CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

200678Orig1s000

OTHER 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

PATIENT LABELING REVIEW

Date:	October 14, 2010
To:	Mary Parks, M.D., Director **Division of Metabolism and Endocrinology Products (DMEP)**
Through:	LaShawn Griffiths, RN, MSHS-PH, BSN Acting Team Leader, Patient Labeling Reviewer **Division of Risk Management (DRISK)** Barbara Fuller, RN, MSN, CWOCN Patient Labeling Reviewer **Division of Risk Management**
From:	Latonia M. Ford, RN, BSN, MBA Patient Labeling Reviewer **Division of Risk Management**
Subject:	DRISK Review of Patient Labeling (Patient Package Insert)
Drug Name (established name):	TRADENAME (saxagliptin/metformin hydrochloride extended-release) Tablets
Application Type/Number:	NDA 200678
Applicant:	Bristol-Myers Squibb (BMS) Company
OSE RCM #:	2010-2031

1 INTRODUCTION

This review is written in response to a request by the Division of Metabolic and Endocrine Products (DMEP) for the Division of Risk Management (DRISK) to review the Applicant's proposed Patient Package Insert (PPI) for TRADENAME (saxagliptin/metformin HCl extended-release) Tablets.

Bristol-Myers Squibb (BMS) Company submitted a New Drug Application (NDA) for TRADENAME (saxagliptin/metformin HCl extended-release) tablets on December 29, 2009. TRADENAME (saxagliptin/metformin HCl extended-release) tablets is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate.

DRISK conferred with DMEPA and a separate DMEPA review of the PPI has been submitted and placed in DARRTS dated July 2, 2010.

2 MATERIAL REVIEWED

- Draft TRADENAME (saxagliptin/metformin HCL extended-release) Tablets Patient Package Insert (PPI) received on December 29, 2009, revised by the Review Division throughout the current review and sent by the Review Division to DRISK on September 29, 2010.
- Draft TRADENAME (saxagliptin/metformin HCL extended-release) Tablets Prescribing Information (PI) received on December 29, 2009, revised by the Review Division throughout the current review and sent by the Review Division to DRISK on September 29, 2010.
- Approved Janumet (sitagliptin/metformin HCl) Tablets comparator labeling dated, September 24, 2010
- Approved Onglyza (saxagliptin) Tablets comparator labeling dated, July 31, 2009

3 REVIEW METHODS

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%. A reading ease score of 60% corresponds to an 8th grade reading level. In our review of the PPI the target reading level is at or below an 8th grade level.

Additionally, in 2008 the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss. The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss. We have reformatted the PPI document using the Verdana font, size 11.

In our review of the PPI we have:

- simplified wording and clarified concepts where possible

- removed unnecessary or redundant information
- ensured that the PPI is consistent with the PI
- ensured that the PPI meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)

4 CONCLUSIONS

The PPI is acceptable with our recommended changes.

5 RECOMMENDATIONS

- Please send these comments to the Applicant and copy DRISK on the correspondence.
- Our annotated versions of the PPI are appended to this memo. Consult DRISK regarding any additional revisions made to the PI to determine if corresponding revisions need to be made to the PPI

Please let us know if you have any questions.

16 Page(s) of Draft Labeling have been Withheld inFull as b4 (CCI/TS) immediately following this page

---

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

/s/

LATONIA M FORD
10/15/2010
Saxagliptin and metformin DRISK Final PPI

LASHAWN M GRIFFITHS
10/15/2010

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.