

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
050824Orig1s000

PROPRIETARY NAME REVIEW(S)

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND

RESEARCH

MEETING DATE: January 11, 2011
TIME: 11:15 AM
LOCATION: WO 22 Room 5394
APPLICATION: NDA 050824
DRUG NAME: Omeprazole/Clarithromycin/Amoxicillin
TYPE OF MEETING: Proposed Primary Proprietary Name

APPLICANT : DAVA

MEETING CHAIR: Melina Griffis

MEETING RECORDER: Karen Townsend

FDA ATTENDEES:

Melina Griffis., BCPS, Team Leader, DMEPA
Lubna Merchant, M.S., Pharm.D., ,Safety Evaluator, DMEPA
Karen Townsend, RPh, Safety Regulatory Project Manager, OSE
Judit Milstein,Chief,Project Management Staff
Joette Meyer, BS,Pharm.D., Clinical Team Lead

EXTERNAL CONSTITUENT ATTENDEES:

Susan Hamet , Vice President Regulatory Affairs

Background:

DMEPA requested this teleconference to inform the Applicant of preliminary concerns identified during the review of the proposed proprietary name (b) (4) and discuss regulatory options related to the proprietary name review process in light of the upcoming NDA PDUFA due date.

Discussion

In the interest of the Application PDUFA date, we wanted to notify you of our preliminary findings and safety concerns with regards to your proprietary name

(b) (4)

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Based on these findings, DMEPA is likely to find the proposed name, (b) (4) unacceptable.

We wanted to discuss the regulatory options.

Choice #1: Wait until DMEPA completes a full review and issues you a formal letter with our decision by our PDUFA date

OR

Choice #2: Withdraw the proposed proprietary name (b) (4) and submit an alternate name.

Conclusion

The Applicant decided to withdraw the name and asked for advice on how to proceed forward giving the PDUFA date for the application is very close and they have submitted several names previously that have not been approvable.

DMEPA advised them to submit several names with the next submission and they wouldl make all attempts to try to complete the review before the OND PDUFA goal.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KAREN F TOWNSEND
02/08/2011