

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**201281Orig1s000**

**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  
Office of Medication Error Prevention and Risk Management**

**Proprietary Name Review--Final**

Date: January 26, 2012

Reviewer(s): Carlos M Mena-Grillasca, RPh, Team Leader  
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh  
Division of Medication Error Prevention and Analysis

Drug Name(s) and Strength(s): Jentaduetto (Linagliptin and Metformin Hydrochloride) Tablets,  
2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg

Application Type/Number: NDA 201281

Applicant/sponsor: Boehringer Ingelheim Inc.

OSE RCM #: 2012-204

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

# CONTENTS

1	INTRODUCTION .....	3
2	METHODS AND DISCUSSION .....	3
3	CONCLUSIONS.....	3
3.1	Comments to the Applicant.....	3
4	REFERENCES .....	4

## 1 INTRODUCTION

This re-assessment of the proposed proprietary name, Jentaduetto is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Jentaduetto, acceptable in OSE Review 2011-3166 dated November 9, 2011.

## 2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2011-3166. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded no new names thought to look or sound similar to Jentaduetto and represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of January 23, 2012. The Office of Prescription Drug Promotion OPDP reviewed the proposed name on August 25, 2011 and had no concerns regarding the proposed name from a promotional perspective.

## 3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Jentaduetto, did not identify any vulnerabilities that would result in medication errors with any additional name noted in this review. Thus, DMEPA has no objection to the proprietary name, Jentaduetto, for this product at this time.

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.

If you have further questions or need clarifications, please contact Margarita Tossa, OSE project manager, at 301-796-4053.

### 3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Jentaduetto, and have concluded that this name is acceptable.

The proposed proprietary name, Jentaduetto, will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

If **any** of the proposed product characteristics as stated in your January 17, 2012, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

## 4 REFERENCES

### 1. OSE Review

Fava, W. OSE Review #2011-3166: Proprietary Name Review for Jentadueto; November 9, 2011.

### 2. *Drugs@FDA* (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.

### 3. *USAN Stems* (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>)

USAN Stems List contains all the recognized USAN stems.

### 4. *Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request*

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

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

/s/  
-----

CARLOS M MENA-GRILLASCA  
01/26/2012

CAROL A HOLQUIST  
01/26/2012

**Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Surveillance and Epidemiology  
Office of Medication Error Prevention and Risk Management**

**Proprietary Name Review**

Date: November 09, 2011

Reviewer(s): Walter Fava, RPh, MEd, Safety Evaluator  
Division of Medication Error Prevention and Analysis

Team Leader Carlos Mena-Grillasca, RPh  
Division of Medication Error Prevention and Analysis

Division Director Carol Holquist, RPh  
Division of Medication Error Prevention and Analysis

Drug Name(s): Jentaduetto (Linagliptin and Metformin Hydrochloride) Tablets  
2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg

Application Type/Number: NDA 201281

Applicant/sponsor: Boehringer Ingelheim Inc.

OSE RCM #: 2011-3166

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

## CONTENTS

1	INTRODUCTION.....	2
1.1	Product Information.....	2
2	RESULTS.....	2
2.1	Promotional Assessment.....	2
2.2	Safety Assessment.....	2
3	CONCLUSIONS.....	4
3.1	Comments to the Applicant.....	4
4	REFERENCES.....	5
	APPENDICES.....	7

## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Jentadueto, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

### 1.1 PRODUCT INFORMATION

Jentadueto is a dipeptidyl peptidase-4 (DDP-4) inhibitor and biguanide fixed combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate. The product will be available in three combination strengths of linagliptin and metformin hydrochloride (2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg). The recommended dose is one tablet by mouth twice a day with meals. Gradual dose escalation is recommended to reduce gastrointestinal side effects due to metformin. The maximum recommended dose is 2.5 mg linagliptin/1000 mg metformin hydrochloride twice daily. All dosing strengths will be available in 14 count sample bottles and retail bottles of 60, 180, and 2000 tablets. The 14 count sample bottle and retail bottles of 60 and 180 tablets are packaged in (b) (4) container closure systems. All bottles should be stored at 25°C (77°F), with excursions permitted to 15-30°C (75°F -86°F) and protected from exposure to high humidity.

Tradjenta (linagliptin) tablet, 5 mg was approved on May 2, 2011.

## 2 RESULTS

The following sections provide the information obtained and considered in the evaluation of the proposed proprietary name.

### 2.1 PROMOTIONAL ASSESSMENT

OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Metabolic and Endocrine Products (DMEP) concurred with the findings of OPDP's promotional assessment of the proposed name.

### 2.2 SAFETY ASSESSMENT

The following aspects of the name were considered in the overall evaluation.

#### 2.2.1 *United States Adopted Names (USAN) SEARCH*

The United States Adopted Name (USAN) stem search conducted on October 24, 2011 identified that a USAN stem is not present in the proposed proprietary name.

#### 2.2.2 *Components of the Proposed Proprietary Name*

This proprietary name is comprised of as single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error. The name includes the letter string, 'Jenta' which is derived from the proprietary name, Tradjenta (linagliptin).

### 2.2.3 FDA Name Simulation Studies

Thirty-eight practitioners participated in DMEPA’s prescription studies. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies. Of note, in the inpatient study the initial letter “J” was misinterpreted for a “T” (n=9) and an “L” (n=5). All but one of the participants from the voice study misinterpreted the initial letter “J” for a “G” (n=9). None of the responses were identified as a marketed product.

### 2.2.4 Comments from Other Review Disciplines

In response to the OSE, September 6, 2011 e-mail, the Division of Metabolic and Endocrinology Products (DMEP) responded that the “review team has no objection” to the proposed name at the initial phase of the name review.

### 2.2.5 Failure Mode and Effects Analysis of Similar Names

Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Jentaducto (see Appendix B). These names were identified by the primary reviewer, the Expert Panel Discussion (EPD), other review disciplines. Table 1 also included the names identified by DSI that were not previously identified by DMEPA and require further evaluation.

**Table 1: Collective List of Potentially Similar Names (DMEPA, EPD and Other Disciplines)**

<b>Look Similar</b>					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Jantoven	FDA, DSI	Jenloga	FDA, DSI	Zenapax	FDA
Jevantique	FDA	Tradjenta	FDA	Tenuate	FDA
Jevtana	FDA, DSI	Tenathan	FDA	Jenest-28	FDA, DSI
Janumet	FDA, DSI	Tenormin	FDA	Zestoretic	FDA
Lenalidomide	FDA	Tensilon	FDA	Terbutaline	FDA
Gentacidin	FDA	Janimine	FDA	Tindazole	FDA
Acetadote	FDA	Januvia	FDA	Just for Kids	FDA
Quadramet	FDA	Loratidine	FDA	Temozolomide	FDA
Duetact	FDA, DSI	Tobradex	FDA		
Penetate	FDA	Zenate Prenatal	FDA		
<b>Sound Similar</b>					
<b>No Names Identified</b>					
<b>Look and Sound Similar</b>					
Jentaducto	FDA	Duet	DSI	Duet DHA	DSI
Gentamicin	DSI				

Our analysis of the 32 names contained in Table 1 considered the information obtained in the previous sections along with the product characteristics for these names. We determined the thirty-two names will not pose a risk for confusion as described in Appendix D through E.

DMEPA communicated these findings to the Division of Metabolic and Endocrinology Products via e-mail on November 2, 2011. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolic and Endocrinology Products on November 7, 2011, they stated no additional concerns with the proposed proprietary name, Jentadueto.

### **3 CONCLUSIONS**

DMEPA concludes the proposed proprietary name is acceptable from both a promotional and safety perspective. The Applicant will be notified of this conclusion via letter.

If you have further questions or need clarifications, please contact Margarita Tossa, OSE project manager, at 301-796-4053.

#### **3.1 COMMENTS TO THE APPLICANT**

We have completed our review of the proposed proprietary name, Jentadueto, and have concluded that this name is acceptable.

However, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

## 4 REFERENCES

1. ***Micromedex Integrated Index*** (<http://csi.micromedex.com>)

Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. ***Drug Facts and Comparisons, online version, St. Louis, MO***  
(<http://factsandcomparisons.com> )

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

6. ***Drugs@FDA*** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and “Chemical Type 6” approvals.

7. ***Electronic online version of the FDA Orange Book***  
(<http://www.fda.gov/cder/ob/default.htm>)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

8. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)

USPTO provides information regarding patent and trademarks.

**9. *Clinical Pharmacology Online* ([www.clinicalpharmacology-ip.com](http://www.clinicalpharmacology-ip.com))**

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

**10. *Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at* ([www.thomson-thomson.com](http://www.thomson-thomson.com))**

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

**11. *Natural Medicines Comprehensive Databases* ([www.naturaldatabase.com](http://www.naturaldatabase.com))**

Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

**12. *Access Medicine* ([www.accessmedicine.com](http://www.accessmedicine.com))**

Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

**13. *USAN Stems* (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)**

USAN Stems List contains all the recognized USAN stems.

**14. *Red Book Pharmacy's Fundamental Reference***

Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

**15. *Lexi-Comp* ([www.lexi.com](http://www.lexi.com))**

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

**16. *Medical Abbreviations Book***

Medical Abbreviations Book contains commonly used medical abbreviations and their definitions.

## APPENDICES

### Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.<sup>1</sup>

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

---

<sup>1</sup> National Coordinating Council for Medication Error Reporting and Prevention.  
<http://www.nccmerp.org/about/MedErrors.html>. Last accessed 10/11/2007.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.<sup>2</sup> The product characteristics considered for this review appears in Appendix B1 of this review.

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor’s intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., “T” may look like “F,” lower case ‘a’ looks like a lower case ‘u,’ etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

**Table 1.** Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

<b>Type of Similarity</b>	<b>Considerations when Searching the Databases</b>		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> </ul>

<sup>2</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Look-alike			<ul style="list-style-type: none"> <li>Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

### 1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the

name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

## **2. Expert Panel Discussion**

DMEPA gathers CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

## **3. FDA Prescription Simulation Studies**

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

## **4. Comments from Other Review Disciplines**

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept

or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

## **5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name**

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>3</sup> When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix B1 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

***“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And Are there any components of the name that may function as a source of error beyond sound/look-alike”***

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

---

<sup>3</sup> Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

***“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”***

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval.

Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners’ vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

**Appendix B:** Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Jentaducto	Scripted May Appear as	Spoken May Be Interpreted as
Capital ‘J’	‘F’, ‘g’, ‘L’, ‘S’, ‘T’	‘G’, ‘Ch’
lower case ‘e’	‘a’, ‘i’, ‘l’, ‘o’, ‘u’, ‘p’	any vowel
lower case ‘n’	‘h’, ‘m’, ‘u’, ‘x’, ‘r’, ‘s’	‘m’, ‘dn’, ‘gn’, ‘kn’, ‘mn’, ‘pn’
lower case ‘t’	‘f’, ‘A’, ‘r’, ‘x’	‘d’
lower case ‘a’	‘e’, ‘o’, ‘u’, ‘el’, ‘ei’, ‘ci’, ‘cl’, ‘d’	any vowel
lower case ‘d’	‘ci’, ‘cl’, ‘ol’	‘b’, ‘t’
lower case ‘u’	‘n’, ‘y’, ‘v’, ‘w’, any vowel	any vowel
lower case ‘o’	‘a’, ‘e’, ‘c’, ‘u’	any vowel

**Appendix C: Prescription Simulation Samples and Results**

**Figure 1. Jentadueto Study (Conducted on 10/13/2011)**

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Jentadueto 2.5mg/500mg T po bid</i></p>	<p>Jentadueto 2.5 mg/500 mg</p> <p>Take one tablet by mouth twice a day #60</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Jentadueto 2.5mg/500mg</i> <i>T po BID #60</i></p>	

**FDA Prescription Simulation Responses.**

85 People Received Study		
38 People Responded		
Study Name: Jentadueto		
INPATIENT	VOICE	OUTPATIENT
FENTADUETS (1)	GENTADUETO (2)	JENTADUCTO (1)
JENTADUETS (1)	GENTADUETTO (3)	JENTADUETO (5)
LENTADUCTO (1)	GENTIDEWADO (1)	JENTADUETS (1)
LENTADUETO (4)	GENTIDUETO (1)	JENTODUCTO (1)
TENTADUCTO (2)	GENTODUATO (1)	JENTODUETO (2)
TENTADUCTS (1)	GENTOWETTA (1)	ZENTADUCTO (1)
TENTADUETA (1)	JENTADUETO (1)	ZENTADUETO (1)
TENTADUETO (4)		
TENTADUETS (1)		

**Appendix D:** Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

Proprietary Name	Similarity to Jentadueto	Failure preventions
Tenormin	Look	Lacks convincing orthographic similarity
Lenalidomide	Look	
Janimine	Look	
Januvia	Look	
Zenate Prenatal	Look	
Just for Kids	Look	
Temozolomide	Look	
Terbinafene	Look	
Tobradex	Look	
Gentamicin	Look	
Zenapax	Look	
Penetate	Look	Not found in any drug reference and no information found online
Tenathan	Look	NDA 017675 withdrawn in 1996. No generic equivalents available.

**Appendix E:** Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

Proposed name: Jentadueto	Strength(s): 2.5 mg/500 mg 2.5 mg/850 mg 2.5 mg/1000 mg	Usual dose: One tablet by mouth twice a day
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Jantoven (Warfarin) 1 mg, 2 mg, 2.5 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7.5 mg, and 10 mg Tablets</p> <p><u>Usual dose:</u> One tablet by mouth once a day</p>	<p><u>Orthographic similarities:</u> <i>Both names begin with the letter, 'J' and share the letters 'a', 'n', 't', 'e', and 'o'</i></p> <p><u>Product Characteristics:</u> Dosage Form (Tablet) Route of Administration (Oral) Dose (One tablet) Numerical Overlap in Strength (2.5 mg)</p>	<p><b><u>Orthographic Differences:</u></b> Jentadueto contains ten letters and appears longer when scripted when compared to Jantoven which has eight letters. In addition, Jentadueto contains four upstroke letters, 'J', 't', 'd', and 't', and has a different shape when scripted compared to Jantoven, which contains two upstroke letters, 'J' and 't'.</p> <p><b><u>Frequency of Administration:</u></b> Twice a day vs once a day</p>
<p>Jevantique (Ethinyl Estradiol and Norethindrone Acetate) 5 mcg/1 mg</p> <p><u>Usual dose:</u> Take one tablet by mouth daily</p>	<p><u>Orthographic similarities:</u> <i>Both names contain ten letters and appear similar in length when scripted. In addition, both names begin with the letters, 'Je', and share the letters, 'a', 'n', 't', 'u', and 'e'.</i></p> <p><u>Product characteristics:</u> Dosage Form (Tablet) Route of Administration (Oral) Dose (One tablet) Frequency of Administration (Once a day)</p>	<p><b><u>Orthographic Differences:</u></b> Jentadueto contains four upstroke letters, 'J', 't', 'd', and 't', giving it a different shape when scripted compared to the two upstroke letters, 'J' and 't' in Jevantique. Also, Jevantique has a downstroke letter, 'q' which Jentadueto does not have.</p> <p><b><u>Strength:</u></b> Multiple (2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg) vs Single (5 mcg/1 mg)</p>

Proposed name: Jentadueto	Strength(s): 2.5 mg/500 mg 2.5 mg/850 mg 2.5 mg/1000 mg	Usual dose: One tablet by mouth twice a day
<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>
<p>Jevtana (Cabazitaxel) 60 mg Injection</p> <p><u>Usual dose:</u> Infuse 25 mg/m<sup>2</sup> intravenously over one hour on day 1 in combination with prednisone (10 mg by mouth once a day), repeat cycles every 3 weeks</p>	<p><u>Orthographic similarities:</u> <i>Both names begin with the letters, 'Je' and share the letters, 'a', 'n' and 't'.</i></p>	<p><b><u>Orthographic Differences:</u></b> Jentadueto contains four upstroke letters, 'J', 't', 'd', and 't' giving it a different shape when scripted compared to the two upstroke letters, 'J' and 't' in Jevtana. In addition, Jentadueto contains ten letters and appears longer when scripted compared to the seven letters in Jevtana.</p> <p><b><u>Dosage Form:</u></b> Tablet vs Injection</p> <p><b><u>Route of Administration:</u></b> Oral vs Intravenous</p> <p><b><u>Frequency of Administration:</u></b> Twice a day vs once a day on day one of the cycle repeated every 3 weeks</p> <p><b><u>Strength:</u></b> Multiple (2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg) vs Single (60 mg)</p>
<p>Janumet (Sitagliptin and Metformin) 50 mg/500 mg, 50 mg/1000 mg Tablet</p> <p><u>Usual dose:</u> One tablet by mouth twice a day with meals</p>	<p><u>Orthographic similarities:</u> <i>Both names begin with the letter, 'J' and share the letters, 'a', 'n', 't', 'u' and 'e'.</i></p> <p><u>Product Characteristics:</u> Dosage Form (Tablet) Route of Administration (Oral) Frequency of Administration (Twice a day) Dose (One tablet) Numerical Overlap in Strength (500 mg)</p>	<p><b><u>Orthographic Differences:</u></b> Jentadueto contains ten letters and appears longer when scripted compared to the seven letters in Janumet. In addition, Jentadueto contains four upstroke letters, 'J', 't', 'd', and 't', giving it a different shape when scripted compared to the two upstroke letters, 'J' and 't' in Janumet.</p>

<p><b>Proposed name:</b></p> <p><b>Jentadueto</b></p>	<p><b>Strength(s):</b></p> <p>2.5 mg/500 mg 2.5 mg/850 mg 2.5 mg/1000 mg</p>	<p><b>Usual dose:</b></p> <p>One tablet by mouth twice a day</p>
<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p>Gentacidin (Gentamicin)</p> <p>0.3% Ophthalmic solution and ointment</p> <p><u>Usual dose:</u></p> <p>Instill one to two drops into affected eye(s) every 4 hours</p>	<p><u>Orthographic similarities:</u> <i>Both names contain ten letters and appear similar in length when scripted. In addition, both names share the letter string, 'enta' and also share the letter, 'd'.</i></p>	<p><b>Orthographic Differences:</b> Jentadueto contains four upstroke letters, 'J', 't', 'd', and 't', giving it a different shape when scripted compared to the three upstroke letters, 'G', 't', and 'd' in Gentacidin. The ending letters 'ueto' look different than the corresponding letters 'idin'.</p> <p><b>Dosage Form:</b> Tablet vs Ophthalmic Solution and Ointment</p> <p><b>Route of Administration:</b> Oral vs Ophthalmic</p> <p><b>Frequency of Administration:</b> Twice a day vs every 4 hours</p> <p><b>Strength:</b> Multiple (2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg) vs Single (0.3%)</p>
<p>Acetadote (Acetylcysteine)</p> <p>200 mg/mL Injection</p> <p><u>Usual dose:</u></p> <p><i>Initial:</i> 150 mg/kg intravenously over 60 minutes followed by 50 mg/kg intravenously over 4 hours and then 100 mg/kg intravenously over 16 hours</p>	<p><u>Orthographic similarities:</u> <i>Both names contain the letters, 'a', 'e', 't', 'd' and 'o'. Both names also contain four upstroke letters in similar positions giving them a similar shape when scripted.</i></p>	<p><b>Dosage Form:</b> Tablet vs Injection</p> <p><b>Route of Administration:</b> Oral vs Intravenous</p> <p><b>Frequency of Administration:</b> Twice a day vs Three doses administered as a continuous infusion over 21 hours</p> <p><b>Strength:</b> Multiple (2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg) vs Single (200 mg/mL)</p>
<p>Quadramet (Samarium-153 Lexidronam)</p> <p>50 mCi/mL Injection</p> <p><u>Usual dose:</u></p> <p>1 mCi/kg intravenously as a single dose.</p>	<p><u>Orthographic similarities:</u> <i>Both names contain the letters, 'u', 'a', 'd', 't', and 'e'.</i></p> <p><u>Product Characteristics:</u></p> <p>Numerical Overlap in Strength (500 mg vs 50 mCi)</p>	<p><b>Orthographic Differences:</b> The beginning letters, 'J' in Jentadueto look different when scripted compared to the beginning letters, 'Q' in Quadramet. Also, the ending letters, 'eto' in Jentadueto look different when scripted compared to the ending letters, 'met' in Quadramet.</p> <p><b>Dosage Form:</b> Tablet vs Injection</p> <p><b>Route of Administration:</b> Oral vs Intravenous</p> <p><b>Frequency of Administration:</b> Twice a day vs One time</p> <p><b>Strength:</b> Multiple (2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg) vs Single (50 mCi/mL)</p> <p><b>Setting of Use:</b> Retail/Hospital vs Nuclear Pharmacy</p>

Proposed name: Jentadueto	Strength(s): 2.5 mg/500 mg 2.5 mg/850 mg 2.5 mg/1000 mg	Usual dose: One tablet by mouth twice a day
<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>
<p>Duetact (Glimepiride and Pioglitazone Hydrochloride) 2 mg/30 mg; 4 mg/30 mg Tablet</p> <p><u>Usual dose:</u> Take one tablet by mouth daily with food.</p>	<p><u>Orthographic similarities:</u> <i>Both names share the letter string, 'Duet' and contain the letter 'a'.</i></p> <p><u>Product Characteristics:</u> Dosage Form (Tablet) Route of Administration (Oral) Dose (one tablet)</p>	<p><b><u>Orthographic Differences:</u></b> Jentadueto contains ten letters and appears longer when scripted compared to the seven letters in Duetact. In addition, Jentadueto has four upstroke letters, 'J', 't', 'd', and 't', giving it a different shape when scripted compared to the three upstroke letters, 'D', 't', and 't' in Duetact. The similar letter string 'Duet' appears at the end of the name in Jentadueto, compared to the beginning of the name in Duetact. These orthographic differences may help to differentiate this name pair when scripted.</p> <p><b><u>Frequency of Administration:</u></b> Twice a day vs once a day</p>
<p>Jenloga (Clonidine) 0.1 mg, 0.2 mg Tablet</p> <p><u>Usual dose:</u> Take one tablet by mouth twice a day</p>	<p><u>Orthographic similarities:</u> <i>Both names begin with the letter string, 'Jen' and share the letter, 'a'.</i></p> <p><u>Product Characteristics:</u> Dosage Form (Tablet) Route of Administration (Oral) Dose (one tablet) Frequency of administration (twice daily)</p>	<p><b><u>Orthographic Differences:</u></b> Jentadueto contains four upstroke letters, 'J', 't', 'd', 't', and has a different shape when scripted compared to the two upstroke letters, 'J' and 'l' in Jenloga. In addition, Jenloga contains the downstroke letter 'g' which Jentadueto does not have. Jentadueto also appears longer when scripted (10 letters vs 7 letters).</p>

Proposed name: Jentadueto	Strength(s): 2.5 mg/500 mg 2.5 mg/850 mg 2.5 mg/1000 mg	Usual dose: One tablet by mouth twice a day
<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>
Tradjenta (Linagliptin) 5 mg Tablet <u>Usual dose:</u> Take one tablet by mouth once a day	<u>Orthographic similarities:</u> <i>Both names share the letter string, 'jenta' and appear similar in length when scripted (10 letters vs 9 letters)</i>  <u>Overlapping Product Characteristics:</u> Dosage Form (Tablet) Route of Administration (Oral) Dose (One tablet) Active Ingredient (Linagliptin)	<u>Orthographic Differences:</u> Jentadueto contains four upstroke letters, 'J', 't', 'd', 't' and has a different shape when scripted compared to the three upstroke letters, 'T', 'd', 't'. There is one down stroke letter in Tradjenta ('j') and no down stroke in Jentadueto. The shared letter string 'jenta' appears at the end of the name in Tradjenta, but at the beginning of the name in Jentadueto.  <u>Frequency of Administration:</u> Twice a day vs once a day  <u>Strength:</u> Multiple (2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg) vs Single (5 mg)
Tensilon (Edrophonium Chloride) 10 mg/mL Injection <u>Usual dose:</u> Inject 0.1 mL (1 mg) intravenously, monitor heart rate, followed by 0.1 mL intravenously	<u>Orthographic similarities:</u> <i>The beginning letter, 'J' in Jentadueto may look similar to the beginning letter, 'T' in Tensilon when scripted. Both names also share the letters, 'e', 'n', and 'o'.</i>	<u>Orthographic Differences:</u> Jentadueto contains four upstroke letters, 'J', 't', 'd', 't' and has a different shape when scripted compared to the two upstroke letters, 'T' and 'l' in Tensilon. Jentadueto also contains 10 letters and appears longer when scripted compared to the eight letters in Tensilon.  <u>Dosage Form:</u> Tablet vs Injection  <u>Route of Administration:</u> Oral vs Intravenous  <u>Frequency of Administration:</u> Twice a day vs one time  <u>Strength:</u> Multiple (2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg) vs Single (10 mg/mL)

Proposed name: Jentadueto	Strength(s): 2.5 mg/500 mg 2.5 mg/850 mg 2.5 mg/1000 mg	Usual dose: One tablet by mouth twice a day
<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>
Loratadine 10 mg Tablet <u>Usual dose:</u> Take one tablet by mouth once a day.	<u>Orthographic similarities:</u> <i>Both names contain ten letters and appear similar in length when scripted. They also share the letters, 't', 'a', 'd', 'e', and 'o'.</i> <u>Product Characteristics:</u> Dosage Form (Tablet) Route of Administration (Oral) Dose (One tablet)	<u>Orthographic Differences:</u> Jentadueto contains four upstroke letters, 'J', 't', 'd', 't' and has a different shape when scripted compared to the three upstroke letters, 'L', 't', and 'd' in Loratidine. <u>Frequency of Administration:</u> Twice a day vs once a day <u>Strength:</u> Multiple (2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg) vs Single 10 mg
Tenuate (Diethypropion) 25 mg Tablet <u>Usual dose:</u> Take one tablet by mouth three times a day.	<u>Orthographic similarities:</u> <i>The beginning letter, 'J' in Jentadueto may look similar to the beginning letter, 'T' in Tenuate and both names have the letters, 'en' in the second and third positions respectively. They also share the letters, 't', 'u', and 'a'.</i> <u>Product Characteristics:</u> Dosage Form (Tablet) Route of Administration (Oral) Dose (One tablet)	<u>Orthographic Differences:</u> Jentadueto contains four upstroke letters, 'J', 't', 'd', 't' and has a different shape when scripted compared to the two upstroke letters, 'T' and 't' in Tenuate. In addition, Jentadueto contains ten letters and appears longer when scripted compared to the seven letters in Tenuate. <u>Frequency of Administration:</u> Twice a day vs three times a day <u>Strength:</u> Multiple (2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg) vs Single (25 mg)

Proposed name: Jentadueto	Strength(s): 2.5 mg/500 mg 2.5 mg/850 mg 2.5 mg/1000 mg	Usual dose: One tablet by mouth twice a day
<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>
<p>Jenest-28 (Ethinyl Estradiol and Norethindrone) 0.035 mg/0.4 mg Tablet</p> <p><u>Usual dose:</u> Take one tablet by mouth daily.</p>	<p><u>Orthographic similarities:</u> <i>Both names begin with the letters, 'Jen' and share the letter, 't'.</i></p> <p><u>Product Characteristics:</u> Dosage Form (Tablet) Route of Administration (Oral) Dose (One tablet)</p>	<p><b><u>Orthographic Differences:</u></b> Jentadueto contains four upstroke letters, 'J', 't', 'd', 't' and has a different shape when scripted compared to the two upstroke letters, 'J' and 't' in Jenest-28. In addition, Jentadueto contains ten letters and appears longer when scripted compared to the six letters in Jenest-28. The numerical modifier, '28' in Jenest-28 will also provide orthographic differentiation between the names.</p> <p><b><u>Frequency of Administration:</u></b> Twice a day vs once a day</p> <p><b><u>Strength:</u></b> Multiple (2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg) vs Single (0.35 mg/0.4 mg)</p>
<p>Zestoretic (Lisinopril and Hydrochlorothiazide) 10 mg/12.5 mg, 20 mg /12.5 mg, 20 mg/25 mg Tablet</p> <p><u>Usual dose:</u> Take one tablet by mouth once a day.</p>	<p><u>Orthographic similarities:</u> <i>Both names contain ten letters and appear similar in length when scripted. The beginning letter, 'J' in Jentadueto may look similar to the beginning letter, 'Z' when scripted. The names also share the letters, 'e', 't', and 'o'.</i></p> <p><u>Product characteristics:</u> Dosage Form (Tablet) Route of Administration (Oral) Dose (One tablet)</p>	<p><b><u>Orthographic Differences:</u></b> Jentadueto contains four upstroke letters, 'J', 't', 'd', 't' and has a different shape when scripted compared to the three upstroke letters, 'Z', 't', and 't' in Zestoretic. Although both names have two upstroke letters, 't', Jentadueto upstroke letter 'd' between the two 't' letters helps to differentiate the names.</p> <p><b><u>Frequency of Administration:</u></b> Twice a day vs once a day</p>

Proposed name: Jentadueto	Strength(s): 2.5 mg/500 mg 2.5 mg/850 mg 2.5 mg/1000 mg	Usual dose: One tablet by mouth twice a day
<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>
<p>Terbutaline 2.5 mg, 5 mg Tablet 1 mg/mL Injection</p> <p><u>Usual dose:</u></p> <p><i>Oral tablet:</i> Take one tablet by mouth three times a day</p> <p><i>Injection:</i> Inject 0.25 mg subcutaneously and repeat in 15 to 30 minutes if no improvement.</p>	<p><u>Orthographic similarities:</u> <i>Both names contain ten letters and appear similar in length and shape when scripted. They also share the letters, ‘t’, ‘a’, ‘e’, ‘u’ and ‘n’. In addition, the beginning letter, ‘J’ in Jentadueto may look similar to the beginning letter, ‘T’ in Terbutaline.</i></p> <p><u>Product characteristics:</u></p> <p>Dosage Form (Tablet) Route of Administration (Oral) Dose (One tablet) Numerical strength overlap (2.5 mg)</p>	<p><b><u>Orthographic Differences:</u></b> The ending letters, ‘ueto’ in Jentadueto look different than the ending letters, ‘line’ in Terbutaline when scripted. In addition, the letters, ‘tad’ in Jentadueto look different from the corresponding letter string, ‘but’ in Terbutaline.</p> <p><b><u>Frequency of Administration:</u></b> Twice a day vs three times a day or for one time treatment of acute breathing difficulties.</p>
<p>Terbinafine 250 mg Tablet 1% Cream</p> <p><u>Usual dose:</u></p> <p><i>Oral:</i> Take one tablet by mouth daily</p> <p><i>Topical:</i> Apply to affected area once a day.</p>	<p><u>Orthographic similarities:</u> <i>Both names are similar in length when scripted (10 letters in Jentadueto vs 11 letters in Terbinafine) and share the letters, ‘t’, ‘a’, ‘n’, and ‘e’.</i></p> <p><u>Product Characteristics:</u></p> <p>Dosage Form (Tablet) Route of Administration (Oral) Dose (One tablet)</p>	<p><b><u>Orthographic Differences:</u></b> Jentadeuto contains four upstroke letters, ‘J’, ‘t’, ‘d’, ‘t’ and has a different shape when scripted compared to the three upstroke letters, ‘T’, ‘b’, and ‘f’ in Terbinafine. The ending letter string, ‘ueto’ in Jentadueto looks different from the ending letter string, ‘fine’ in Terbinafine. In addition, Terbinafine contains two dotted letters, ‘i’ which Jentadueto does not have and may help to differentiate this name pair when scripted.</p> <p><b><u>Frequency of Administration:</u></b> Twice a day vs once a day</p> <p><b><u>Strength:</u></b> Multiple (2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg) vs Single (250 mg) for the tablet formulation</p>

<p><b>Proposed name:</b></p> <p><b>Jentadueto</b></p>	<p><b>Strength(s):</b></p> <p>2.5 mg/500 mg 2.5 mg/850 mg 2.5 mg/1000 mg</p>	<p><b>Usual dose:</b></p> <p>One tablet by mouth twice a day</p>
<p><b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b></p>	<p><b>Causes (could be multiple)</b></p>	<p><b>Prevention of Failure Mode</b></p>
<p>Tinidazole 250 mg and 500 mg Tablets <u>Usual dose:</u> <i>Amebiasis:</i> Take 2 grams by mouth once a day for three days <i>Trichomoniasis and Giardiasis:</i> Take 2 grams by mouth as a single dose</p>	<p><u>Orthographic similarities:</u> <i>Both names contain ten letters and appear similar in length when scripted. The beginning letter, 'J' in Jentadueto may look similar to the beginning letter, 'T' in Tinidazole.</i></p> <p><u>Product Characteristics:</u> Dosage Form (Tablet) Route of Administration (Oral) Numerical strength overlap (500 mg)</p>	<p><u>Orthographic Differences:</u> Jentadueto contains four upstroke letters, 'J', 't', 'd', 't' and has a different shape when scripted compared to the three upstroke letters, 'T', 'd', and 'l' in Tinidazole. The ending letter string 'ueto' look different that then corresponding letter string 'azole'. The letter 'z' in Tinidazole can provide a down stroke when scripted. In addition, Tinidazole contains two dotted letters, 'i', which Jentadueto does not have and may help differentiate this name pair when scripted.</p> <p><u>Frequency of Administration:</u> Twice a day vs one time or once a day for 3 days</p>
<p>Duet (Ascorbic Acid, Beta-Carotene, Calcium Carbonate, Cholecalciferol, Cupric Oxide, Cyanocobalamin, Alpha Tocopheryl Acetate, Folic Acid, Iron, Magnesium Oxide, Niacinamide, Pyridoxine, Riboflavin, Thiamine Mononitrate, Zinc Oxide) 120 mg/3,000 IU/ 100 mg/400 IU/2 mg/ 12 mcg/30 IU/1 mg/ 29 mg/25 mg/20 mg/ 25 mg/4 mg/1.8 mg/25 mg Chewable Tablet <u>Usual Dose:</u> Chew one tablet by mouth daily.</p>	<p><u>Orthographic similarities:</u> <i>Both names share the letter string, 'duet'.</i></p> <p><u>Product Characteristics:</u> Dosage Form (Tablet) Route of Administration (Oral) Dose (One tablet)</p>	<p><u>Orthographic Differences:</u> Jentadueto contains ten letters and appears longer when scripted compared to four letters in Duet. In addition, Jentadueto contains four upstroke letters, 'J', 't', 'd', and 't', giving it a different shape when scripted compared to the two upstroke letters, 'D' and 't' in Duet.</p> <p><u>Frequency of Administration:</u> Twice a day vs once a day</p> <p><u>Strength:</u> Multiple (2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg) vs Single</p>

<b>Proposed name:</b> <b>Jentadueto</b>	<b>Strength(s):</b> <b>2.5 mg/500 mg</b> <b>2.5 mg/850 mg</b> <b>2.5 mg/1000 mg</b>	<b>Usual dose:</b> <b>One tablet by mouth twice a day</b>
<b>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</b>	<b>Causes (could be multiple)</b>	<b>Prevention of Failure Mode</b>
<p>Duet DHA (Ascorbic Acid, Beta-Carotene, Calcium Carbonate, Cholecalciferol, Cupric Oxide, Cyanocobalamin, Alpha Tocopheryl Acetate, Folic Acid, Iron, Magnesium Oxide, Niacinamide, Pyridoxine, Riboflavin, Thiamine Mononitrate, Zinc Oxide, Omega-3 fatty acid)</p> <p>120 mg/3,000 IU/  100 mg/400 IU/2 mg/  12 mcg/30 IU/1 mg/  29 mg/25 mg/20 mg/  25 mg/4 mg/1.8 mg/25 mg</p> <p>Tablet</p> <p><u>Usual Dose:</u>  Take one tablet by mouth daily.</p>	<p><u>Orthographic similarities:</u>  <i>Both names share the letter string, 'duet'.</i></p> <p><u>Product Characteristics:</u>  Dosage Form (Tablet)  Route of Administration (Oral)  Dose (One tablet)</p>	<p><b><u>Orthographic Differences:</u></b> Jentadueto contains ten letters and appears longer when scripted compared to the seven letters in Duet DHA. Also, the modifier 'DHA' in Duet DHA provide orthographic distinction when scripted for this name pair.</p> <p><b><u>Frequency of Administration:</u></b> Twice a day vs once a day</p> <p><b><u>Strength:</u></b> Multiple (2.5 mg/500 mg, 2.5 mg/850 mg, 2.5 mg/1000 mg) vs Single</p>

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

/s/  
-----

WALTER L FAVA  
11/09/2011

CARLOS M MENA-GRILLASCA  
11/09/2011

CAROL A HOLQUIST  
11/09/2011

**Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Surveillance and Epidemiology  
Office of Medication Error Prevention and Risk Management**

**Proprietary Name Review**

Date: July 11, 2011

Reviewer(s): Carlos M Mena-Grillasca, RPh, Team Leader  
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh  
Division of Medication Error Prevention and Analysis

Drug Name(s): (b) (4)  
(Linagliptin and Metformin Hydrochloride) Tablets  
2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg

Application Type/Number: NDA 201281

Applicant/sponsor: Boeringer Ingelheim Pharmaceuticals, Inc.

OSE RCM #: 2011-1286

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

21 pages has been withheld in full as B(4) 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/  
-----

CARLOS M MENA-GRILLASCA  
07/11/2011

CAROL A HOLQUIST  
07/11/2011