CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-350

OTHER REVIEW(S)

DIVISION OF METABOLISM AND ENDOCRINOLOGY PRODUCTS
SAFETY TEAM
MEMO TO THE FILE

NDA/Submission #/Submission type: 22-350/000/NDA 1

Product Name: ONGLYZA (saxagliptin)

Application submission date: 30 June 2008

Safety team reviewer: Amy G. Egan, M.D., M.P.H.

Safety review completion date: 30 July 2009

Action goal date: 30 July 2009

Reason for Review: New PPI

Items Reviewed: PI/PPI/CDTL memo

Synopsis of Findings: Saxagliptin is a depeptidyl peptidase-4 inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Safety issues identified during the review cycle or based on experience with other drugs in the class include severe hypersensitivity reactions and severe cutaneous reactions; hepatotoxicity; pancreatitis; decreased lymphocyte counts; and infections. In addition, a safety requirement for all new antidiabetic drugs, including saxagliptin, is to rule out an unacceptably increased risk of ischemic cardiovascular events. This is consistent with the December 2008 Guidance to Industry, entitled Diabetes Mellitus: Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes. All of these safety concerns are being adequately addressed in 3 post-marketing required studies/trials – a cardiovascular safety trial and 2 epidemiological studies.

The sponsor's PPI provides basic information about saxagliptin in patient friendly language which has been reviewed and approved by DRISK. There are no significant safety issues identified in the PI or PPI that would suggest that a Medication Guide would be more appropriate or that a REMS would be needed.

Determination:

REMS triggered: Y [redacted] I

If yes (Y) or indeterminate (I), was submission referred to the SRT?: Y N

Date submitted:

Date response received:

SRT response:

If no (N), why not?:

If no (N), please check one (or more) of the following reasons below:

__X__No significant safety issue identified

_____Only editorial changes made

_____Changes pertain only to proper use of a device

_____Other:

Linked Applications	Submission Type/Number	Sponsor Name	Drug Name / Subject
NDA 22350	ORIG 1	BRISTOL MYERS SQUIBB CO	SAXAGLIPTIN

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

/s/

AMY G EGAN
07/30/2009

Karen A. Hicks, M.D.
Division of Cardiovascular and Renal Products, HFD-110

Food and Drug Administration
10903 New Hampshire Avenue, Building 22, Room 4182
Silver Spring, MD 20993-0002
Tel: (301) 796-1089
FAX: (301) 796-9841

Memorandum

FROM: Karen A. Hicks, M.D., Medical Officer
Division of Cardiovascular and Renal Products

THROUGH: Norman L. Stockbridge, M.D., Ph.D., Director
Division of Cardiovascular and Renal Products

TO: Julie Marchick and Rachel Hartford
Project Managers
Division of Metabolism and Endocrinology Products (HFD-510)
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

and

Hylton Joffe, M.D.
Diabetes Team Leader
Division of Metabolism and Endocrinology Products (HFD-510)

SUBJECT: Draft CV Outcomes Study Design Concept Document D1680C0003 entitled "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 4 Trial to Evaluate the Effect of Saxagliptin on the Incidence of Major Adverse Cardiovascular Events in Patients with Type 2 Diabetes," dated April 17, 2009 (BMS Document No. 930035959) (NDA 22,350 Saxagliptin)

DATE RECEIVED: April 24, 2009

DATE COMPLETED: July 15, 2009

Materials Reviewed:

1. Draft CV Outcomes Study Design Concept Document D1680C0003 entitled "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 4 Trial to Evaluate the Effect of Saxagliptin on the Incidence of Major Adverse Cardiovascular Events in Patients with Type 2 Diabetes," dated April 17, 2009 (BMS Document No. 930035959)

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