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APPLICATION NUMBER:

50-784 / S-004, S-006

PHARMACOLOGY REVIEW

INTEROFFICE MEMORANDUM

DATE: 5/9/03

TO: Judit Milstein
Project Manager, HFD-520

FROM: Amy L. Ellis, Ph.D.
Pharmacologist, HFD-520

THROUGH: Robert E. Osterberg, Ph.D.
Pharmacology Team Leader, HFD-520

RE: NDA 50,784 SE1-004; Zithromax (azithromycin) Tablets, 500 mg
Efficacy Supplement for Acute Bacterial Sinusitis (will also apply to
NDAs 50,710 and 50,711 for azithromycin oral suspension and 250 mg
tablets covered by the same label)

The indication proposed in this NDA supplement will use an adult dosing regimen (500 mg once daily for 3 days) that was previously approved for the treatment of acute bacterial exacerbation of chronic obstructive pulmonary disease and a pediatric dosage regimen (10 mg/kg/day for 3 days for children \geq 6 months of age) previously approved for acute otitis media. Additionally, a pediatric dosing regimen of 12 mg/kg/day for 5 days for children \geq 2 years of age has been previously approved for the treatment of pharyngitis/tonsillitis.

The current supplement is not requesting an increase in either the daily dose of azithromycin or the length of therapy; thus, the dose proposed for the supplemental indication is supported by previous clinical experience with the drug as well as nonclinical data that were used to support the approved NDAs for Zithromax. Consequently, NDA 50,784 SE1-004 does not contain any nonclinical data and none is necessary. A pharm/tox review is not needed for this supplement; cross reference of the original Zithromax NDA 50,670, which the sponsor has requested, is adequate. The sections of the Zithromax label dealing with Carcinogenesis, Mutagenesis, Impairment of Fertility, Pregnancy, and Animal Toxicology do not require modification. There is, however, no section on Overdosage. The Division should consider asking the Sponsor to add one.

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this page is the manifestation of the electronic signature.**

/s/

Amy Ellis

5/16/03 02:05:48 PM

PHARMACOLOGIST

There are no new pharm/tox data in this supplement
and none are necessary to support the requested
indication. The label for this product has no
Overdosage section and the Division should consider asking
the Sponsor to add one.

Bob- You signed the paper copy of this memo on 5/16/03.

Robert Osterberg

5/16/03 02:44:26 PM

PHARMACOLOGIST