to 27 mg/mL
Sponsor	Pfizer
Proposed Indication	Treatment of community-acquired pneumonia (CAP) in pediatric patients

1. Background

Azithromycin Sustained Release Oral Powder for Suspension (azithromycin SR) is a formulation composed of azithromycin microspheres (containing (b) (2) poloxamer 407), (b) (4), sucrose and magnesium hydroxide. Azithromycin SR is a sustained release formulation that provides a full course of antibacterial therapy in a single dose.

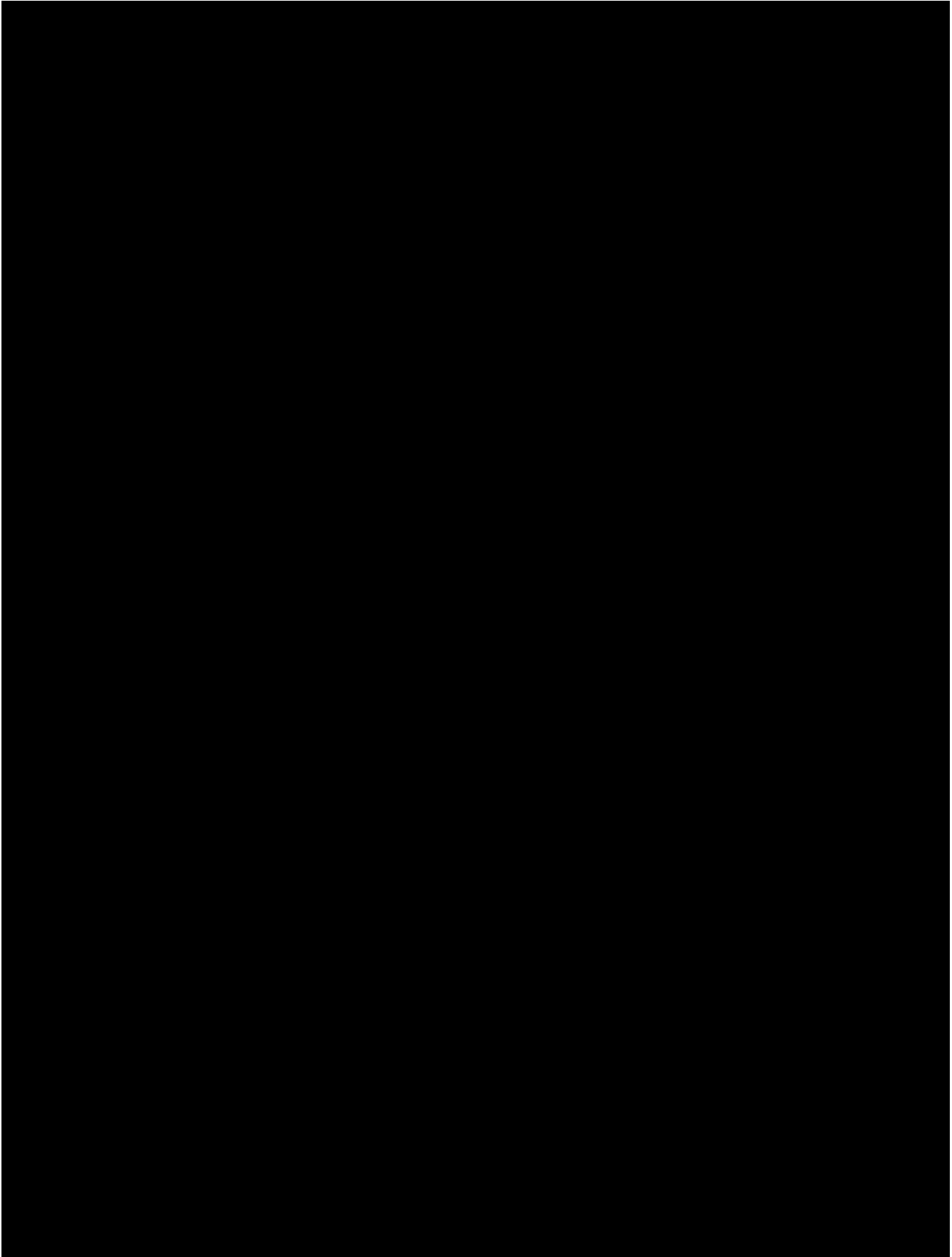
(b) (4)

The use of azithromycin SR for pediatric acute bacterial sinusitis (ABS) and community acquired pneumonia (CAP) were requested under the pediatric rule. (b) (4), the FDA provided revised labeling which included the treatment of CAP in adults and children 6 months and older. On 19OCT2007 Pfizer submitted sNDA 50-797/S-008 for Zmax® (azithromycin extended release) for oral suspension, 2 g, for the treatment of CAP in pediatric patients. This sNDA contained an updated label based on the labeling submitted (b) (4). The Agency provided revised labeling via email on 19MAR2008, and the Applicant responded with suggested changes on 31MAR2008 which were agreed upon by the Agency on 11APR2008. The Agency provided a draft version of the label via email on 09MAY2008 and the Applicant accepted all changes and provided additional changes via email on 14MAY2008. The Agency confirmed the changes were acceptable on 21MAY2008 and requested that the Applicant submit an amendment to S-008 with final versions of the label and container and carton labels (current submission dated 22MAY2008). The purpose of this memorandum is to document Clinical Pharmacology review and concurrence with the Applicant's final proposed label for Zmax® (azithromycin extended release) for oral suspension, 2 g, for the treatment of community acquired pneumonia in pediatric patients.

2. Clinical Pharmacology Findings

Labeling Recommendations

The following sections of the label pertaining to Clinical Pharmacology were agreed upon by both the Applicant and Agency.



3. Summary and Conclusions

The label proposed by the Applicant in the current submission following changes made to the label submitted (b) (4) and revised in S-008 (dated 19OCT2007) and through subsequent labeling discussions (dated 19MAR2008, 31MAR2008, 11APR2008, 09MAY2008, 14MAY2008, 21MAY2008), is acceptable from a Clinical Pharmacology perspective.

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/s/

Kimberly Bergman
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Charles Bonapace
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