CENTER FOR DRUG EVALUATION AND RESEARCH

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PROPRIETARY NAME 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:	April 8, 2011
Application Type/Number:	NDA 201280
Through:	Zachary Oleszczuk, Pharm.D., Team Leader Carol Holquist, R.Ph, Director Division of Medication Error Prevention and Analysis
From:	Yelena Maslov, Pharm.D., Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s):	Tradjenta (Linagliptin) Tablets, 5 mg
Applicant/sponsor:	Boehringer Ingelheim Pharmaceuticals, Inc.
OSE RCM #:	2010-2473

*** This document contains proprietary and confidential information that should not be released to the public.***

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EXECUTIVE SUMMARY

This review summarizes DMEPA's evaluation of proposed proprietary name, Tradjenta for Linagliptin Tablets. Our evaluation did not identify concerns that would render the name unacceptable based on product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name, Tradjenta, acceptable for this product.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, The Division of Metabolism and Endocrinology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date. Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be re-submitted for review. The conclusions upon re-review are subject to change.

1 BACKGROUND

1.1 INTRODUCTION

This review responds to the request from Boehringer Ingelheim Pharmaceuticals, Inc., dated February 1, 2011, for an assessment of the proposed proprietary name, Tradjenta, regarding the promotional nature and potential name confusion with other proprietary or established drug names in the usual practice setting.

1.2 REGULATORY HISTORY

This is the third proposed proprietary name for this product. DMEPA found the first proposed proprietary name, Ondero, unacceptable in OSE Review #2010-1510, dated October 6, 2010 (b) (4) DMEPA found the second proposed proprietary name, Trajenta, unacceptable (b) (4) and informed the Applicant of the unacceptability of the name via teleconference held on January 19, 2011.

1.3 PRODUCT INFORMATION

Tradjenta (Linagliptin) is a dipeptidyl peptidase-4 (DPP-4) inhibitor proposed as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The recommended dose is 5 mg orally once daily. Tradjenta may be taken with or without food. No dose adjustment is recommended for patients with renal or hepatic impairment. Tradjenta will be available as 5 mg tablets in bottles containing 30, 90, or 1000 tablets and in physician samples packaged in blister packs of seven tablets each. The tablets should be stored at 25º C (77º F); excursions permitted to 15º to 30º C (59º to 86º F).

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Tradjenta.

2.1 SEARCH CRITERIA

For this review, a particular consideration was given to drug names beginning with the letter 'T' when searching to identify potentially similar drug names, as 75% of the confused drug names

reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.[1,2]

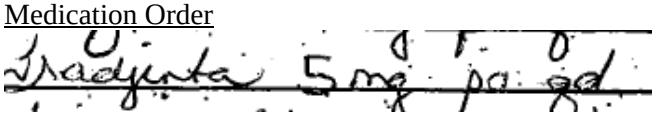
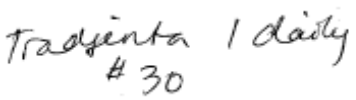
To identify drug names that may look similar to Tradjenta, the DMEPA safety evaluators also consider the orthographic appearance of the name on the lined and unlined orders. Specific attributes taken into the consideration include the length of the name (nine letters), upstrokes (three, the first capital letter 'T' and lower case letters 'd' and 't'), down strokes (one, lower case letter 'j'), cross-strokes (one, lower case letter 't'), and dotted letters (one, lower case letter 'j'). Additionally, several letters in the proposed name, Tradjenta, may be vulnerable to ambiguity when scripted (See Appendix B). As such, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Tradjenta.

When searching to identify potential names that may sound similar to Tradjenta, the DMEPA safety evaluators search for names with similar number of syllables (three), stresses (TRAD-jen-ta, trad-JEN-ta, or trad-jen-TA), and placement of vowel and consonant sounds. Additionally, DMEPA safety evaluators consider that pronunciation of part of the name can vary (see Appendix B). The Applicant's intended pronunciation [TRAD-gen-ta] was also taken into consideration, as it was included in the Proprietary Name Review Request. Moreover, names are often mispronounced or spoken with regional accents and dialects, so other pronunciations of the names are considered.

2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient and verbal orders were communicated during FDA prescription studies on February 11, 2011.

Figure 1: Tradjenta study samples

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order  Outpatient Prescription 	Tradjenta 5 mg po qd

[1] Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

[2] Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

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