

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-314

**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 6, 2009

To: Norman Stockbridge, M.D. Director
Division of Cardiovascular and Renal Products

Through: Jodi Duckhorn, MA, Team Leader
Division of Risk Management

From: LaShawn Griffiths, MSHS-PH, BSN, RN
Patient Product Information Reviewer
Division of Risk Management

Subject: DRISK Review of Patient Labeling (Patient Package Insert)

Drug Name(s): EXFORGE HCT (amlodipine, valsartan, and hydrochlorothiazide) tablets

Application Type/Number: NDA 22-314

Applicant/sponsor: Novartis Pharmaceuticals Corporation
OSE RCM #: 2008-1346

1 INTRODUCTION

Novartis Pharmaceuticals submitted a New Drug Application (NDA 22-314) for Exforge HCT tablets dated June 28, 2008 and submitted June 30, 2008. The submission includes proposed Professional Information (PI) in PLR format, with Patient Labeling Information (Patient Package Insert) included in section 17 Patient Counseling Information. Exforge HCT is indicated for the treatment of hypertension.

The Division of Cardiovascular and Renal Products requested that the Division of Risk Management's Patient Labeling and Education Team review the Applicant's proposed Patient Package Insert (PPI). This review is written in response to that request.

2 MATERIAL REVIEWED

- DRAFT Exforge HCT Patient Package Insert (PPI) submitted June 30, 2008, and revised by the Review Division throughout the current review cycle
- DRAFT Exforge HCT Prescribing Information (PI) submitted June 30, 2008, and revised by the Review Division throughout the current review cycle

3 DISCUSSION

The purpose of patient directed labeling is to facilitate and enhance appropriate use and provide important risk information about medications. Our recommended changes are consistent with current research to improve risk communication to a broad audience, including those with lower literacy.

The draft PPI submitted by the Applicant has a Flesch Kinkaid grade level of 7.0, and a Flesch Reading Ease score of 65.7%. To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60% (60% corresponds to an 8th grade reading level). The reading scores as submitted by the Applicant are acceptable.

In our review of the PPI, we have:

- simplified wording and clarified concepts where possible,
- ensured that the PPI is consistent with the PI,
- removed unnecessary or redundant information,
- ensured that the PPI meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006).

In 2008, The American Society of Consultant Pharmacists Foundation in collaboration with The American Foundation for the Blind published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. They recommend using fonts such as Arial, Verdana, or APHont to make medical information more accessible for patients with low vision. We have reformatted the PPI document using the font APHont, which was developed by the American Printing House for the Blind specifically for low vision readers.

See the attached document for our recommended revisions to the PPI. Comments to the review division are **bolded, underlined and italicized**.

We are providing the review division a marked-up and clean copy of the revised PPI. We recommend using the clean copy as the working document.

11 Page(s) Withheld

 Trade Secret / Confidential (b4)

X Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)

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/s/

LaShawn Griffiths
4/7/2009 01:16:37 PM
DRUG SAFETY OFFICE REVIEWER

Jodi Duckhorn
4/7/2009 03:16:56 PM
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