

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

50-797

PHARMACOLOGY REVIEW

MEMO TO FILE, NDA 50-797

DATE: 6/9/05
TO: File, NDA 50-797
FROM: Amy L. Ellis, Ph.D.
Pharmacologist, HFD-520
RE: Label for Zmax Complete NDA 50-797, Submission 0027 dated 6/3/05

The sponsor's proposal for revising the *Carcinogenesis, Mutagenesis, Impairment of Fertility* section of the label is acceptable. The pharmacologist agrees with the sponsor's calculation for dose comparison (rat 10 mg/kg dose is approximately 0.05X adult human 2 g dose based on body surface area), though she is surprised that this was the highest dose used in a fertility study considering the larger doses used in most of the other rat studies.

The sponsor has committed to harmonizing all of the labels for Zithromax products when their next labeling supplements are submitted.

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/s/

Amy Ellis

6/9/05 04:55:03 PM

PHARMACOLOGIST

Proposal for label revision is acceptable.

INTEROFFICE MEMORANDUM

DATE: 5/17/05

TO: Judit Milstein
Project Manager, HFD-520
and
File, NDA 50,797

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

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

RE: Pharmacology/Toxicology Labeling Review for Zmax [REDACTED] NDA 50,797

There are currently 2 different labels for approved IV and oral formulations of azithromycin. It would be preferable to harmonize all of the labels for the azithromycin products where possible.



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/s/

Amy Ellis

6/1/05 03:45:58 PM

PHARMACOLOGIST

These comments have already been conveyed to the sponsor
by J. Milstein.

Bob- You signed the paper copy of this memo on 5/17.

Robert Osterberg

6/1/05 04:04:19 PM

PHARMACOLOGIST

INTEROFFICE MEMORANDUM

DATE: 8/24/04

TO: Judit Milstein
Project Manager, HFD-520
and
File, NDA 50,797

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

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

RE: Pharmacology/Toxicology Review for Zmax, [REDACTED] NDA 50,797

This NDA is for a new formulation of azithromycin that is administered as a single 2 g dose and was designed to have better GI tolerability than the single dose formulation that is currently marketed. The sponsor is requesting approval of the new formulation for adult patients with [REDACTED] ABS, and CAP. [REDACTED]

The sponsor has requested that the Division use the nonclinical data from previously approved Zithromax NDA 50,670 to support the current NDA. This is appropriate. No new nonclinical studies were requested by the division nor performed by the sponsor. Thus, this supplement does not need a pharm/tox review. There is no objection to the approval of this NDA based on the nonclinical data. However, the sponsor removed the dose comparison data from the nonclinical sections of the proposed label and does not specify what animal species were used to conduct fertility studies. Thus, some negotiations on label content between the Division pharmacologists and the Sponsor will be necessary at the appropriate time.

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/s/

Amy Ellis

8/30/04 05:45:50 PM

PHARMACOLOGIST

Nonclinical data from previous azithromycin applications are used to support this NDA. This is acceptable. Label discussions with the sponsor will be necessary at the appropriate time.

Bob- You've signed the paper copy of this memo.

Robert Osterberg

9/3/04 07:48:37 AM

PHARMACOLOGIST