CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-350

PROPRIETARY NAME REVIEW(S)

7/2/09

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:	July 2, 2009
To:	Mary Parks , Director Division of Metabolism and Endocrinology Products
Through:	Carol Holquist, R.Ph. Director Division of Medication Error Prevention and Analysis
From:	Melina Griffis, R.Ph., Acting Team Leader Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s):	Onglyza (saxagliptin) Tablets, 5 mg and ~~~
Application Type/Number:	NDA 22-350
Applicant/sponsor:	Bristol-Myers Squibb
OSE RCM #:	2009-994

1 INTRODUCTION

This review was written in response to notification that the Division of Metabolism and Endocrinology Products is going to take an approval action on this application. The proprietary name Onglyza was last reviewed on February 11, 2009 and found to be acceptable (see OSE review 2008-967).

1.1 PRODUCT DESCRIPTION

Onglyza (Saxagliptin tablets) is a dipeptidyl peptidase 4 (DPP4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. The recommended dose of Onglyza is 5 mg once daily with or without food. A single dosage adjustment of 2.5 mg daily is recommended for patients with moderate or severe renal impairment, or end stage renal disease. Onglyza will be available as 2.5 mg and 5 mg oral film-coated tablets. All strengths of Onglyza will be available in bottles of 30 and 90 tablets, and the 5 mg tablets will be available in 500 count bottles and blister packs of 100. Additionally, physicians will be given seven day sample packs of the 5 mg tablets.

2 DISCUSSION

During our final review of the proposed proprietary name, Onglyza, DMEPA identified 13 names not previously reviewed in OSE review 2008-967 (listed in Appendix A). Our FMEA determined that the 13 identified names were unlikely to result in medication errors with Onglyza. Therefore, we have concluded that the proposed proprietary name Onglyza remains acceptable for this product.

3 CONCLUSIONS AND RECOMMENDATIONS

We have completed our review of the proposed proprietary name, Onglyza, and have concluded that it is acceptable. However, if the product approval is delayed beyond 90 day from the date of this memo, the proposed name must be resubmitted for evaluation.

If you have further questions or need clarifications, please contact Mildred Wright, project manager, at 301-796-1027.

Appendix A: Additional names identified and reason to discard

Proprietary Name	Reason to Discard
b(4) ( )	Unapproved orphan designated drug product
( )	Unapproved orphan designated drug product
( )	Proposed trademarks listed in USPTO but not located in any other drug database
Unga-Eze	Originally identified in Micromedix however, unable to locate in any pharmaceutical database including Micromedix
Angyton	International brand for Amiodarone (marketed in Brazil)
Onyxsan	Withdrawn by Commissioner on 7/24/1970
b(4) ( )	Unapproved drug product as of — no recent activity in DSS
Abilify	Although there is an overlap in dose (5 mg and 10 mg) between Abilify and Onglyza orthographic differences in the names will likely minimize the risk of medication errors. [Abilify contains 3 cross-stokes letters vs 1 for Onglyza. Additionally, Onglyza does not contain any dotted letters and contains one additional downstoke. These names when written are of different shapes.]
Agrylin	Although there is a numerical overlap in dose (5 mg vs 0.5 mg) between Abilify and Agrylin orthographic differences in the names will likely minimize the risk of medication errors. [Abilify contains 3 cross-stokes letters vs 1 for Agrylin. Additionally, Agrylin contains one additional downstoke. These names when written are of different shapes.]
Ony-Clear (1% benzalkonium topical solution)	Different strength availability, dosage form and route of administration

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/s/

Melina Griffis
7/2/2009 08:24:25 AM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
7/2/2009 08:58:12 AM
DRUG SAFETY OFFICE REVIEWER

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