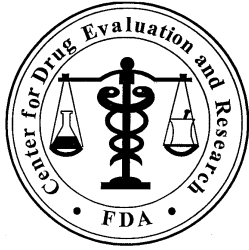


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
022497Orig1s000

**RISK ASSESSMENT and RISK MITIGATION
REVIEW(S)**



**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology**

Date: March 03, 2010

To: Thomas Laughren, MD, Director
Division of Psychiatry Products (DPP)

Through: Claudia Karwoski, PharmD, Director
Division of Risk Management (DRISK)
LaShawn Griffiths, MSHS-PH, BSN, RN, Acting Team Leader
Division of Risk Management (DRISK)

From: Shawna Hutchins, RN, BSN, Patient Labeling Reviewer
Division of Risk Management (DRISK)

Subject: Memo to File re: Review of Medication Guide (MG) and Risk Evaluation and Mitigation Strategy (REMS)

Drug Name(s): Forfivo XL (bupropion HCL 450mg ER)

Application Type/Number: NDA 22-497

Applicant/sponsor: Cary Pharmaceuticals Inc.

OSE RCM #: 2009-2043

The Division of Psychiatry Products (DPP) requested that the Division of Risk Management (DRISK) review the proposed patient labeling and proposed Risk Evaluation and Mitigation and Strategy (REMS), for New Drug Application (NDA) 22-497 submitted by Cary Pharmaceuticals Inc. on October 26, 2009 for Forfivo XL (bupropion HCL 450mg ER).

DPP does not plan to address labeling during this review cycle; therefore, we will defer our review of the Medication Guide (MG) and proposed Risk Evaluation and Mitigation and Strategy (REMS) until such time as the review division plans to address labeling. Please send us a new consult request at that time. This memo serves to close-out the consult request for Forfivo XL (bupropion HCL 450mg ER).

Please let us know if you have any questions.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22497	ORIG-1	CARY PHARMACEUTICA LS INC	BUP-450 (BUPROPION HCL)450MG ER ORAL TAB

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

/s/

SHAWNA L HUTCHINS
03/03/2010

CLAUDIA B KARWOSKI
03/03/2010
concur