CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022283Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review--Final

Date:	November 1, 2011
Reviewer:	Chi-Ming (Alice), Tu PharmD, Safety Evaluator Division of Medication Error Prevention and Analysis
Team Leader	Carlos M. Mena-Grillasca, RPh, Team Leader Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis
Drug Name/ Strength:	Zegerid OTC (Omeprazole and Sodium Bicarbonate) Powder for Oral Suspension, 20 mg/1680 mg
Application Type/Number:	NDA 22283
Applicant/sponsor:	Schering Plough
OSE RCM #:	2011-2871

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

1 INTRODUCTION

This re-assessment of the proposed proprietary name Zegerid OTC is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Zegerid OTC, acceptable in OSE Review 2008-610, dated August 4, 2008; and OSE Review 2009-1411, dated October 26, 2009.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2008-610 and OSE Review 2009-1411. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded no new names thought to look or sound similar to Zegerid OTC and represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of October 7, 2011. DDMAC re-reviewed the proposed name on September 15, 2011 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

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

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Nonprescription Clinical Evaluation (DNCE) should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Cherye Milburn, OSE project manager, at 301-796-2084.

4 REFERENCES

1. **OSE Reviews**

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

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

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

   USAN Stems List contains all the recognized USAN stems.

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

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

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

/s/

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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:	August 04, 2008
To:	Andrea Leonard-Segal. M.D., M.S. Director, Division of Nonprescription Clinical Evaluation Office of Nonprescription Products
Through:	Todd Bridges, RPh, Team Leader Denise Toyer, PharmD, Deputy Director Carol Holquist, RPh, Director Division of Medication Errors Prevention
From:	Zachary Oleszczuk, PharmD, Safety Evaluator Division of Medication Error Prevention
Subject:	Proprietary Name, Label, and Labeling Review
Drug Name(s):	Zegerid OTC (Omeprazole and Sodium Bicarbonate) Capsules 20 mg/1100 mg
Application Type/Number:	NDA 22-281
	Zegerid OTC (Omeprazole and Sodium Bicarbonate) Powder for Oral Suspension 20 mg/1680 mg NDA 22-283
Applicant:	Schering-Plough
OSE RCM #:	2008-610

CONTENTS

EXECUTIVE SUMMARY

The Proprietary Name Risk Assessment findings indicate that the proposed name, Zegerid OTC, appears to be vulnerable to name confusion with the prescription product Zegerid (20 mg). However, this confusion would result in patients receiving a product identical to the intended product. Since the patient would receive a product identical to the intended product if name confusion occurred this would not be considered a medication error. As such, the Medication Error Prevention Staff does not object to the use of the proprietary name, Zegerid OTC, for this product.

The results of the Label and Labeling Risk Assessment found that the presentation of tradename on the proposed carton labeling and container labels appears to be vulnerable to confusion that could lead to medication errors. The medication error prevention staff believes the risk we have identified can be addressed prior to approval of the application and provides a recommendation in Section 5.2 that aims at reducing the risk of medication errors.

1 BACKGROUND

1.1 INTRODUCTION

This review was written in response to a request from the Division of Nonprescription Clinical Evaluation, Office of Nonprescription Products (DNCE), for assessment of the proprietary name, Zegerid OTC, regarding potential name confusion with other proprietary or established drug names. Draft container labels, carton and insert labeling were provided for review and comment.

1.2 REGULATORY HISTORY

On March 10th, 2008 the Applicant submitted a 505(b)(2) application for Zegerid OTC that provides for capsules of omeprazole 20 mg and sodium bicarbonate 1100 mg. Nine days later on March 19th, 2008 the Applicant submitted a second 505(b)(2) application for Zegerid OTC that provides for powder for oral suspension of omeprazole 20 mg and sodium bicarbonate 1680 mg. The reference listed drug is Prilosec OTC (NDA# 21-229).

The sodium bicarbonate contained in Zegerid OTC acts only to aide in the absorption of omeprazole. However, in other doses and frequencies sodium bicarbonate is a well known antacid. Therefore, the Division of Nonprescription Clinical Evaluation is evaluating language to use when referring to the activity of sodium bicarbonate in Zegerid OTC so consumers understand that the sodium bicarbonate in Zegerid OTC is only to aide in the absorption of omeprazole. At the time of this review final language has not be established. Zegerid OTC is an over-the-counter product used for the treatment of frequent heartburn.

1.3 PRODUCT INFORMATION

Zegerid OTC will be supplied as a capsule and powder for oral suspension. Zegerid OTC capsules will contain 20 mg of omeprazole and 1100 mg of sodium bicarbonate. Zegerid OTC powder for oral suspension will contain 20 mg of omeprazole and 1680 mg of sodium bicarbonate. Zegerid OTC is an acid reducer. The active ingredient of Zegerid OTC, omeprazole works by inhibiting the proton pumps in the stomach.

The reference listed drug, Prilosec OTC only comes as a tablet. Additionally, Prilosec OTC only contains the active ingredient omeprazole and does not contain sodium bicarbonate to aide in the absorption of omeprazole. Prilosec OTC is also an acid reducer used to treat frequent heartburn.

The dosing regimen for the Zegerid OTC capsules is one capsule, by mouth, once a day before breakfast for 14 days. The capsules will be supplied as a blister cards in packs of 14, 28, or 42 capsules.

The dosing regimen for the Zegerid OTC powder for oral suspension is to take one packet of powder for oral suspension orally once a day before breakfast for 14 days. The directions for use of the Powder for Oral Suspension require two steps to receive the correct dose of medication. To prepare the suspension mix the powder for oral suspension with 2 tablespoons of water, stir well and drink immediately. Refill the cup with water and drink. The powder for oral suspension will be packaged in individual packets and will be supplied as a package of 14 packets.

The root name, Zegerid, of the proposed name Zegerid OTC is a proprietary name associated with 4 NDA's. Two of the NDA's (NDA 21-636 and 21-849) are currently prescription status, one NDA (21-850) is not currently marketed and one NDA (21-706) has been discontinued.

NDA#	Tradename	Ingredients and Strengths	Marketing Status
21-636	Zegerid	20 mg omeprazole and 1680 mg sodium bicarbonate powder for suspension and 40 mg omeprazole and 1680 mg sodium bicarbonate powder for oral suspension	Prescription
21-849	Zegerid	20 mg omeprazole and 1100 mg sodium bicarbonate capsules and Zegerid 40 mg omeprazole and 1100 mg sodium bicarbonate capsules	Prescription
21-850	Zegerid	700 mg magnesium hydroxide, 20 mg omeprazole, and 600 mg sodium bicarbonate chewable tablets and 700 mg magnesium hydroxide, 40 mg omeprazole, and 600 mg sodium bicarbonate chewable tablets	Prescription (not marketed)
21-706	Zegerid	40 mg omeprazole and 1680 mg sodium bicarbonate powder for oral suspension	Discontinued

Both prescription products of Zegerid and all strengths (4 total products) that are currently marketed will remain on the market as prescription status when Zegerid OTC is approved. Prescription status Zegerid and Zegerid OTC will share overlapping characteristic such as dosage forms, strengths, dosage, route and frequency, but will not share approved indications. Prescription Zegerid is currently approved for treatment of Duodenal Ulcers, Gastric Ulcers, Symptomatic GERD, Erosive Esophagitis, maintenance of healing of Erosive Esophagitis and Reduction of Risk of Upper Gastrointestinal Bleeding in Critically Ill Patients while Zegerid OTC will only be approved for frequent heartburn.

2 METHODS AND MATERIALS

This section consists of two sections which describe the methods and materials used by the Division of Medication Error Prevention staff conducting a proprietary name risk assessment (see 2.1 Proprietary Name Risk Assessment) and label, labeling, and/or packaging risk assessment (see 2.2 Container Label, Carton Labeling, and Insert Labeling Risk Assessment). The primary focus for both of the assessments is to identify and remedy potential sources of medication error prior to drug approval. The Division of Medication Error Prevention 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]

2.1 PROPRIETARY NAME RISK ASSESSMENT

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name, Zegerid OTC, and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, and ANDA products currently under review by the Agency. Additionally, the modifier 'OTC' was assessed for resemblance to any numbers, dosing instructions, or medical abbreviations. Furthermore, the Division of Medication Error Prevention evaluated the appropriateness of the proposed modifier, considered the potential for the modifier's omission or misinterpretation, and verified that the modifier does not appear on the error-prone abbreviation list maintained by the Institute of Safe Medication Practices (ISMP).

For the proprietary name, Zegerid OTC, the medication error staff of the Division of Medication Error Prevention search a standard set of databases and information sources to identify names with orthographic and phonetic similarity (see Sections 2.1.1 for detail) and held an CDER Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (see 2.1.3). We also conduct internal CDER prescription analysis studies (see 2.1.4), and, when provided, external prescription analysis studies results are considered and incorporated into the overall risk assessment (see detail 2.1.5).

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 (see detail 2.1.5). The overall risk assessment is based on the findings of a Failure Modes and Effects Analysis (FMEA) of the proprietary name, and is focused on the avoidance of medication errors. FMEA is a systematic tool for evaluating a process and identifying where and how it might fail. [2] FMEA is used to analyze whether the drug names identified with look- or sound-alike similarity to the proposed name could cause confusion that subsequently leads to medication errors in the clinical setting. The Division of Medication Error Prevention uses the clinical expertise of the medication error staff to anticipate the conditions of the clinical setting that the product is likely to be used in 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. As such, the Staff consider the product characteristics associated with the proposed drug throughout the risk assessment, since the product characteristics of the proposed may provide a context for communication of the drug name and

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

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

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 drug name include, but are not limited to established name of the proposed product, the proposed indication, 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, the Division of Medication Error Prevention 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.[3]

2.1.1 Search Criteria

The Medication Error Staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted as outlined in Appendix A.

For this review, particular consideration was given to drug names beginning with the letter 'Z' 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.[4,5]

To identify drug names that may look similar to Zegerid OTC the Staff also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (10 letters), upstrokes (5, capital letter 'Z', lower case letter 'd', capital letters 'O', 'T', and 'C'), downstrokes (1, 'g'), cross-strokes (1, capital letter 'T'), and dotted letters (1, 'i'). Additionally, several letters in Zegerid OTC may be vulnerable to ambiguity when scripted, including the letter 'Z' may appear as capital 'L' 'T' or 'M'; lower case 'e' may appear as a lower case 'a', 'i', 'l', or 'p'; lower case 'g' may appear as a lower case 'j', 'q', or 's'; lower case 'r' may appear as a lower case 'n', 'v', or 'x'; lower case 'i' may appear as a lower case 'e'; lower case 'd' may appear as the lower case letter combination 'cl'; capital letter 'O' may appear as a capital 'A'; capital 'T' may appear as a capital 'F' or 'Z'; and capital letter 'c' may appear as a capital 'A'. As such, the Staff also consider these alternate appearances when identifying drug names that may look similar to Zegerid OTC.

When searching to identify potential names that may sound similar to Zegerid OTC, the Medication Error Staff search for names with similar number of syllables (6 total with 3 syllables in the first term and 3 syllables in the second term), stresses (ZEGG-a-rid-OHH-TEE-CEE and zegg-a-RID-OHH-TEE-CEE) and placement of vowel and consonant sounds. In addition, several letters in Zegerid OTC may be subject to interpretation when spoken, including the letter 'Z' may be interpreted as 'S', 'X' or "C"; the letter 'd' may be interpreted as 't'; the letter 't' may be interpreted as 'd'; and the letter 'C' may be interpreted as 'Z' or 'K'. The Applicant's intended pronunciation of the proprietary name could not be expressly taken into consideration, as this was not provided with the proposed name submission.

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[3] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

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

[5] Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artifical Inteligence in Medicine (2005)

The Staff also consider the product characteristics associated with the proposed drug throughout the identification of similar drug names, since the product characteristics of the proposed drug ultimately determine the use of the product in the clinical practice setting For this review, the Medication Error Staff were provided with the following information about the proposed product: the proposed proprietary name (Zegerid OTC), the established name (omeprazole and sodium bicarbonate), proposed indication (treats frequent heart burn), strength (omeprazole 20 mg and sodium bicarbonate 1100 mg for the capsules; omeprazole 20 mg and sodium bicarbonate 1680 mg for the powder for oral suspension), dose (one capsule or powder packet), frequency of administration (daily before breakfast), route (orally) and dosage form of the product (capsules and powder for oral suspension). Appendix B provides a more detailed listing of the product characteristics the Medication Error Staff general take into consideration.

Lastly, the Medication Error Staff also consider the potential for the proposed 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. As such, these broader safety implications of the name are considered and evaluated throughout this assessment and the Medication Error Staff provide additional comments related to the safety of the proposed name or product based on their professional experience with medication errors.

2.1.2 *Database and information sources*

The proposed proprietary name, Zegerid OTC, was provided to the medication error staff of the Division of Medication Error Prevention to conduct a search 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 Zegerid OTC using the criteria outlined in 2.1.1. A standard description of the databases used in the searches is provided in Section 6. To complement the process, the Medication Error 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 Medication Error Prevention Staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The findings of the individual Safety Evaluators were then pooled and presented to the Expert Panel.

2.1.3 CDER Expert Panel Discussion

An Expert Panel Discussion is held by the Division of Medication Error Prevention to gather CDER professional opinions on the safety of the product and the proprietary name, Zegerid OTC. Potential concerns regarding drug marketing and promotion related to the proposed names are also discussed. This group is composed of Medication Errors Prevention Staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC).

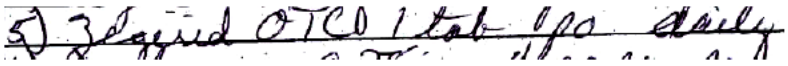
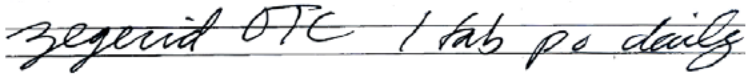
The pooled results of the medication error staff were presented to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of names, additional searches by the Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

2.1.4 CDER 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 Zegerid OTC 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 a total of 123 healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The results are used by the Safety Evaluator to identify any orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of Zegerid OTC in handwriting and verbal communication of the name, inpatient medication orders are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These prescriptions are optically scanned and one prescription is delivered to a random sample of 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 the medication error staff.

Figure 1. Zegerid OTC (conducted on April 29, 2008)

HANDWRITTEN PRESCRIPITON AND MEDICATION ORDER	VERBAL PRESCRIPTION
Inpatient Medication Order #1: 	Zegerid OTC 1 tablet by mouth daily
Inpatient Medication Order #2: 	

2.1.5 Adverse Events Reporting System (AERS)

Since the proprietary name Zegerid is currently marketed in the United States marketplace, the Division of Medication Error Prevention conducted a search of the Adverse Event Reporting System (AERS) database to determine if there are any medication errors associated with name confusion or labeling confusion which may be indicative of potential name confusion with Zegerid OTC. The Division of Medication Error Prevention performed an AERS search using the MedRA High Level Group Term (HLGT) "Medication Errors" and Preferred Term (PT) "Pharmaceutical product complaint" as search criteria for Reactions. The search criteria used for Products were active ingredients "Sodium Bi%" and "Omeprazo%", trade name "Zeg%" and verbatim substance names "Zeg%", "omep%", and "Sodium Bi%".

The cases were manually reviewed to determine if a medication error occurred. Those cases that did not describe a medication error were excluded from further analysis. The cases that did describe a medication were categorized by type of error. Our Division reviewed the cases within each category to identify factors that contributed to the medication errors, and to ascertain if these risks might apply to the proposed Zegerid OTC.

2.1.6 Safety Evaluator Risk Assessment of the Proposed Proprietary Name

Based on the criteria set forth in Section 2.1.1, the Safety Evaluator Risk Assessment applies their individual expertise gained from evaluating medication errors reported to FDA to conduct a Failure Modes and Effects Analysis and provide an overall risk 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, the Division of Medication Error Prevention seeks to evaluate the potential for a proposed name to be confused with another drug name as a result of the name confusion and 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 look- or sound-alike drug names prior to approval, where actions to overcome these issues are easier and more effective then remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is not yet marketed, the Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix B. 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 evaluation, and studies, and identifies potential failure modes by asking: "Is the name Zegerid OTC 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 Zegerid OTC 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 and the name is eliminated from further review.

In the second stage of the Risk Assessment, all potential failure modes are evaluated 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 ultimately not be a source of medication errors in the usual practice setting, the name is eliminated 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 that an alternate proprietary name be used. In rare instances, the FMEA findings may provide other risk-reduction strategies, such as product reformulation to avoid an overlap in strength or an alternate modifier designation may be recommended as a means of reducing the risk of medication errors resulting from drug name confusion.

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

The Division of Medication Error Prevention will object to the use of proposed proprietary name when the one or more of the following conditions are identified in the Safety Evaluator's Risk Assessment:

1. 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 trade name or otherwise. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n)].
2. We identify 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)].
3. FMEA identifies potential for confusion between the proposed proprietary name and other proprietary or established drug names, and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
4. The proposed proprietary name contains an USAN stem, particularly in a manner that is contradictory to the USAN Council's definition.
5. Medication Error Staff identify a potential source of medication error within the proposed proprietary name. 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.

In the event that we object to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, we will provide a contingency objection based on the date of approval: whichever product is awarded approval first has the right to the use the name, while we will recommend that the second product to reach approval seek an alternative name.

If none of these conditions are met, then we will not object to the use of the proprietary name. If any of these conditions are met, then we will object to the use of the proprietary 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 1 through 5 are supported either by Food and Drug Administration Regulation or by external healthcare authorities, including the Institute of Medicine, World Health Organization, Joint Commission, and Institute for Safe Medication Practices. 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.

Furthermore, the Division of Medication Error Preventions 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, can be identified and remedied prior to approval to avoid patient harm.

Additionally, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to remedy post-approval. Educational efforts and so on are low-leverage strategies that have proven to have limited effectiveness at alleviating the medication errors involving drug name confusion. Higher-leverage strategies, such as drug name changes, have been undertaken 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 the approving the error-prone proprietary name. Moreover, even after Applicant's have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioner's vocabulary, and as such, the Agency has continued to receive reports of drug name confusion long after

a name change in some instances. Therefore, we believe 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 limitations of the process).

If we object to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the FMEA process is used to identify strategies to reduce the risk of medication errors. Our Division is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for review by our Division. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name, and so we may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error would render the proposed name acceptable.

2.2 LABEL AND LABELING RISK ASSESSMENT

The label and labeling of a drug product are the primary means by which practitioners and patients (depending on configuration) interact with the pharmaceutical product. The carton labeling and container labels communicate critical information including proprietary and established name, strength, form, container quantity, expiration, and so on. The insert labeling is intended to communicate to practitioners all information relevant to the approved uses of the drug, including the correct dosing and administration.

Given the critical role that the label and labeling has in the safe use of drug products, it is not surprising that 33 percent of medication errors reported to the USP-ISMP Medication Error Reporting Program may be attributed to the packaging and labeling of drug products, including 30 percent of fatal errors.[7]

Because the Division of Medication Error Prevention staff analyze reported misuse of drugs, the Division of Medication Error Prevention staff are able to use this experience to identify potential errors with all medication similarly packaged, labeled or prescribed. The Division of Medication Error Prevention staff uses FMEA and the principles of human factors to identify potential sources of error with the proposed product labels and insert labeling, and provided recommendations that aim at reducing the risk of medication errors.

The following labels and labeling were submitted by the applicant for review and comment. Labels and labeling for Zegerid OTC Capsules and Zegerid OTC Powder for Oral Suspension were submitted on March 10, 2008 and March 19, 2008 respectively (see Appendix I, J, K, L, M, N, O, P, and Q for images):

- Carton Labeling for Capsules (14, 28, and 42 count)
- Blister Labels for Capsules
- Carton Labeling for Powder for Oral Suspension (14 count)
- Container label for Powder for Oral Suspension Packets

(b) (4)

[redacted]

[7] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006. p275.

3 RESULTS

3.1 PROPRIETARY NAME RISK ASSESSMENT

3.1.1 Database and information sources

We conducted a search of the internet, several standard published databases and information sources (see Section 6 References) for existing drug names which sound-alike or look-alike to Zegerid OTC to a degree where potential confusion between drug names could occur and result in medication errors in the usual clinical practice settings. In total, 22 names were identified as having some similarity to the name Zegerid OTC.

Fourteen (14) of the twenty-two (22) names were thought to look like Zegerid OTC, these names include: Zestoretic, Segamol, Fazaclo ODT, Tepanil, Maginex, Synercid, (b) (4) Zephrex, Zephiran, Omeprazole, Prilosec OTC, Migranal, Legatrin, and Magnacal. Four additional names (Zelnorm, Zegerid (prescription), Zegerid (chewable tablets), and Zestril) were thought to look and sound similar to Zegerid OTC. Four names, Xigris, Zerit, Tegaserod, and Secretin, were thought to sound similar to Zegerid OTC.

The proposed modifier 'OTC' does not resemble any numbers or dosing instructions and does not appear on the ISMP "List of Error Prone Abbreviations, Symbols, and Dose Designations." Additionally, one product (Prilosec OTC) listed in the Orange Book contains the Modifier 'OTC' in its proprietary name. The proprietary name found in the Orange Book and the proposed proprietary name use the "OTC" modifier to describe the "over-the-counter" availability of the product.

The proposed proprietary name, Zegerid, does not contain a USAN stem as of the last date searched, April 23, 2008.

3.1.2 Expert panel discussion

The Expert Panel reviewed the pool of names identified by the Medication Error Staff (see section 3.1 above), and commented to review to difference in sodium bicarbonate between the capsule and the powder for oral suspension to see if the difference will be problematic.

DDMAC had no objections regarding the proposed name, Zegerid OTC, from a promotional perspective.

3.1.3 CDER Prescription analysis studies

A total of 29 practitioners responded, six total respondents omitted the modifier OTC, and four of the responses overlapped with an existing drug name. Two respondents in the written inpatient prescription study #1 and two respondents from the inpatient written prescription study #2 omitted the modifier and misinterpreted Zegerid OTC as currently marketed "Zegerid". Two additional respondents also omitted the modifier, but did not misinterpret "Zegerid OTC" as an existing product. About half of the participants (n=15) interpreted the name correctly as "Zegerid OTC," with correct interpretation occurring more frequently in the written studies. The remainder of the responses misinterpreted the drug name. The majority of misinterpretations occurred in the written inpatient prescription study #2, with the 'g' in Zegerid OTC reported as 'q' or the second 'e' reported as an 'i'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.1.4 Adverse Events Reporting System (AERS)

The FDA Adverse Event Reporting System (AERS) search conducted on April 28, 2008 yielded one case associated with name confusion between prescription Zegerid and Zestril. The error involved an illegible written prescription with Zegerid misspelled as "Zegrid". The error was discovered by a nurse before the error reached the patient. The reporter stated that the error occurred because the names are similar. However, the risk of confusion between Zestril and the proposed product is minimized since Zegerid OTC will contain a modifier 'OTC' to further differentiate the two names.

3.1.5 Safety evaluator risk assessment

Independent searches by the primary Safety Evaluator identified an additional name, (b) (4) as a look alike to Zegerid OTC and representing a potential source of drug name confusion. As such, a total of 23 names were analyzed to determine if the drug names could be confused with Zegerid OTC and if the drug name confusion would likely result in a medication error.

All of the identified names were determined to have some orthographic and/or phonetic similarity to Zegerid OTC, and thus determined to present some risk for confusion. Failure modes and effects analysis (FMEA) was then applied to determine if Zegerid, Zegerid OTC, or OTC could potentially be confused with any of the 23 names and lead to medication error.

Seven of the names identified: Zestoretic, Xigris, Zerit, Zephiran, Omeprazole, Prilosec OTC, and Zelnorm were not considered further because they lack convincing orthographic and/or phonetic similarities with Zegerid OTC (see Appendix D).

Three of the 23 names (Legatrin, (b) (4) and Segamol), are drug products that do not appear in common references such as Clinical pharmacology, Drugs@FDA, The Orange Book, Lexi-Comp, or Rxlist.com and thus FMEA determined that medication errors were unlikely to occur in the usual practice setting.

One of the names identified (b) (4) and thus FMEA determined that medication errors with Zegerid OTC were unlikely to occur.

For five of the 23 names (Tepanil, Zepherex, Tegaserod, Zegerid (chewable tablets), and Magnacal), FMEA determined that medication errors were unlikely because the products do not overlap in strength and have been discontinued (see Appendix E).

For two of the names (Fazaclo ODT and Secretin) FMEA determined that medication errors were unlikely because the products do not overlap in strength or dose with Zegerid OTC and have minimal orthographic and/or phonetic similarity to Zegerid OTC (see Appendix F).

Three of the names (Maginex, Synercid, and Migranal) are available in one strength thus, leading to the potential omission of the strength in a prescription or requisition for the product. However, FMEA determined the products contain multiple differentiating product characteristics such as dose, dosage form, route of administration, and indication which minimize the potential for confusion between these products (see Appendix G)

One of the names, Zestril, was identified as a look and sound alike name to Zegerid OTC. Additionally, the AERS search uncovered 1 case of an error involving Zestril and the route name Zegerid that never reached the patient. However, FMEA determined that medications errors are unlikely because of the phonetic and orthographic differences and the anticipated decrease in prescriptions for Zegerid (see Appendix H).

One name, Zegerid was identified as a look and sound alike name to Zegerid OTC. Zegerid is phonetically and orthographically identical to Zegerid OTC if the modifier "OTC" is inadvertently omitted. The Division of Medication Error Prevention believes that the potential for confusion between the prescription and OTC drug products is likely during the initial product launch and beyond, as there will be an overlap in the prescription and OTC strength of Zegerid (20 mg). However, analysis of the failure mode determined that confusion between these products would result in the patient receiving a product identical to the intended product.

3.2 LABEL AND LABELING RISK ASSESSMENT

Review of the container and carton labels noted that the modifier "OTC" on the primary display panels is smaller and less prominent than the rest of the tradename "Zegerid".

4 DISCUSSION

4.1 PROPRIETARY NAME RISK ASSESSMENT

The results of the Proprietary Name Risk Assessment found that the proposed name, Zegerid OTC, appears to be vulnerable to name confusion with the prescription product Zegerid (20 mg). However, this confusion would result in patients receiving a product identical to the intended product. Since the patient would receive a product identical to the intended product if name confusion occurred this would not be considered a medication error and is not cause for name objection.

The findings of the Proprietary Name Risk Assessment are based upon current understanding of factors that contribute to medication errors involving name confusion. Although we believe the findings of the Risk Assessment to be robust, our findings do have limitations. First, because our assessment involves a limited number of practitioners, it is possible that the analysis did not identify a potentially confusing name. Also, there is some possibility that our Risk Assessment failed to consider a circumstance in which confusion could arise. However, the Division of Medication Error Prevention believes that these limitations are sufficiently minimized by the use of an Expert Panel.

However, our risk assessment also faces limitations beyond the control of the Agency. First, our risk assessment is based on current health care practices and drug product characteristics, future changes to either could increase the vulnerability of the proposed name to confusion. Since these changes cannot be predicted for or accounted by the current Proprietary Name Risk Assessment process, such changes limit our findings. To help counterbalance this impact, the Division of Medication Error Prevention recommends that the proprietary name be re-submitted for review if approval of the product is delayed beyond 90 days.

4.2 LABEL AND LABELING RISK ASSESSMENT

The results of the Label and Labeling Risk Assessment found that the presentation of the tradename and design of the proposed container labels and carton labeling appears to be vulnerable to confusion that could lead to medication errors.

Review of the container and carton labels noted that the modifier 'OTC' is smaller and less prominent than the rest of the tradename "Zegerid". Presenting the modifier 'OTC' in a smaller font below the root name, Zegerid, may lead healthcare providers, patients, and consumers to believe that that modifier 'OTC' is not part of the tradename for this product and encourage omission of the modifier 'OTC'. The modifier is necessary to distinguish the proposed over-the-counter product from the prescription product.

The Division of Medication Error Prevention believes the risks we have identified can be addressed and mitigated prior to drug approval, and provides recommendations in Section 5 that aim at reducing the risk of medication errors.

Overall, our Risk Assessment is limited by our current understanding of medication errors and causality. The successful application of Failure Modes and Effect Analysis depends upon the learning gained for a spontaneous reporting program. It is quite possible that our understanding of medication error causality would benefit from unreported medication errors; and, that this understanding could have enabled the Staff to identify vulnerability in the proposed name, packaging, and labeling that was not identified in this assessment. To help minimize this limitation in future assessments, we encourage the Applicant to provide the Agency with medication error reports involving their marketed drug products regardless of adverse event severity.

5 5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Zegerid OTC, appears to be vulnerable to name confusion with the prescription product Zegerid (20 mg). However, this confusion would result in patients receiving a product identical to the intended product.

Additionally, DDMAC has no objections to the proposed name, Zegerid OTC, from a promotional perspective.

5.1 COMMENTS TO THE DIVISION

The Division of Medication Error Prevention has no objections to the use of the proprietary name, Zegerid OTC, for this product.

If any of the proposed product characteristics as stated in this review are altered prior to approval of the product, the Division of Medication Error Prevention rescinds this Risk Assessment finding, and recommends that the name be resubmitted for review. Furthermore, this name must be re-evaluated approximately 90 days prior to the expected approval of the NDA. A re-review of the name prior to NDA approval will rule out any objections based upon approval of other proprietary or established names from the signature date of this document.

The Division of Medication Error Prevention would appreciate feedback on the final outcome of this review. Please copy the Division of Medication Error Prevention on any communication to the Sponsor with regard to this review. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Cherye Milburn, Project Manager, at 301-796-2084.

5.2 COMMENTS TO THE APPLICANT

5.2.1 Proprietary Name

The Division of Medication Error Prevention has no objections to the use of the proprietary name, Zegerid OTC, for this product. If any of the proposed product characteristics as stated in this review are altered prior to approval of the product, the Division of Medication Error Prevention rescinds this Risk Assessment finding, and recommends that the name be resubmitted for review.

5.2.2 Labels and Labeling

Revise the presentation of the tradename “Zegerid OTC” to be presented in the same font size, type style, and color type. Additionally, ensure that the entire tradename appears on the same plane on the primary display panel.

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 manufactures 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 postmarketing 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://weblern/)

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 DMETS, FDA.

4. Drug Facts and Comparisons, online version, St. Louis, MO (http://weblern/)

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

5. AMF Decision Support System [DSS]

DSS is a government database used to track individual submissions and assignments in review divisions.

6. Division of Medication Errors and Technical Support proprietary name consultation requests

This is a list of proposed and pending names that is generated by DMETS 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 and generic drugs and therapeutic biological products; prescription and over-the-counter human drugs and therapeutic biologicals, 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. WWW location http://www.uspto.gov.

Provides information regarding patent and trademarks.

10. Clinical Pharmacology Online (http://weblern/)

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 tradenames that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

12. Natural Medicines Comprehensive Databases (http://weblern/)

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

13. Stat!Ref (http://weblern/)

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.pharmacist.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:

The Medication Error Staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMETS also compare the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. The Medication Error Staff also examine 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* dissimilarly spelled drug name pairs to appear very similar to one another and the similar appearance of drug names when scripted has lead to medication errors. The Medication Error Staff apply their expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (i.e. "T" may look like "F," lower case 'a' looks like a lower case 'u,' etc), along with other orthographic attributes that determine the overall appearance of the drug name when scripted (see detail in Table 1 below). Additionally, since verbal communication of medication names is common in clinical settings, the Medication Error Staff compare the pronunciation of the proposed proprietary name with the pronunciation of other drug names. If provided, DMETS will consider the Applicant's intended pronunciation of the proprietary name. However, because the Applicant has little control over how the name will be spoken in practice, DMETS also considers a variety of pronunciations that could occur in the English language.

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	• 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 Downstrokes Cross-stokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• 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	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Appendix C: CDER Prescription Study Responses

Inpatient Medication Order #1	Inpatient Medication Order #2	Voice Prescription
Zegared OTC	Zegerid	???? OTC
Zegerid	Zegerid	Segorid
Zegerid	Zegerid OTC	Zegaria OTC
Zegerid OTC	Zegerid OTC	Zegrid OTC
Zegerid OTC	Zegerid OTC	
Zegerid OTC	Zegerid OTC	
Zegerid OTC	Zegerid OTC	
Zegerid OTC	Zegerid OTC	
Zegerid OTC	Zegerid OTC	
	Zegerid OTC	
	Zegirid OTC	
	Zegirid OTC	
	Zegirid OTC	
	Zegrerid OTC	
	Zeqerid OTC	
	Zequirid	

Appendix D: Products that lack orthographic and phonetic similarity to Zegerid OTC.

Product name with potential for confusion	**Similarity to Zegerid OTC**
Zestoretic	Look
Xigris	Sound
Zerit	Sound
Zephiran	Look
Omeprazole	Look
Prilosec OTC	Look
Zelnorm	Look and Sound

Appendix E: Products with no numerical overlap in strength and are discontinued.

Product name with potential for confusion	Similarity to Zegerid OTC	Strength	Usual Dose (if applicable)	Marketing Status
Zegerid OTC (Omeprazole and Sodium Bicarbonate)		**Capsules: Omeprazole and Sodium Bicarbonate 20 mg/1100 mg** **Powder for Oral Suspension: Omeprazole and Sodium Bicarbonate 20 mg/1680 mg**	**Usual dose:** **Take one capsule orally once daily in the morning before breakfast for 14 days.** **Take one powder packet mixed in 2 tablespoons (30 ml) or water orally once daily in the morning before breakfast for 14 days.**	
Tepanil (diethylproprion hydrochloride)	Look	Tablet: 25 mg	Discontinued by Drugs@FDA	Discontinued by Drugs@FDA Not listed in the Red Book
Zephrex (Guafieniesin and Pseudoephedrine)	Look	Tablets: 400 mg of Guafieniesin and 60 mg of Pseudoephedrine	Discontinued by Clinical Pharmacology	Discontinued by Clinical Pharmacology Not listed in the Red Book
Tegaserod	Sound	Tablets: 2 mg and 6 mg	**IBS with Constipation:** 6 mg taken twice daily orally before meals for 4 to 6 weeks. **Chronic Idiopathic Constipation:** 6 mg taken twice daily orally before meals.	Discontinued by Drugs@FDA Not listed in the Red Book

Zegerid (Magnesium Hydroxide, Omeprazole and Sodium Bicarbonate)	Look and Sound	Chewable tablets 700 mg Magnesium Hydroxide, 20 mg Omeprazole, and 600 mg Sodium Bicarbonate and 700 mg Magnesium Hydroxide, 40 mg Omeprazole, and 600 mg Sodium Bicarbonate	Take 1 tablet daily for 4 to 8 weeks	Discontinued by Drugs@FDA Not listed in the Red Book
Magnacal (Calcium from citrate (equivalent to 625 mg) 125 mg, Magnesium from oxide (equivalent to 206 mg) 125 mg, Vitamin D (as Vitamin D3) 100 IU)	Look	Nutritional supplement	Nutritional supplement Discontinued by Walgreens.com	Discontinued by Walgreens.com Not listed in the Red Book

Appendix F: Products with no numerical overlap in strength or dose

Product name with potential for confusion	Similarity to Zegerid OTC	Strength	Usual Dose (if applicable)	Source
Zegerid OTC (Omeprazole and Sodium Bicarbonate)		**Capsules: Omeprazole and Sodium Bicarbonate 20 mg/1100 mg** **Powder for Suspension: Omeprazole and Sodium Bicarbonate 20 mg/1680 mg**	**Usual dose:** **Take one capsule orally once daily in the morning before breakfast for 14 days.** **Take one powder packet mixed in 2 tablespoons (30 ml) or water orally once daily in the morning before breakfast for 14 days.**	
Fazaclo ODT (clozapine)	Look	Orally disintegrating tablets: 12.5 mg, 25 mg, 50 mg, and 100 mg	Initial Treatment: 12.5 mg orally once or twice daily Maintenance Dose: 300 mg to 450 mg orally per day in divided doses.	Facts and Comparison
Secretin	Sound	Injection: 16 mcg vials and 40 IU vials	0.2 mcg/kg over 1 minute times one dose Or 0.4 mcg/kg over 1 minute times one dose	Facts and Comparisons

Appendix G: Products with a single strength but have multiple differentiating product characteristics

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose	Other differentiating product characteristics (excluding dose and frequency)
Zegerid OTC (Omeprazole and Sodium Bicarbonate)		**Capsules: Omeprazole and Sodium Bicarbonate 20 mg/1100 mg** **Powder for Suspension: Omeprazole and Sodium Bicarbonate 20 mg/1680 mg**	**Usual dose:** **Take one capsule orally once daily in the morning before breakfast for 14 days.** **Take one powder packet mixed in 2 tablespoons (30 ml) or water orally once daily in the morning before breakfast for 14 days.**	**N/A**
Maginex (magnesium-L-aspartate HCl)	Look	Tablets, enteric coated: 615 magnesium-L-aspartate HCl (61 mg elemental magnesium)	2 tablets orally up to three times daily.	Indication and dosage
Synercid (quinupristin and dalfopristin)	Look	Powder for Injection: 500 mg (150 mg quinupristin; 350mg dalfopristin)/10 mL	Vancomycin-resistant Enterococcus faecium: 7.5 mg per kg intravenously every 8 hours. Complicated skin and structure infections: 7.5 mg per kg every 12 hours	Indication, dosage form, frequency, and route of administration
Migranal (Dihydroergotamine Mesylate)	Look	0.5 mg/Inhalation	1 spray in each nostril followed in 15 minutes by an additional spray in each nostril, for a total of 4 sprays.	Indication, dosage form, route of administration, and frequency

Appendix H: Potential confusing name with numerical overlap in strength or dose

Failure Mode: **Name confusion**	**Causes** **(could be multiple)**	**Effects**
Zegerid OTC (Omeprazole and Sodium Bicarbonate)		**Capsules: Omeprazole and Sodium Bicarbonate 20 mg/1100 mg** **Powder for Oral Suspension: Omeprazole and Sodium Bicarbonate 20 mg/1680 mg**
Zestril (Lisinopril)	Phonetic similarity ('Zes -' vs. 'Zeg-' may sound similar when spoken) Orthographic similarity (both names contain the same number of dotted letters (1) in the same position, (6th letter), both names contain the same numbers of cross strokes (1), both contain the same beginning 'Ze-', both names contain the letter 'r' in the same position (5th letter), and the letters 's' and 'g' may look similar when scripted) Overlapping dose (20 mg) if the sodium bicarbonate component is omitted from the prescription (for example: Zegerid OTC 20 mg), Same frequency (once daily), same route of administration (oral)	Phonetic and orthographic differences and the anticipation of a decrease in prescriptions for Zegerid minimize the likelihood of medication error in the usual practice setting. *Rationale:* The risk for medication error is minimized by the phonetic differences in the names. Zestril has a different number of syllables (2 vs. 3 if the modifier is omitted or 6 if the modifier 'OTC' is included with Zegerid OTC). Additionally the ending of each name ('-tril' vs. '-erid' if the modifier 'OTC' is omitted or 'erid OTC' if the modifier 'OTC' is included with Zegerid OTC) name sounds different when spoken. The risk for medication error is also minimized by the orthographic differences in the names. The names contain a different number of upstrokes (3, capital 'Z', lower case 't and 'l' vs. 2, capital 'Z' and lower case 'd' if the modifier is omitted or 5, capital letter 'Z', lower case 'd', capital 'O', 'T' and 'C' if the modifier 'OTC' is included with Zegerid OTC), and contain a different number of downstrokes (none vs. 1, 'g'). Additionally the ending of each name ('-tril' vs. '-erid' if the modifier 'OTC' is omitted or 'erid OTC' if the modifier 'OTC' is included with Zegerid OTC) name appears different when scripted. Despite an overlapping dose, frequency, strength, route of administration; the phonetic and orthographic differences in addition to the anticipated decrease in prescriptions for Zegerid minimizes the potential for confusion between Zestril and Zegerid OTC.

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