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APPLICATION NUMBER:

22-175Orig1s000

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

Date: February 7, 2012

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Division of Medication Error Prevention and Analysis

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Drug Name and Strength(s): Pertzye (Pancrelipase) Delayed-release Capsules
8,000 USP units Lipase;
(b) (4) Amylase;
Protease
and
16,000 USP units Lipase;
(b) (4) Amylase;
Protease

Application Type/Number: NDA 022175

Applicant: Digestive Care, Inc.

OSE RCM #: 2011-4357

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

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Pertzye, 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 REGULATORY HISTORY

This product was marketed under the proprietary names Pancrecarb MS-4, Pancrecarb MS-8, and Pancrecarb MS-16 since 1995 as an unapproved product. A Federal Registry (FR) Notice dated April 20, 2004, notified manufacturers of pancreatic insufficiency products that FDA approval, via submission of a New Drug Application (NDA), would be required by April 2008 (deadline was extended to April 2010) for these products to remain in the US marketplace. In accordance to this FR notice, the manufacturer of Pertzye submitted an NDA for this product on October 27, 2008.

The Division of Medication Error Prevention and Analysis (DMEPA) evaluated the name, Pancrecarb, in OSE Review #2008-2000, dated March 19, 2009, and found the name unacceptable (b) (4)

The Applicant submitted a request for reconsideration of the proposed proprietary name, Pancrecarb, on June 29, 2009 and DMEPA re-reviewed the proposed proprietary name, Pancrecarb in OSE Review #2009-1216, dated September 24, 2009. DMEPA acknowledged the Reconsideration Request on September 24, 2009 indicating that we would defer our decision on the proposed proprietary name, Pancrecarb until after the Applicant responded to the Agency's Complete Response letter dated August 27, 2009. On March 25, 2010, the Applicant submitted a Complete Response in addition to a request to review the new proposed proprietary name, Pertzye, as well as an external study conducted by (b) (4) in support of their proposed proprietary name. DMEPA found the name, Pertzye acceptable in OSE Review #2010-440, dated June 3, 2010.

On January 27, 2011, the Agency issued a Complete Response letter for this Application due to a number of identified deficiencies. As part of a Class-II resubmission dated November 18, 2011, the Applicant submitted a new request for the review of the proposed proprietary name, Pertzye. (b) (4)

Therefore, DMEPA's evaluation of the proposed proprietary name, Pertzye, considered the proposed strengths of 8,000 USP Lipase units and 16,000 USP Lipase units, (b) (4)

The Applicant also submitted draft container labels, carton labeling, and Prescribing Information which will be reviewed separately under OSE Review #2011-4358.

1.2 PRODUCT INFORMATION

The following product information is provided in the November 18, 2011 proprietary name submission.

- Active Ingredient: Pancrelipase
- Indication of Use: Treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.
- Route of administration: Oral
- Dosage form: Delayed-release Capsules
- Strength: 8,000 USP units of Lipase and 16,000 USP units of Lipase.
(b) (4)
- Dose and frequency: (b) (4)
Children between 12 months and 4 years of age: begin with 1,000 Lipase units/kg/meal to a maximum of 2,500 Lipase units/kg/meal (or maximum of 10,000 USP units of Lipase/kg/day), or less than 4,000 Lipase units/gram fat ingested/day; *Children 4 years and older and adults:* begin with 500 Lipase units/kg/meal to a maximum of 2,500 Lipase units/kg/meal (or maximum of 10,000 USP units of Lipase/kg/day), or less than 4,000 Lipase units/gram fat ingested per day.
- How Supplied: Supplied in bottles containing (b) (4) 250 capsules
- Storage: Room temperature 20 to 25°C (68 to 77°F). Pertzye hard gelatin capsules should be stored in a dry place in the original container.
- Container and Closure systems: The buffered Pancrelipase enteric-coated microspheres are filled into clear hard gelatin capsules that are packaged into a white high density polyethylene (HDPE) bottle, along with a (b) (4) desiccant packet, and sealed with a white (b) (4) screw cap with (b) (4) aluminum liner and induction safety seal. Each bottle is provided in a (b) (4) carton containing the full Prescribing Information and Medication Guide.

2. RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Gastroenterology and Inborn Errors Products 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

On November 24, 2011, the United States Adopted Name (USAN) stem search 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 comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that is misleading or can contribute to medication error. Additionally, in their submission, the Applicant states that the proposed proprietary name, Pertzye is an empty vessel or a blank canvas name that does not have any inherent meaning.

2.2.3 FDA Name Simulation Studies

Twenty-nine practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Fourteen participants interpreted the name correctly as Pertzye (6 participants from the inpatient prescription studies and 8 participants from the outpatient prescription studies). Three participants in the inpatient prescription studies and two participants from the outpatient prescription studies misinterpreted letter 'z' as letter 'y' and letter 'y' as letter 'z' (i.e. Pertyze). Two participants in the voice prescription studies misinterpreted letter 'z' as letter 's' and omitted letter 'e' at the end of the name, and two participants omitted letter 'y' from the name. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE December 9, 2011 e-mail, the Division of Gastroenterology and Inborn Errors Products (DGIEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Pertzye. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Pertzye identified by the primary reviewer (PR) and the Expert Panel Discussion (EPD). Table 1 also includes the names identified in OSE Review #2010-440, dated June 3, 2010, as well as the names identified by (b) (4) that were not identified by DMEPA, and require further evaluation.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, and (b) (4))

Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Enzyte	(b) (4)	Cerezyme	EPD	Partaject	EPD
Fentora	EPD	Percodan	EPD	Penlac	EPD
Pangestyme	(b) (4)	Percorten	EPD	Pentasa	EPD
Patanol	(b) (4)	Permitil	EPD	Pentrax	EPD
Pentacel	EPD	Porfimer	EPD	Pentazine	EPD
Pentazocine	(b) (4)	Peg-Lyte	EPD	Perative	EPD
Pepcid	(b) (4)	Prelay	EPD	Peridex	EPD
Percocet	(b) (4)	(b) (4)	EPD	Perloxx	EPD
Pergolide	(b) (4)	(b) (4)	EPD	Peroxyl	EPD
PerioRx	EPD	Pertzyme	EPD	Portagen	EPD
Permax	(b) (4)	Bentyl	EPD	Potiga	EPD
Prezista	EPD	DentaGel	EPD	Pradaxa	PR
Prinzide	(b) (4)	Duradryl	EPD	Pristiq	EPD
Protonix	(b) (4)	Fabrazyme	EPD	Protegra	EPD
Revaspa	EPD	Fentanyl	EPD	Pulmozyme	EPD
Revlimid	EPD	Fortaz	EPD	(b) (4)	EPD

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Table 1: Continued

		Look Similar			
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Reyataz	(b) (4)	Panoxyl	EPD	Razadyne	EPD
Rezira	EPD	Pardryl	EPD	Rotarix	EPD
Reziris	EPD	Balziva	PR	Relenza	PR
Sound Similar					
(b) (4)	EPD				
Look and Sound Similar					
Pertzye	EPD	Pancreaze	EPD	Pertuzumab	EPD

Our analysis of the 62 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 62 names will not pose a risk for confusion as described in Appendix D through E.

2.2.7 Communication of DMEPA’s Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Gastroenterology and Inborn Errors Products via e-mail on January 9, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Gastroenterology and Inborn Errors Products on January 17, 2012, they stated no additional concerns with the proposed proprietary name, Pertzye.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Nitin Patel, OSE project manager, at 301-796-5412

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Pertzye, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your November 18, 2011 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review. Additionally, this proprietary name must be re-evaluated 90 days prior to the approval of the application. The conclusions upon re-review are subject to change.

4 REFERENCES

OSE Review #2010-440, Proprietary Name Review of Pertzye (Pancrelipase) Delayed-release Capsules; Chan, Irene Z., June 3, 2010.

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. This database also lists the orphan drugs.

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

USPTO provides information regarding patent and trademarks.

8. ***Clinical Pharmacology Online*** (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.

9. ***Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at*** (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.

10. ***Natural Medicines Comprehensive Databases*** (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.

11. ***Access Medicine*** (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.

12. ***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.

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

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

14. ***Lexi-Comp*** (www.lexi.com)

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

15. ***Medical Abbreviations Book***

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

16. ***CVS/Pharmacy*** (www.CVS.com)

This database contains commonly used over the counter products not usually identified in other databases.

17. Walgreens (www.walgreens.com)

This database contains commonly used over the counter products not usually identified in other databases.

18. Rx List (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. Dogpile (www.dogpile.com)

Dogpile is a [Metasearch](#) engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

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.¹

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.

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

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.

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.²

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).

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

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

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

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 Division of Drug Marketing, Advertising, and Communications (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.³ 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

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

characteristics listed in Section 1.2 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 possess 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:

“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

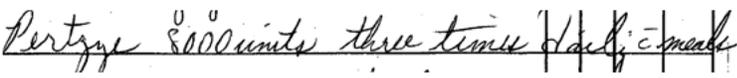
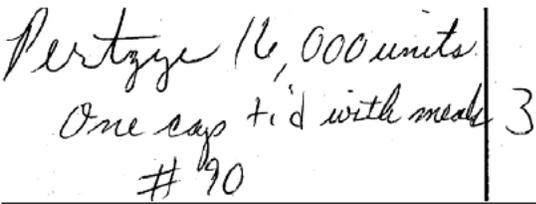
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval 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, NAME	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'P'	B, D, F, R, X	b
Lower case 'p'	x, yn ys	b
Lower case 'e'	a, c, i, l, o, r, u	Any vowel
Lower case 'r'	e, n, s, v, a	
Lower case 't'	b, d, f, l, x	D
Lower case 'z'	r, s, y, x, c, j	S
Lower case 'y'	u, g, z, x, j	e, i

Appendix C: Prescription Simulation Samples and Results

Figure 1. Pertzze Study (Conducted on 12/14/2011)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u> </p> <p><u>Outpatient Prescription:</u> </p>	<p>Pertzze 16,000 units</p> <p>One capsule by mouth 3 times daily with meals.</p> <p># 90</p>

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

85 People Received Study

29 People Responded

Study Name: Pertzye

Total	10	8	11	
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
PERTCE	0	1	0	1
PERTGYZE	1	0	0	1
PERTSE	0	1	0	1
PERTSY	0	2	0	2
PERTYZE	3	0	2	5
PERTZE	0	2	0	2
PERTZIE	0	1	0	1
PERTZY	0	1	0	1
PERTZYE	6	0	8	14
PERTZZI	0	0	1	1

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

Proprietary Name	Active Ingredient	Similarity to Pertzye	Failure preventions
Enzyte	An herbal male enhancement product	Look and sound	Name lacks convincing orthographic and/or phonetic similarities to Pertzye.
Fentora	Fentanyl Citrate Buccal Tablets	Look	Name lacks convincing orthographic and/or phonetic similarities to Pertzye
Pangestyme	Lipase, Amylase, and Protease	Look and sound	Name lacks convincing orthographic and/or phonetic similarities to Pertzye
Patanol	Olopatadine Hydrochloride	Look and sound	Name lacks convincing orthographic and/or phonetic similarities to Pertzye
Pentacel	Diphtheria Toxoid Adsorbed, Pertussis Vaccine, Acellular, Poliovirus Vaccine, Inactivated, Tetanus Toxoid Suspension for injection, Haemophilus B Conjugate Vaccine	Look	Name lacks convincing orthographic and/or phonetic similarities to Pertzye
Pentazocine	Naloxone Hydrochloride, Pentazocine Hydrochloride	Look and sound	Name lacks convincing orthographic and/or phonetic similarities to Pertzye
Pepcid	Famotidine	Look and sound	Name lacks convincing orthographic and/or phonetic similarities to Pertzye
Percocet	Oxycodone Hydrochloride and Acetaminophen	Look and sound	Name lacks convincing orthographic and/or phonetic similarities to Pertzye
Pergolide	Established name for Permax	Look and sound	Name lacks convincing orthographic and/or phonetic similarities to Pertzye
PerioRx	Chlorhexidine Gluconate Dental Solution	Look	Name lacks convincing orthographic and/or phonetic similarities to Pertzye
Permax	Pergolide Mesylate	Look and sound	Name lacks convincing orthographic and/or phonetic similarities to Pertzye
Pertuzumab	Established name for Vemurafenib	Look	Name lacks convincing orthographic and/or phonetic similarities to Pertzye

Proprietary Name	Active Ingredient	Similarity to Name of drug	Failure preventions
Prezista	Darunavir	Look	Name lacks convincing orthographic and/or phonetic similarities to Pertzze
Prinzide	Lisinopril Hydrochloride	Look and sound	Name lacks convincing orthographic and/or phonetic similarities to Pertzze
Protonix	Pantoprazole Sodium	Look and sound	Name lacks convincing orthographic and/or phonetic similarities to Pertzze
Revaspa	Not identified as a drug product	Look	Name lacks convincing orthographic and/or phonetic similarities to Pertzze
Revlimid	Lenalidomide	Look	Name lacks convincing orthographic and/or phonetic similarities to Pertzze
Reyataz	Atazanavir Sulfate Oral Capsules	Look and sound	Name lacks convincing orthographic and/or phonetic similarities to Pertzze
Rezira	Hydrocodone Bitartrate, Pseudoephedrine Hydrochloride	Look	Name lacks convincing orthographic and/or phonetic similarities to Pertzze
Reziris	Not available-A registered trademark that was abandoned on January 12, 2009	Look	Name lacks convincing orthographic and/or phonetic similarities to Pertzze
Pancreaze	Lipase, Amylase, Protease	Look and sound	Name lacks convincing orthographic and/or phonetic similarities to Pertzze
Cerezyme	Imiglucerase	Look	Name lacks convincing orthographic and/or phonetic similarities to Pertzze
Percodan	Oxycodone Hydrochloride and Aspirin	Look	Name lacks convincing orthographic and/or phonetic similarities to Pertzze
Percorten	Desoxycorticosterone Acetate	Look	Name lacks convincing orthographic and/or phonetic similarities to Pertzze
Pertzze	Pancrelipase	Look and sound	The proposed proprietary name under evaluation in this review.
Permitil	Fluphenazine	Look	Name lacks convincing orthographic and/or phonetic similarities to Pertzze
Porfimer	Active Ingredient of Photofrin	Look	Name lacks convincing orthographic and/or phonetic similarities to Pertzze

Proprietary Name	Active Ingredient	Similarity to Name of drug	Failure preventions
Peg-Lyte	Polyethylene glycol 3350; Potassium chloride; Sodium bicarbonate; Sodium chloride; Sodium sulfate anhydrous) Powder for suspension	Look	Application withdrawn FR effective 2/17/98.
Prelay	Troglitazone	Look	Application withdrawn FR effective 2/17/98
(b) (4)			
Pertzyme	N/A	Not identified	Not a drug product or found in any of the databases available. The Safety Evaluator indicated the source as "self".

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

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.

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>1</p> <p>Bentyl (Dicyclomine) Capsule, 10 mg Tablet, 20 mg Syrup, 20 mg/5 mL Solution for Injection, 10 mg/mL</p> <p>Usual Dose: Initially, 20 mg PO four times per day. Increase up to 40 mg PO four times per day. 20 mg IM every 4-6 hours for 1-2 days. Maximum 80 mg/day IM. Replace with oral therapy as soon as feasible</p>	<p>Orthographic: The letter string ‘Pertz-’ and the letter ‘e’ (in the seventh position) in Pertzye may appear similar to the letter string ‘Benty-’ and the letter ‘l’ in Bentyl, respectively, when scripted.</p> <p>Route of Administration: Oral</p> <p>Overlap in the Dosage Form: Capsule</p> <p>Overlap in the Frequency of Administration: 4 times daily (per meal/snack in Pertzye)</p> <p>Partial Numerical Overlap in the Usual Dose: One capsule</p>	<p>Strength: 8,000 or 16,000 USP Lipase units vs. 10 mg, 20 mg, 20 mg/5 mL, or 10 mg/mL</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>2</p>	<p>DentaGel (Sodium Fluoride) Dental Gel, 1.1%</p> <p>Usual Dose: 10 ml rinsed around the teeth for 1 minute, then expectorated, use once a week after brushing and flossing.</p>	<p>Orthographic: Letter strings ‘Pert-’ and ‘-ye’ in Pertzye may appear similar to letter strings ‘Dent-’ and ‘-ge-’ in Dentagel, respectively, when scripted.</p> <p>Route of Administration: Oral</p>	<p>Frequency of Administration: Per meal vs. once a week.</p> <p>Strength: 8,000 and 16,000 USP Lipase units vs. 1.1%</p> <p>Usual Dose: (b) (4) vs. 10 MI</p>
<p>3</p>	<p>Duradryl (Chlorpheniramine Mal, Methscopolamine Nitrate, PE HCl) Extended-release Chewable Tablet 2 mg/1.25 mg/10 mg</p> <p>Usual Dose: 1 to 2 tablets PO every 12 hours. Do not exceed 4 tablets per day.</p>	<p>Orthographic: Letter strings ‘Per-’ and ‘-zye’ and letter ‘t’ in Pertzye may appear similar to letter strings ‘Dur-’ and ‘-ryl’ and letter ‘d’ in Duradryl, respectively, when scripted.</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Solid oral</p> <p>Partial Numerical Overlap in the Usual Dose: One</p>	<p>Strength: 8,000 and 16,000 USP Lipase units vs. 2 mg/1.25 mg/10 mg</p> <p>Frequency of Administration: Per meal vs. every 12 hours</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>4</p>	<p>Fabrazyme (Agalsidase beta) Solution for Injection 5 mg, 35 mg</p> <p>Usual Dose: 1 mg/kg intravenously every two weeks.</p>	<p>Orthographic: Both names share the letter string '-zy-' and end with letter 'e'. Additionally, letter string 'Pe-' and letter 't' in Pertzye may appear similar to letter string 'Fa-' and letter 'b' in Fabrazyme, respectively, when scripted.</p> <p>Possible Overlap in the Usual Dose: The final calculated dose of Fabrazyme (since weight-based) may be 80 mg which can be misinterpreted as 8,000 USP units in Pertzye (if 80 is scripted with trailing zeros)</p>	<p>Orthographic: Letters 'r', 'a', and 'm' in Fabrazyme provide a longer length for Fabrazyme and can help differentiate Pertzye and Fabrazyme when scripted.</p> <p>Strength: 8,000 and 16,000 USP Lipase units vs. 5 mg and 35 mg</p> <p>Frequency of Administration: Per meal vs. every 2 weeks</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>5 Fentanyl Established names for Duragesic, Actiq, and Sublimaze) Transdermal Patch 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr Lozenges 200 mcg, 400 mcg, 1200 mcg, 1600 mcg Solution for Injection 50 mcg/ml</p> <p>Usual Dose: Patch: Apply 12 mcg to 100 mcg every 72 hours. Lozenges: The initial dose for breakthrough pain is 100 mcg (Fentora only) placed above a rear molar between the upper cheek and gum. Injection: loading dose of 1 to 2 mcg/kg intravenous is usually given, followed by a continuous intravenous infusion of 1 to 2 mcg/kg/hour</p>	<p>Orthographic: Letter strings ‘pert-‘ and ‘-ye’ and letter ‘z’ in Pertzye may appear similar to letter strings ‘Fent’- and ‘-yl’ and letter ‘n’ (in the sixth position) in Fentanyl, respectively, when scripted.</p> <p>Overlap in the Route of Administration: Oral</p> <p>Overlap in the Dosage Form: Solid oral</p> <p>Possible Partial Overlap in the Strength: 1600 mcg in Fentanyl may be misinterpreted as 16,000 USP units in Pertzye.</p> <p>Possible Partial Overlap in the Usual Dose: One (lozenge vs. capsule) or 1600 mcg (can be misinterpreted as 16,000 USP units in Pertzye.</p>	<p>Orthographic: The letter string ‘-zye’ in Pertzye appears different than the letter string ‘-anyl’ when scripted and can help differentiate Pertzye and Fentanyl. Additionally, letter ‘a’ in Fentanyl provides a longer length for this name and can help differentiate Pertzye and Fentanyl when scripted.</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>6 Fortaz (Ceftazimide Pentahydrate) Powder for Injection 500 mg, 1g, 2 g</p> <p>Usual Dose: Adults: 1 to 2 gram intravenously or intramuscularly every eight hours. Infants: 30 to 50 mg/kg intravenously every eight hours. Maximum of 6 g/day.</p>	<p>Orthographic: Letter string ‘Pert-‘ in pertye may appear similar to letter string ‘Fort-‘ in Fortaz when scripted. Additionally, both names share the letter ‘z’ in a similar position (fifth position in Pertye vs. the sixth position in Fortaz).</p> <p>Possible Overlap in the Frequency of Administration: Per meal vs. every 8 hours</p> <p>Possible Numerical Overlap in the Usual Dose: 2 g (or 2000 mg) in Fortaz vs. 2000 USP units in Pertye, or the final calculated dose in Fortaz (i.e. in an 16 kg infant is 800 mg) may be misinterpreted as 8,000 USP units in Pertye.</p>	<p>Orthographic: Letter ‘y’ in Pertye provides a different shape and length for this name and can help differentiate Pertye and Fortaz when scripted.</p> <p>Strength: 8,000 and 16,000 USP Lipase units vs. 500 mg, 1 g, and 2 g</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>7</p>	<p>Panoxyl (Benzoyl Peroxide) Topical Gel, 5%, 10%</p> <p>Usual Dose: Apply topically to the affected areas once daily. May gradually increase to four applications per day as needed.</p>	<p>Orthographic: Both names consist of seven letters. Additionally, letter strings 'Per-' and '-zye' in Pertzye may appear similar to letter strings 'Pan-' and '-xyl' in Panoxyl when scripted.</p>	<p>Orthographic: Letter 't' in Pertzye provides a different shape for this name and can help differentiate Pertzye and Panoxyl when scripted.</p> <p>Strength: 8,000 and 16,000 USP Lipase units vs. 5% and 10%</p> <p>Frequency of Administration: Per meal vs. once daily</p> <p>Usual Dose: (b) (4) vs. one application.</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>8</p>	<p>Pardryl (Diphenhydramine) Tablets or Capsules 25 mg (a monograph product)</p> <p>Usual Dose: As a sleeping aid, one tablet 30 minutes before bedtime. Or, one to two capsules by mouth every 4 to 6 hours. Maximum daily dose is 300 mg/day.</p>	<p>Orthographic: Both names consist of seven letters. Additionally, letter strings ‘Pert-‘ and ‘-zye’ in Pertzye may appear similar to letter strings ‘Pard-‘ and ‘-ryl’ in Pardryl, respectively, when scripted.</p> <p>Overlap in the Frequency of Administration: Every 4 to 6 hours (vs. per meal)</p> <p>Partial Numerical Overlap in the Usual Dose: One</p>	<p>Strength: 8,000 and 16,000 USP Lipase units vs. 25 mg</p>
<p>9</p>	<p>Partaject (Busulfan) (An orphan drug for treatment of neoplastic meningitis, it also received orphan drug designation for treatment of pediatric BMT)</p> <p>Usual Dose: In clinical studies, intrathecal doses of 2.5 mg up to 21.25 mg were tested.</p>	<p>Orthographic: Letter strings ‘Pert-‘ and ‘-ye-‘ in Pertzye may appear similar to letter strings ‘Part-‘ and ‘-je-‘ in Partaject, respectively, when scripted.</p>	<p>Orthographic: Letter string ‘-ct’ in Partaject provides a different shape and length for this name and can help differentiate Pertzye and Partaject when scripted.</p> <p>Strength: 8,000 and 16,000 USP Lipase units vs. 2.5 mg to 21.25 mg</p> <p>Usual Dose: (b) (4) vs. 2.5 mg up to 21.25 mg in phase I studies.</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>10</p>	<p>Penlac (Ciclopirox) Solution, 8%</p> <p>Usual Dose: Apply to the affected nail(s) once daily</p>	<p>Orthographic: Letter string 'Pert-' and letter 'z' in Pertzye may appear similar to letter string 'Penl-' and letter 'c' in Penlac, respectively, when scripted.</p>	<p>Orthographic: Letter string '-ye' in Pertzye provides a different shape and length for this name and can help differentiate Pertzye and Penlac when scripted.</p> <p>Strength: 8,000 and 16,000 USP Lipase units vs. 8%</p> <p>Frequency of Administration: Per meal vs. once daily</p> <p>Usual Dose: (b) (4) vs. one application.</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>11</p>	<p>Pentasa (Mesalamine) Capsules 250 mg, 500 mg</p> <p>Usual Dose: 1 gram by mouth 4 times daily.</p>	<p>Orthographic: Both names consist of seven letters. Additionally, letter string 'Pert-' and letter 'e' (in the seventh position) in Pertzye may appear similar to letter string 'Pent-' and letter 'a' (in the seventh position) in Pentasa, respectively, when scripted.</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Capsules</p> <p>Overlap in the Frequency of Administration: 4 times daily vs. per meal</p> <p>Partial Numerical Overlap in the Usual Dose: One</p>	<p>Orthographic: Letter 'y' in pertzye provides a different shape for this name and can help differentiate Pertzye and Pentasa when scripted.</p> <p>Strength: 8,000 and 16,000 USP Lipase units vs. 250 mg and 500 mg</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>12</p>	<p>Pentrax (Coal tar) Shampoo 5%</p> <p>Usual Dose: Add 60 to 90 mL to bath water up to once daily.</p>	<p>Orthographic: Both names consist of seven letters. Additionally, letter string ‘Pert-‘ and letters ‘z’ and ‘y’ in Pertzye may appear similar to letter string ‘Pent-‘ and letters ‘r’ and ‘x’ in Pentrax, respectively, when scripted.</p>	<p>Strength: 8,000 and 16,000 USP Lipase units vs. 5%</p> <p>Frequency of Administration: Per meal vs. once daily</p> <p>Usual Dose: (b) (4) vs. 60 to 90 mL</p>
<p>13</p>	<p>Pentazine (Promethazine Hydrochloride) Syrup, 6.25 mg/5 mL Solution for Injection, 50 mg/mL</p> <p>Usual Dose: 12.5 to 25 mg orally, intravenously, or intramuscularly every 4 to 6 hours as needed.</p>	<p>Orthographic: Letter string ‘Pert-‘ in Pertzye may appear similar to letter string ‘Pent-‘ in Pentazine when scripted. Additionally both names share letter ‘z’ in a similar position (fifth position in Pertzye vs. sixth position in Pentazine) and both names end with letter ‘e’.</p> <p>Overlap in the Route of Administration: Oral</p> <p>Overlap in the Frequency of Administration: Every 4 to 6 hours vs. per meal</p> <p>Partial Numerical Overlap in the Usual Dose: One (teaspoon vs. capsule)</p>	<p>Orthographic: Letter ‘y’ in pertzye and and letters ‘i’ and ‘n’ in Pentazine provide a different shape and length for each of these names and can help differentiate Pertzye and Pentazine when scripted.</p> <p>Strength: 8,000 and 16,000 USP Lipase units vs. 6.25 mg/5 mL and 50 mg/mL</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>14</p>	<p>Perative (Nutritional supplement containing protein, fiber, enzymes, vitamins and minerals, for the management of metabolically stressed patients with injuries such as multiple fractures, pressure ulcers, wounds, or burns.) 1.3 Cal/mL</p> <p>Usual Dose: For daily use as needed.</p>	<p>Orthographic: Both names begin with the letter string 'Per-', end with letter 'e' and share letter 't' in a similar position (fourth position in Pertzye vs. fifth position in Perative). Additionally, letter 'y' in Pertzye may appear similar to letter 'v' in Perative when scripted.</p> <p>Route of Administration: Oral</p> <p>Possible Overlap in the Frequency of Administration: Since Perative is a nutritional supplement and the usual dose may vary based on individual's needs, it is possible that a patient may be instructed to use the product 'per meal'.</p>	<p>Strength: 8,000 and 16,000 USP Lipase units vs. single strength</p> <p>Usual Dose: (b) (4) vs. varies based on individual's needs.</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And (b) (4) 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>15</p>	<p>Peridex (Chlorhexidine Gluconate) Oral Rinse, 0.12%</p> <p>Usual Dose: Rinse mouth with 15 ml of chlorhexidine oral rinse for 30 seconds twice daily following toothbrushing.</p>	<p>Orthographic: Both names consist of seven letters and begin with the letter string 'Per-'. Additionally, letters 't' and 'y' in Pertzye may appear similar to letters 'd' and 'x' in Peridex, respectively, when scripted.</p> <p>Route of Administration: Oral</p>	<p>Orthographic: Letter 'e' at the end of the name, Pertzye (vs. no additional letters after the letter 'x' in Peridex) provides a different shape for this name and can help differentiate Pertzye and Peridex when scripted.</p> <p>Strength: 8,000 and 16,000 USP Lipase units vs. 0.12%</p> <p>Frequency of Administration: Per meal vs. twice daily</p> <p>Usual Dose: (b) (4) vs. rinse with 15 mL</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>16</p>	<p>Perloxx (Oxycodone Hydrochloride and Acetaminophen) Tablets 2.5 mg/300 mg, 5 mg/300 mg, 7.5 mg/300 mg, 10 mg/300 mg</p> <p>Usual Dose: 1 to 2 tablets by mouth every 6 hours as needed.</p>	<p>Orthographic: Both names consist of seven letters and begin with the letter string 'Per-'. Additionally, letters 't', 'z', and 'y' in Pertzye may appear similar to letters 'l' and 'x' (in both the sixth and seventh positions) in Perloxx, respectively, when scripted.</p> <p>Route of Administration: Oral</p> <p>Dosage Form Solid oral</p> <p>Possible Overlap in the Frequency of Administration: Every 6 hours vs. per meal</p> <p>Partial Numerical Overlap in the Usual Dose: One</p>	<p>Orthographic: Letter 'e' at the end of the name, Pertzye (vs. no additional letters after the letter 'x' in Perloxx) provides a different shape for this name and can help differentiate Pertzye and Perloxx when scripted.</p> <p>Strength: 8,000 and 16,000 Lipase units vs. 2.5 mg, 5 mg, 7.5 mg, and 10 mg per 300 mg</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>17</p>	<p>Peroxyl (Antibacterial oral cleanser) Oral Rinse</p> <p>Usual Dose: Gargle with 1 to 2 capfuls three to four times daily.</p>	<p>Orthographic: Both names consist of seven letters and begin with the letter string 'Per-'. Additionally, the letter string '-zye' in Pertzye may appear similar to the letter string '-xyl' in Peroxyl when scripted.</p> <p>Route of Administration: Oral</p> <p>Possible Overlap in the Frequency of Administration: 3 to 4 times daily vs. per meal</p>	<p>Orthographic: Letter 't' in Pertzye provides a different shape for this name and can help differentiate Pertzye and Peroxyl when scripted.</p> <p>Strength: 8,000 and 16,000 USP Lipase units vs. single strength</p> <p>Usual Dose: (b) (4) vs. 1 to 2 capfuls</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>18</p>	<p>Portagen (Nutritional supplement) Powder (Monograph product)</p> <p>Usual Dose: Based on individual caloric needs under medical supervision.</p>	<p>Orthographic: Letter strings ‘Pert-’ and ‘-ye’ in Pertzye may appear similar to letter strings ‘Port-’ and ‘-ge’- in Portagen, respectively, when scripted.</p> <p>Route of Administration: Oral</p> <p>Possible Overlap in the Frequency of Administration: Since Portagen is a nutritional supplement, it may be dosed similar to Pertzye (i.e. per meal)</p>	<p>Strength: 8,000 and 16,000 USP Lipase units vs. single strength</p> <p>Usual Dose: (b) (4) vs. based on individual requirements</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>19 Potiga (Retigabine) Tablets 50 mg, 200 mg, 300 mg, 400 mg</p> <p>Usual Dose: 200 to 400 mg by mouth three times daily in adult patients (not for pediatric use).</p>	<p>Orthographic: Letter strings 'Pe-' and '-ye' in Pertzye may appear similar to letter strings 'Po-' and '-ga' in Potiga, respectively, when scripted. Additionally, both names share the letter 't' in a similar position (fourth position in Pertzye vs. the third position in Potiga).</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Solid oral</p> <p>Possible Overlap in the Frequency of Administration: 3 times daily vs. per meal</p> <p>Partial Numerical Overlap in the Usual Dose: One</p>	<p>Orthographic: The name Pertzye appears longer than Potiga when scripted because Pertzye contains one extra letter and the wide letter 'z' which helps elongate the name. Potiga contains one less letter and the skinny letter 'i' which shortens the name when scripted.</p> <p>Frequency: (b) (4) vs. 3 times daily.</p> <p>(b) (4)</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>20</p>	<p>Pradaxa (Dabigatran Etexilate) Capsules, 75 mg, 150 mg</p> <p>Usual Dose: 75 mg or 150 mg by mouth twice daily.</p>	<p>Orthographic: Both names consist of seven letters, begin with letter 'p', and share the letter 'r' in a similar position (third position in Pertzye vs. the second position in Pradaxa). Additionally, letter 't' and letter string '-ye' in Pertzye may appear similar to letter 'd' and letter string '-xa' in Pradaxa, respectively, when scripted.</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Capsule</p> <p>Partial Numerical Overlap in the Usual Dose: One</p>	<p>Strength 8,000 and 16,000 USP Lipase units vs 75 mg and 150 mg</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>21</p>	<p>Pristiq (Desvenlafaxine Succinate) Tablets, 50 mg, 100 mg</p> <p>Usual Dose: 50 to 100 mg by mouth once daily.</p>	<p>Orthographic: Both names consist of seven letters, begin with letter 'P', and share letter 't' and letter 'r' in similar positions. Additionally, letter 'y' in Pertzye may appear similar to letter 'q' in pristiq when scripted.</p> <p>Route of Administration: Oral</p> <p>Dosage Form Solid oral</p> <p>Partial Numerical Overlap in the Usual Dose: One</p>	<p>Orthographic: Letter 'e' at the end of the name Pertzye provides a different shape for this name and can help differentiate Pertzye and Pristiq when scripted.</p> <p>Frequency of Administration: Per meal vs. once daily</p> <p>Strength: 8,000 and 16,000 USP Lipase units vs. 50 mg and 100 mg</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>22</p>	<p>Protegra (An antioxidant nutritional supplement) Capsules</p> <p>Usual Dose: 1 to 2 capsules by mouth once daily or as directed by a healthcare practitioner.</p>	<p>Orthographic: Letter strings ‘Pert-‘ and ‘-ye’ in Pertzye may appear similar to letter strings ‘Prot-‘ and ‘-gr’ in Protegra, respectively, when scripted.</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Capsule</p> <p>Partial Numerical Overlap in the Usual Dose: One</p>	<p>Strength: 8,000 and 16,000 USP Lipase units vs. single strength.</p> <p>Frequency of Administration: Per meal vs. once daily.</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>23</p>	<p>Pulmozyme (Dornase Alpha) Solution for Inhalation 1 mg/mL</p> <p>Usual Dose: 2.5 mg via oral inhalation once daily using a recommended nebulizer.</p>	<p>Orthographic: Letter string 'Pe-' and letter 't' in Pertzye may appear similar to letter string 'Pu-' and letter 'l' in Pulmozyme, respectively, when scripted. Additionally, both names share the letter string '-zy-' in a similar position and end with letter 'e'.</p> <p>Route of Administration: Oral</p>	<p>Orthographic: Letter 'm' (in both the fourth and the eighth position) in Pulmozyme provides a different length for this name and can help differentiate Pertzye and Pulmozyme when scripted.</p> <p>Strength: 8,000 and 16,000 USP Lipase units vs. 1 mg/mL</p> <p>Frequency of Administration: Per meal vs. once daily.</p> <p>Usual Dose: (b) (4) vs. 2.5 mg.</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>24</p>	<p>(b) (4)</p>	

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<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>25</p>	<p>Razadyne (Galantamine Hydrobromide) Tablets, 4 mg, 8 mg, 12 mg Extended-release Capsules, 8 mg, 16 mg, 24 mg Oral Solution, 4 mg/mL</p> <p>Usual Dose: Immediate-release: 4 to 12 mg by mouth twice daily. Extended-release: 8 to 24 mg by mouth once daily.</p>	<p>Orthographic: Letter strings ‘Per-’ and ‘-zye’ and letter ‘t’ in Pertzye may appear similar to letter strings ‘Raz-’ and ‘-yne’ and letter ‘d’ in Razadyne, respectively, when scripted.</p> <p>Route of Administration: Oral</p> <p>Overlap in the Dosage Form: Capsules</p> <p>Partial Numerical Overlap in the Usual Dose: One</p>	<p>Orthographic: The two letter ‘a’s and the letter ‘n’ in Razadyne provide a longer length for this name and can help differentiate Pertzye and Razadyne when scripted.</p> <p>Frequency of Administration: Per meal vs. twice daily or once daily.</p>
<p>26</p>	<p>Rotarix (Rotavirus) Vaccine Live Oral Suspension</p> <p>Usual Dose: Two 1-mL doses administered orally at least four weeks apart beginning at 6 weeks of age and should be completed by 24 weeks of age.</p>	<p>Orthographic: Both names consist of seven letters and share the letter ‘t’ in a similar position (fourth position in Pertzye vs. the third position in Rotarix). Additionally, letter string ‘Pe-’ and letters ‘z’ and ‘y’ in Pertzye may appear similar to letter string ‘Ro-’ and letters ‘r’ and ‘x’ in Rotarix, respectively, when scripted.</p>	<p>Strength: 8,000 and 16,000 USP Lipase units vs. single strength.</p> <p>Frequency of Administration: Per meal vs. two doses administered 4 weeks apart.</p> <p>Usual Dose: (b) (4) vs. 1 mL.</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000/ (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>27 Relenza (Zanamivir) Powder for Inhalation 5 mg</p> <p>Usual Dose: Adults, Adolescents, and Children older than or equal to 7 years: 2 oral inhalations (one-5 mg blister per inhalation for a total dose of 10 mg) twice per day (roughly 12 hours apart, AM and PM) for 5 days. Take 2 doses on the first day whenever possible, as long as there is at least 2 hours between doses.</p>	<p>Orthographic: Both names consist of seven letters. Additionally, letter strings 'Pe-' and '-zye' and letter 't' in Pertzye may appear similar to letter strings 'Re-' and '-nza' and letter 'l' in Relenza, respectively, when scripted.</p> <p>Route of Administration: Oral</p>	<p>Strength: 8,000 and 16,000 USP Lipase units vs. 5 mg (or no strength specified).</p> <p>Frequency of Administration: Per meal vs. twice daily</p> <p>Usual Dose: (b) (4) vs. 2 inhalations</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>	
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>	
<p>28</p>	<p>Balziva (Ethinyl Estradiol and Norethindrone) Tablets 0.035 mg/0.4 mg</p> <p>Usual Dose: One tablet by mouth once daily.</p>	<p>Orthographic: Both names consist of seven letters and share the letter ‘z’ in a similar position (fourth position in Balziva and fifth position in Pertzye). Additionally, the letter strings ‘Pe-’ and ‘-ye’ and letter ‘t’ in pertzye may appear similar to letter strings ‘Ba-’ and ‘-va’ and letter ‘l’ in Balziva, respectively, when scripted.</p> <p>Route of Administration: Oral</p> <p>Dosage form: Solid oral</p> <p>Partial Numerical Overlap in the Usual Dose: One</p>	<p>Strength: 8,000 and 16,000 USP Lipase units vs. 0.035 mg/0.4 mg (or no strength specified).</p> <p>Frequency of Administration: Per meal vs. once daily</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>29 Benlysta (Belimumab) Powder for Injection 120 mg, 400 mg</p> <p>Usual Dose: 10 mg/kg intravenously over 1 hour every 2 weeks for the first 3 doses then every 4 weeks thereafter.</p>	<p>Orthographic: Letter string ‘Pert-‘ and letter ‘e’ (in the seventh position) in Pertzye may appear similar to letter string ‘Benl-‘ and letter ‘a’ in Benlysta, respectively, when scripted. Additionally, both names share letter ‘y’ in a similar position (sixth position in Pertzye vs. the fifth position in Benlysta).</p> <p>Possible Numerical Overlap in the Usual Dose: The final calculated dose of Benlysta may 800 mg which can be misinterpreted with 8,000 USP units in Pertzye (if scripted with a trailing zero).</p>	<p>Orthographic: Letter ‘t’ in Benlysta provides a different shape for this name and can help differentiate Pertzye and Benlysta when scripted.</p> <p>Strength: 8,000 and 16,000 USP Lipase units vs. 120 mg and 400 mg</p> <p>Frequency of Administration: Per meal vs. every 2 weeks</p>

<p>Proposed name: Pertzye (Pancrelipase) Delayed-release Capsules</p>	<p>Strength(s): Lipase/Amylase/Protease USP units 8,000 (b) (4) And 16,000 (b) (4)</p>	<p>Usual dose: (b) (4) Children older than 12 months and younger than 4 years: 1,000 Lipase units/kg/meal; Children 4 years and older and adults: 500 Lipase units/kg/meal to a maximum of 2,500 units/kg/meal.</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>30</p>	<p>(b) (4)</p>	

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/s/

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**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: June 3, 2010

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Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Pertzye (Pancrelipase) Delayed-Release Capsules
[REDACTED] (b) (4)
Lipase 8,000 USP Units [REDACTED] (b) (4)
[REDACTED] (b) (4)
Lipase 16,000 USP Units [REDACTED] (b) (4)
[REDACTED]

Application Type/Number: NDA 022175

Applicant/Applicant: Digestive Care, Incorporated

OSE RCM #: 2010-440

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EXECUTIVE SUMMARY

This review summarizes the proprietary name risk assessment for Pertzye (Pancrelipase) (b) (4). Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name Pertzye acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

Additionally, 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.

1 BACKGROUND

1.1 INTRODUCTION

This review responds to a request from Digestive Care, Incorporated dated March 25, 2010, for an assessment of the proposed proprietary name, Pertzye, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. The Applicant submitted an external study conducted by (b) (4) in support of their proposed proprietary name. The Applicant also submitted draft container labels, carton and insert labeling. The labels and labeling will be reviewed separately under OSE Review #2010-367.

1.2 REGULATORY HISTORY

This product has been marketed under the proprietary names Pancrecarb MS-4, Pancrecarb MS-8, and Pancrecarb MS-16 since 1995 as an unapproved product. A Federal Register (FR) Notice dated April 20, 2004, notified manufacturers of pancreatic insufficiency products that FDA approval, via the submission of a new drug application (NDA), would be required by April 2008 (deadline was extended to April 2010) for these products to remain in the US marketplace. In accordance to this FR notice, the manufacturer of Pertzye submitted an NDA for this product on October 27, 2008.

The Division of Medication Error Prevention and Analysis (DMEPA) previously evaluated the name, Pancrecarb, in OSE Review 2008-2000, dated March 19, 2009, and found the name unacceptable (b) (4)

The Applicant submitted a request for reconsideration of the proposed proprietary name, Pancrecarb, on June 29, 2009 and DMEPA re-reviewed the proposed proprietary name Pancrecarb (see OSE Review 2009-1216 dated September 24, 2009). DMEPA issued a reconsideration request acknowledgement on September 24, 2009 indicating that we would defer our decision on the proposed proprietary name Pancrecarb until after the Applicant responded to the Agency's Complete Response letter dated August 27, 2009. On March 25, 2010, the Applicant submitted a Complete Response Submission in addition to a request to review the new proposed proprietary name, Pertzye.

As of the date of this review, it has been determined that all three ingredients, lipase, amylase, and protease, are active and will be included on labels and labeling with their respective strengths, even though current dosing practices are only based on the lipase component.

1.3 PRODUCT INFORMATION

Pertzye is indicated for the treatment of exocrine pancreatic insufficiency. Pertzye contains a combination of lipase, protease, and amylase; however, it is dosed in lipase units and will be available in (b) (4) 8,000 USP units of lipase, and 16,000 USP units of lipase. (b) (4)

(b) (4) The 8,000 USP and 16,000 USP units of lipase strengths will be available in 100-count and 250-count bottles. The usual dosage for this product will vary by patient. Patients taking this product will be dosed at 500 USP units of lipase/kg of body weight to 2,500 USP units of lipase/kg of body weight per meal. The maximum daily dose is 10,000 USP units of lipase/kg/day.

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, 2.3, and 2.4 identify specific information associated with the methodology for the proposed proprietary name, Pertzeye.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter “P” 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 Pertzeye, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the root name (7 letters), upstrokes (2, capital letter “P” and lower case “t”), downstrokes (2, lower case “z” when scripted and lower case “y”), cross strokes (1, lower case “t”), dotted letters (none) and modifiers (none). Additionally, several letters in Pertzeye may be vulnerable to ambiguity when scripted (see Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Pertzeye.

When searching to identify potential names that may sound similar to Pertzeye, the DMEPA staff search for names with similar number of syllables (two), stresses (PERT-zye, pert-ZYE), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary (see Appendix B). The Sponsor’s intended pronunciation (PERT-zye) was also taken into consideration, as it was included in the Proprietary Name Review Request. Furthermore, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 FDA ADVERSE EVENT REPORTING SYSTEM (AERS)

Pancrecarb capsules are currently marketed; therefore, DMEPA conducted a search of the FDA Adverse Event Reporting System (AERS) database on March 18, 2010, to identify medication errors involving Pancrecarb.

The MedRA High Level Group Terms (HLGT) “Medication Errors” and “Product Quality Issues” were used as search criteria for Reactions. The search criteria used for Products was verbatim substance search “Pancrec%”. No date limitations were set.

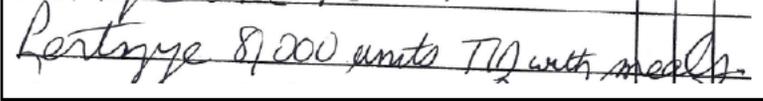
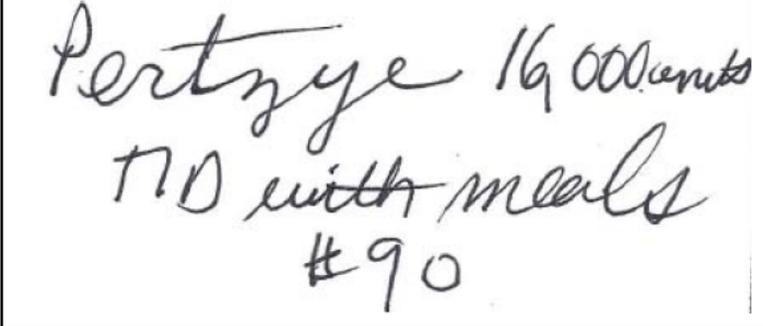
¹ Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

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

2.3 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 medication order, outpatient and verbal prescription was communicated during the FDA prescription studies.

Figure 1. Pertzze Study (conducted on March 5, 2010)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Inpatient Medication Order:</u></p> 	<p>Pertzze 16,000 units 1 capsule three times a day with meals Dispense #90</p>
<p><u>Outpatient Prescription:</u></p> 	

2.4 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

For this product, the Applicant submitted an external evaluation of the proposed proprietary name. The Division of Medication Error Prevention and Analysis conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in DMEPA’s database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator’s Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings.

After the Safety Evaluator has determined the overall risk associated with the proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Sponsor. The Safety Evaluator then determines whether the Division’s risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The DMEPA searches yielded a total of 15 names having some similarity to the name Pertzze. Fourteen of the 15 names were thought to look like Pertzze. These include Peg-Lyte, Bentyl, Pentasa, Fentora, Pentacel, Pristiq, Potiga, PerioRx, Rezira, Revlimid, Reziris, Revaspa, Prezista, and Panoxyl. One name, Pertuzumab, was thought to look and sound like the established name Pancrelipase.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of March 16, 2010.

3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Pertzze.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

3.3 FDA ADVERSE EVENT REPORTING SYSTEM (AERS) DATABASE

The AERS search conducted on March 18, 2010, yielded no cases.

3.4 FDA PRESCRIPTION ANALYSIS STUDIES

A total of 37 practitioners responded in the prescription analysis studies. Eighteen of the 37 practitioners interpreted the name correctly as “Pertzze”. The remainder of the practitioners (n=19) misinterpreted the drug name. In the voice study several practitioners (n= 10) misinterpreted the suffix as “-z” or “-sy” or “-zy” instead of “-zye”. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.5 EXTERNAL STUDY

In the proposed name risk assessment submitted by the Applicant, (b) (4) found the proposed proprietary name, Pertzze, acceptable. (b) (4) identified and evaluated a total of 14 drug names thought to have some potential for confusion with the name Pertzze: Enzyte, Pangestyme, Patanol, Pentasa, Pentazocine, Pepcid, Percocet, Pergolide, Permax, Pertuzumab, Prinzide, Pristiq, Protonix, and Reyataz. Of the names identified by (b) (4), three were also identified by DMEPA during the database searches: Pentasa, Pertuzumab, and Pristiq. The remaining 11 names will be considered in the safety evaluator assessment.

3.6 COMMENTS FROM THE DIVISION OF GASTROENTEROLOGY PRODUCTS (DGP)

3.6.1 Initial Phase of Review

In a response to an e-mail sent by OSE, the Division of Gastroenterology Products (DGP) did not have any issues with the proposed proprietary name, Pertzze.

3.6.2 Midpoint of Review

DMEPA notified the Division of Gastroenterology Products (DGP) via e-mail that we had objections to the proposed proprietary name Pertzze. Per e-mail correspondence from the Division of Gastroenterology Products, they indicated that they have no objections to our assessment of the proposed proprietary name, Pertzze.

3.7 SAFETY EVALUATOR RISK ASSESSMENT OF PROPOSED PROPRIETARY NAME

Independent searches by the primary Safety Evaluator resulted in the identification of six additional names which were thought to look similar to Pertzye and represent a potential source of drug name confusion.

The names identified by the primary Safety Evaluator to have look-alike similarities are (b) (4) Penlac, Prelay, (b) (4), (b) (4), and Rotarix.

Thus, we evaluated a total of 32 names for their similarity to the proposed name: 6 identified by the primary safety evaluator, 11 identified in the External Study, and 15 identified in section 3.1 above.

4 DISCUSSION

Pertzye is the proposed proprietary name for Pancrelipase Delayed-Release Capsules. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly.

4.1 PROMOTIONAL ASSESSMENT

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name. DMEPA and the Division of Gastroenterology Products concurred with the findings of the promotional assessment.

4.2 SAFETY ASSESSMENT

In total, 32 names were identified as potential sources of confusion and evaluated by DMEPA. Twenty-four of the 32 names were not evaluated further for the following reasons (see Appendices D, E, and F): 20 of the 24 names lacked convincing orthographic and/or phonetic similarity to the proposed proprietary name Pertzye, four other names did not undergo failure mode and effect analysis (FMEA) because they were either products not marketed in the U.S or unapproved proprietary names found unacceptable by DMEPA.

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining eight names and lead to medication errors. This analysis determined that the name similarity to Pertzye was unlikely to result in medication errors with any of the eight products for the reasons presented in Appendix G. This finding was consistent with and supported by an independent risk assessment of the proprietary name submitted by the Applicant.

DMEPA did not identify other factors besides names with potential similarity to Pertzye that would render the name unacceptable.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Pertzye, is not promotional nor is it vulnerable to name confusion that can lead to medication errors. Thus the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Pertzye, for this product at this time. Our analysis is consistent with the external risk assessment conducted by (b) (4) that was provided by the Applicant. The Applicant will be notified via letter.

5.1 COMMENTS TO THE SPONSOR

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

The proposed proprietary name will be re-reviewed 90 days before approval of the NDA.

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.

6 REFERENCES

1. *Adverse Events Reporting System (AERS)*

AERS is a database application in CDER FDA that contains adverse event reports for approved drugs and therapeutic biologics. These reports are submitted to the FDA mostly from the manufacturers that have approved products in the U.S. The main utility of a spontaneous reporting system that captures reports from health care professionals and consumers, such as AERS, is to identify potential post marketing safety issues. There are inherent limitations to the voluntary or spontaneous reporting system, such as underreporting and duplicate reporting; for any given report, there is no certainty that the reported suspect product(s) caused the reported adverse event(s); and raw counts from AERS cannot be used to calculate incidence rates or estimates of drug risk for a particular product or used for comparing risk between products.

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

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

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

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. This is a database which was created for the Division of Medication Error Prevention and Analysis, FDA.

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

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

5. *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.

6. *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.

7. *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.

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

Provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

Provides information regarding patent and trademarks.

10. ***Clinical Pharmacology Online*** (www.clinicalpharmacology-ip.com)

Contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. Provides a keyword search engine.

11. ***Data provided by Thomson & Thomson’s SAEGIS™ Online Service, available at***
(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.

12. ***Natural Medicines Comprehensive Databases*** (www.naturaldatabase.com)

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

13. ***Stat!Ref*** (www.statref.com)

Contains full-text information from approximately 30 texts. Includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology and Dictionary of Medical Acronyms Abbreviations.

14. ***USAN Stems*** (<http://www.ama-assn.org/ama/pub/category/4782.html>)

List contains all the recognized USAN stems.

15. ***Red Book Pharmacy’s Fundamental Reference***

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

16. ***Lexi-Comp*** (www.lexi.com)

A web-based searchable version of the Drug Information Handbook.

17. ***Medical Abbreviations Book***

Contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. 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.³

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment 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 focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.⁴ DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. 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.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug 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.

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. Because drug name confusion can occur at any point in the medication use process, DMEPA staff 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.⁵ DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products

³ National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

⁴ Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

⁵ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such 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). In addition, the DMEPA staff 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. If provided, DMEPA will consider the Applicant’s intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

Table 1. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

Type of similarity	Considerations when searching the databases		
	Potential causes of drug name similarity	Attributes examined to identify similar drug names	Potential Effects
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
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"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, the DMEPA staff also 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 staff conducts searches of 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 using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use 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, the DMEPA staff review 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.

2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). 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 DMEPA staff to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of 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 Analysis 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 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 the 123 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 send their interpretations of the orders via e-mail to DMEPA.

4. Comments from the OND review Division or Generic drugs

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary

name and 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 DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or 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 concur/not concur with DMEPA's final decision.

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, conducts a Failure Mode and Effects Analysis, and provides an overall 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.⁶ 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 Section one. 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?”

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. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess 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:

“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

⁶ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

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.

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 Risk Assessment:

- a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC'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.

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 is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to 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 Applicant 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. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), Joint Commission on Accreditation of Hospitals (JCOAH), and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug 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 a preventable source of medication error that, in many instances, the Agency and/or Applicant 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. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Applicant 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 Applicants’ 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 (see Section 4 for limitations of the process).

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in name, Pertzye	Scripted may appear as	Spoken may be interpreted as
Capital ‘P’	B, D, F, R, X	b
lower case ‘p’	x, yn, ys	b
lower case ‘e’	a, c, i, l, o, r, u	any vowel
lower case ‘er’	a, o, u	
lower case ‘r’	e, n, s, v	
lower case ‘t’	b, d, f, l	d
lower case ‘z’	r, s	s
lower case ‘y’	u	e, i
lower case ‘e’	a, c, i, l, o, r, u	any vowel

Appendix C: FDA Prescription Study Responses

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
Pertzeye	Pertzeye	Perc-z
Pertzeye??	Pertzeye	Pert-Z
Pertryze	Pertzeye	Pertzzy
Pent_	Pertzeye	Pertzzy
Pertsye	Pertzeye	Perksy
Pertzyme	Pertzeye	Pertsy
Pertrye?	Pertzeye	Part
Pertzeye	Pertzeye	Pertze
Pertzze	Pertzeye	Pert-z
	Pertzeye	Pert-Z
	Pertzeye	Pertzzy
	Pertzeye	Pertzi
	Pertzeye	Pertsy
	Pertzeye	
	Pertzeye	

Appendix D: Drug names that lack convincing orthographic and/or phonetic similarities

Name	Similarity to Pertzye
Enzyte	(b) (4)
Fentora	Look alike
Pangestyme	(b) (4)
Patanol	(b) (4)
Pentacel	Look alike
Pentazocine	(b) (4)
Pepcid	(b) (4)
Percocet	(b) (4)
Pergolide	(b) (4)
PerioRx	Look alike
Permax	(b) (4)
Pertuzumab	Look alike and sound alike
Prezista	Look alike
Prinzide	(b) (4)
Protonix	(b) (4)
Revaspa	Look alike
Revlimid	Look alike
Reyataz	(b) (4)
Rezira	Look alike
Reziris	Look alike

Appendix E: Names of products withdrawn from the market or not marketed in the U.S.

Proprietary Name	Similarity to Pertzye	Status
Peg-Lyte (Polyethylene glycol 3350; potassium chloride; sodium bicarbonate; sodium chloride; sodium sulfate anhydrous) Powder, For Suspension	Look alike	This is a discontinued product with no therapeutic equivalents.
Prelay (Troglitazone) Tablets	Look alike	This is a discontinued product with no therapeutic equivalents.

Appendix F: Unapproved proprietary names

Proprietary Name	Similarity to Pertzye	Status
(b) (4)		

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

Appendix G: Name confusion is prevented by the combination of stated product characteristics and/or orthographic differences as described.

Product name with potential for confusion	Similarity to Pertzye	Strength	Usual Dosage and Administration	Name confusion is prevented by the stated product characteristics and/or orthographic differences as described.
Pertzye (Pancrelipase) Capsules	N/A	<p style="text-align: right;">(b) (4)</p> <p>Lipase 8,000 USP Units/ Protease Amylase</p> <p>Lipase 16,000 USP Units/ Protease Amylase</p>	<p>500 – 2,500 USP units of lipase/kg of body weight per meal</p>	N/A
Bentyl (Dicyclomine Hydrochloride) Capsules, Tablets, Oral Syrup, or Injectible	Look alike	<p>Capsules: 10 mg</p> <p>Tablets: 20 mg</p> <p>Syrup: 10 mg/5 mL</p> <p>Injectable: 20 mg/2 mL</p>	<p>Oral: 20 - 40 mg four times daily</p> <p>Injectable: 20 mg four times daily (do not use injectable for periods longer than 1-2 days)</p>	<p>Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting.</p> <p><u>Orthographic:</u> “-zye” is longer than “-yl” when scripted and may contain an extra downstroke “z”</p> <p><u>Usual Dose:</u> 500 – 2,500 units of lipase/kg of body weight vs. 20 – 40 mg</p> <p><u>Strength:</u> (b) (4) 8000, or 16,000 lipase units vs. 10 mg, 20 mg, 10 mg/5mL or 20 mg/2mL</p> <p><u>Frequency:</u> Three times a day vs. four times a day</p>
Panoxyl (Benzoyl Peroxide) Bar, Gel, Foam, or Foaming Wash	Look alike	<p>Bar: 5%, 10%</p> <p>Gel: 10%</p> <p>Foaming Wash: 10%</p> <p>Foam: 10%</p>	Apply/use 1-3 times daily if needed or as directed by physician	<p><u>Route of Administration:</u> Oral vs. topical</p> <p><u>Dosage Form:</u> Capsule vs. bar, gel, foam, or foaming wash</p> <p><u>Strength:</u> (b) (4) 8000, or 16,000 lipase units vs. 5% or 10%</p>

Product name with potential for confusion	Similarity to Pertzye	Strength	Usual Dosage and Administration	Name confusion is prevented by the stated product characteristics and/or orthographic differences as described.
Pertzye (Pancrelipase) Capsules	N/A	(b) (4) Lipase 8,000 USP Units/ Protease (b) (4) Amylase Lipase 16,000 USP Units/ Protease (b) (4) Amylase	500 – 2,500 USP units of lipase/kg of body weight per meal	N/A
Penlac (Ciclopirox) Solution	Look alike	8%	Apply once daily to affected nail(s)	<u>Route of Administration:</u> <i>Oral vs. topical</i> <u>Dosage Form:</u> <i>Capsule vs. topical solution</i> <u>Strength:</u> (b) (4) 8000, or 16,000 lipase units vs. 8% <u>Frequency:</u> <i>Three times daily vs. once daily</i>
Pentasa (Mesalamine) Capsules	Look alike	250 mg, 500 mg	Take 1 gram by mouth four times a day	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> <i>“-zye” does not appear similar to “-asa” when scripted and may contain 2 downstrokes unlike “-asa” which does not contain any</i> <u>Usual Dose:</u> <i>500 – 2,500 units of lipase/kg of body weight vs. 1 gram</i> <u>Strength:</u> (b) (4) 8000, or 16,000 lipase units vs. 250 mg or 500 mg <u>Frequency:</u> <i>Three times a day vs. four times a day</i>

Product name with potential for confusion	Similarity to Pertzye	Strength	Usual Dosage and Administration	Name confusion is prevented by the stated product characteristics and/or orthographic differences as described.
Pertzye (Pancrelipase) Capsules	N/A	<div style="text-align: right;">(b) (4)</div> Lipase 8,000 USP Units/ Protease (b) (4) Amylase Lipase 16,000 USP Units/ Protease (b) (4) Amylase	500 – 2,500 USP units of lipase/kg of body weight per meal	N/A
(b) (4)				
Pristiq (Desvenlafaxine Succinate) Tablets	Look alike	50 mg, 100 mg	Take 50 mg by mouth once daily	<u>Usual Dose:</u> 500 – 2,500 units of lipase/kg of body weight vs. 50 mg <u>Strength:</u> (b) (4) 8000, or 16,000 lipase units vs. 50 mg or 100 mg <u>Frequency:</u> Three times a day vs. once daily

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Product name with potential for confusion	Similarity to Pertyze	Strength	Usual Dosage and Administration	Name confusion is prevented by the stated product characteristics and/or orthographic differences as described.
Pertyze (Pancrelipase) Capsules	N/A	(b) (4) Lipase 8,000 USP Units/ Protease (b) (4) Amylase Lipase 16,000 USP Units/ Protease (b) (4) Amylase	500 – 2,500 USP units of lipase/kg of body weight per meal	N/A
Rotarix (Rotavirus) Vaccine, Live Oral Suspension	Look alike	N/A	Two 1-mL doses administered orally at least 4 weeks apart beginning at 6 weeks of age and should be completed by 24 weeks of age	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> <i>“-zye” does not appear similar to “-arix” when scripted. Although “-arix” may appear to have a downstroke if the “x” is extended below the line, “-zye” may contain two downstrokes due to the “z” and the “y”</i> <u>Usual Dose:</u> <i>500 – 2,500 units of lipase/kg of body weight vs. 1 mL</i> <u>Frequency:</u> <i>Three times a day vs. two doses administered 4 weeks apart</i>

(b) (4)

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22175	ORIG-1	DIGESTIVE CARE INC	PANCRECARB

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/s/

IRENE Z CHAN
06/03/2010

MELINA N GRIFFIS
06/04/2010

DENISE P TOYER
06/04/2010

CAROL A HOLQUIST
06/04/2010



**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: September 24, 2009

To: Donna Griebel, MD, Director
Division of Gastroenterology Products

Through: Denise Toyer, Pharm D., Deputy Director
Carol Holquist, RPh, Director
Division of Medication Error Prevention and Analysis

From: Melina Griffis, RPh, Acting Team Leader
Division of Medication Error Prevention and Analysis

Subject: Response to Pancrecarb Proprietary Name Request for
Reconsideration

Drug Name: PANCRECARB (Pancrelipase) Capsules

Application Number: NDA 22-175

Applicant: Digestive Care

OSE RCM #: 2009-1216

EXECUTIVE SUMMARY

The Division of Medication Error Prevention and Analysis (DMEPA) previously evaluated the name, Pancrecarb, in OSE Review 2008-2000, dated March 19, 2009, and found the name unacceptable (b) (4)

[REDACTED]

Therefore, DMEPA does not have sufficient information to make a final determination on the acceptability of the proposed proprietary name Pancrecarb at this time. DMEPA recommends that a proprietary name review be submitted for this product once the product characteristics of the intended marketed Pancrecarb product(s) are confirmed.

1 INTRODUCTION

This review was written in response to a June 29, 2009, request from the Applicant to reconsider the acceptability of the proposed proprietary name, Pancrecarb.

2 REGULATORY HISTORY

DMEPA found the proprietary name, Pancrecarb, unacceptable in OSE Review 2009-2000, dated March 19, 2009, (b) (4)

The Applicant submitted a rebuttal in a letter dated June 29, 2009.

3 MATERIAL REVIEWED

We reviewed the Applicant's rebuttal letter dated June 29, 2009 and the previous OSE review 2009-2000 (b) (4)

In addition, the Complete Response (CR) letter issued to the NDA application dated August 27, 2009 was reviewed.

4 DISCUSSION

DMEPA's original review of the proposed proprietary name Pancrecarb consisted of (b) (4)

[REDACTED]

5 CONCLUSIONS AND RECOMMENDATIONS

Based on our evaluation of the Applicants reconsideration request we continue to have concerns

(b) (4)

Additionally, because of the issuance of the August 27, 2009 CR letter to the Pancrecarb NDA, the final product characteristics of the Pancrecarb products(s) intended for commercial use are unknown at this time. Therefore, DMEPA is unable to

(b) (4)

make a final determination on the acceptability of the proposed proprietary name Pancrecarb for this product at this time. Once the Applicant responds to the August 27, 2009 CR letter we will re-evaluate the proposed proprietary name based on their submission.

We would be willing to meet with the Division for further discussion, if needed. If you have any questions or need clarification, contact Nina Ton, OSE Project Manager, at 301-796-1648.

5.1 COMMENTS TO THE APPLICANT

We have reviewed your request for reconsideration of the name Pancrecarb and have determined the following:

1. [Redacted] (b) (4)

2. [Redacted] (b) (4)

3. We continue to have concerns [Redacted] (b) (4)
The Agency's August 27, 2009 CR letter to the Pancrecarb
NDA application [Redacted] (b) (4)
Based on these [Redacted] (b) (4)
deficiencies the final product characteristics, [Redacted] (b) (4)
have not been finalized. [Redacted] (b) (4)

Therefore,
we defer our decision on the proprietary name Pancrecarb, until after you have responded to the Agency's Complete Response letter.

DMEPA recommends that a proprietary name review be submitted for this product once all the product characteristics of the intended marketed Pancrecarb product(s) are firmly established.

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/s/

MELINA N GRIFFIS
09/24/2009

DENISE P TOYER
09/25/2009

CAROL A HOLQUIST
09/25/2009



**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: March 19, 2009

To: Donna Griebel, MD, Division Director
Division of Gastroenterology Products

Thru: Melina Griffis, RPh, Acting Team Leader
Denise Toyer, Pharm.D., Deputy Director
Carol Holquist, RPh, Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: Robin Duer, RN, MBA, Safety Evaluator
Division of Medication Error Prevention and Analysis

Subject: Proprietary Name Review

Drug Name: PANCRECARB[®] (Pancrelipase) Capsules

Application Type/Number: NDA 22-175

Applicant: Digestive Care, Inc.

OSE RCM #: 2008-2000

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EXECUTIVE SUMMARY

The results of the Proprietary Name Risk Assessment found the proposed name, Pancrecarb, is vulnerable to name confusion that could lead to medication errors (b) (4)

[Redacted]

Thus, the Division of Medication Error Prevention and Analysis objects to the use of the proprietary name, Pancrecarb, for this product.

[Redacted]

(b) (4)

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/s/

Melina Griffis
3/19/2009 01:25:45 PM
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