CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-327

PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	April 24, 2009
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Through:	Kellie Taylor, Pharm.D., Team Leader Denise Toyer, Pharm.D., Deputy Director Carol Holquist, R.Ph., Director Division of Medication Error Prevention and Analysis
From:	Cathy A. Miller, M.P.H., B.S.N., Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s):	Prevacid 24HR (Lansoprazole) Delayed-Release Capsule 15 mg
Application Type/Number:	NDA 22-327
Applicant:	Novartis Consumer Health, Inc.
OSE RCM #:	2008-1423

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EXECUTIVE SUMMARY

The DMEPA evaluation found that the proposed name, Prevacid 24HR, has some similarity to other proprietary and established drug names, but the findings of the FMEA indicated that the proposed name did not appear to be vulnerable to name confusion that could lead to medication errors. However, the Division of Gastroenterology Products (DGP) and the Division of Non-Prescription Clinical Evaluation (DNCE) expressed concerns with the use of the proposed trade name "Prevacid 24HR'. Specifically, there is concern that the modifier '24HR' could be misinterpreted by consumers as relating to the product's duration of action (1 day) or course of treatment (1 day). After discussions between DMEPA, DNCE, DGP and the Applicant, an agreement was reached to incorporate additional language to labels and labeling aimed to provide clarification to the consumer about duration of action and course of treatment. On April 6, 2009, the Applicant submitted revisions to labels and labeling, proposing the addition of the statement *"Make take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours"* to the principal display panel of container labels, carton labeling and package insert labeling. The Applicant's proposed wording mitigated FDA's promotional concerns with the '24HR' modifier and thus, determined to be acceptable by DMEPA as well as DNCE and DGP.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from the Division of Nonprescription Clinical Evaluation submitted to the Division of Medication Error Prevention and Analysis (DMEPA) on September 2, 2008, for the assessment of the proprietary name, Prevacid 24HR for new drug application (NDA 22-327) for the over-the-counter marketing of Lansoprazole Delayed-Release 15 mg Capsules. Along with the proposed proprietary name submission, the Applicant also submitted an external name study for review (Prevacid OTC Name Study Evaluation). Additionally, container labels, carton labeling and package insert were submitted and are reviewed in a separate OSE Review.

1.2 REGULATORY HISTORY

Prevacid (Lanzoprazole) Delayed-Release Capsule (15 mg and 30 mg strengths), is a prescription drug product approved on May 10, 1995 under new drug application (NDA 20-406 marketed by TAP Pharmaceutical Products), for multiple gastric related indications including short-term treatment of active duodenal ulcers, H. Pylori eradication triple therapy and dual therapy, maintenance of healed duodenal ulcers, short-term treatment of active benign gastric ulcers, healing of NSAID-associated gastric ulcers/risk reduction of NSAID-associated gastric ulcer, Gastroesophageal Reflux Disease (GERD), maintenance of healing erosive esophagitis and pathological hypersecretory conditions including Zollinger-Ellision Syndrome.

Novartis Consumer Health, Inc. has an agreement with TAP Pharmaceutical Products, Inc., the holder of NDA 20-406 and IND 30,159 [Prevacid (Lansoprazole) Delayed-Release Capsules], granting Novartis full right of reference to the NDA and IND data in support of all applications related to over-the-counter use Prevacid. In a letter to the Agency dated March 6, 2008, TAP Pharmaceutical Products authorized the Agency to cross-reference these data in support of Novartis' program.

On July 15, 2008, in accordance with 21 C.F.R. 314.50, Novartis Consumer Health, Inc. submitted new drug application (NDA 22-327) for the over-the-counter (OTC) marketing of Lansoprazole Delayed-Release Capsules 15 mg, for the treatment of frequent heartburn (occurring two or more days a week). Novartis has proposed the tradename, Prevacid 24HR, for their over-the-counter Lansoprazole Delayed Release Capsule, citing the name is designed to communicate to consumers that the product is effective over a 24-hour period when taken once a day, as directed, for the fourteen-day course of treatment.

1.3 PRODUCT INFORMATION

Prevacid 24HR (Lansoprazole) Delayed-Release Capsules, 15 mg, is indicated for the treatment of frequent heartburn (occurring two or more days a week) in adults eighteen years of age or older. One capsule of Prevacid 24HR should be taken once daily with a glass of water before eating in the morning. Prevacid 24HR is a fourteen-day course of treatment and should not exceed fourteen days unless directed by a physician. The fourteen-day course of treatment may be repeated every four months.

Prevacid 24HR will be available in a fourteen capsule bottle, to facilitate the fourteen day course of treatment. Packaging for Prevacid 24HR will include three carton sizes including a carton containing one fourteen-count bottle (14 capsules), a carton containing two fourteen-count bottles (28 capsules), and a carton containing three fourteen-count bottles (48 capsules).

2 METHODS AND MATERIALS

This section describes the methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment (See 2.1 Proprietary Name Risk Assessment). The primary objective for the assessment is to identify and remedy potential sources of medication error prior to drug approval. 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]

2.1 PROPRIETARY NAME RISK ASSESSMENT

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.

For the proposed proprietary name, DMEPA staff searched a standard set of databases and information sources to identify names with orthographic and phonetic similarity (See 2.1.1 for details) and held a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (See 2.1.1.2). DMEPA staff also conducts internal CDER prescription analysis studies. When provided, external prescription analysis studies results are considered and incorporated 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 (See 2.1.2 for details). The overall risk assessment is based on the findings of a Failure Mode 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 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 it's 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

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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.

differentiate the products through dissimilarity. Accordingly, DMEPA 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 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

DMEPA considers 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 letters '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.[4,5]

To identify drug names that may look similar to Prevacid 24HR, the DMEPA considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name, Prevacid (eight letters) 24HR (four letters), upstrokes (three capital letters 'P', 'H' and 'R', one 'd'), downstrokes (none), cross-strokes (none) , dotted letters (one 'i') and numbers (two '2' and '4').

Additionally, several letters in Prevacid 24HR may be vulnerable to ambiguity when scripted, including the capital letter 'P' may appear as capital letter case 'B' or 'R'; lower case 'r' may appear as lower case ''n', 'u'or 'v'; lower case 'e' may appear as lower case 'i' or 'l'; lower case 'v' may appear as lower case 'r' or 'u'; lower case 'a' may appear as lower case 'o' or 'u'; lower case 'c' may appear as lower case 'a' or 'o'; lower case 'i' may appear as lower case 'i' or 'l'; and lower case 'd' may appear as lower case 'l' or 'a'. Additionally, the '24HR' is evaluated against other drug names with similar numeric representation '24' and abbreviated alpha-lettering representation 'HR'. As such, the staff also considers these alternate appearances when identifying drug names that may look similar to Prevacid 24HR.

When searching to identify potential names that may sound similar to Prevacid 24HR, DMEPA searches names with similar number of syllables (3), stresses (PRE-va-cid), and placement of vowel and consonant sounds. Phonetic considerations were also given to the pronunciations of Prevacid 24HR that include the 'Pre' being pronounced with a hard 'e' sound rather than a soft 'e' sound, the 'va' being pronounced with a hard 'a' rather than a soft 'a', and 'cid' being pronounced as 'kid'.

DMEPA also considers 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 DMEPA were

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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. Artificial Intelligence in Medicine (2005)

provided with the following information about the proposed product: the proposed proprietary name (Prevacid 24HR), the established name (Lansoprazole), proposed indication (treatment of heartburn occurring more than two days a week), strength (15 mg), dose (15 mg or one capsule) frequency of administration (once daily), duration of therapy (fourteen day course of treatment), route (oral) and dosage form (capsule). Appendix A provides a more detailed listing of the product characteristics DMEPA generally takes into consideration.

Lastly, DMEPA considers 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 DMEPA provides additional comments related to the safety of the proposed name or product based on their professional experience with medication errors.

2.1.1.1 Database and Information Sources

The proposed proprietary name was provided to DMEPA 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 the proposed proprietary name using the criteria outlined in Section 2.1.1. A standard description of the databases used in the searches is provided in Section 7. To complement the process, DMEPA used 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 reviewed the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators were then pooled and presented to the CDER Expert Panel.

2.1.1.2 CDER Expert Panel Discussion

An Expert Panel Discussion is held by DMEPA 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). Potential concerns regarding drug marketing and promotion related to the proposed names are also discussed.

The pooled results of DMEPA 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.

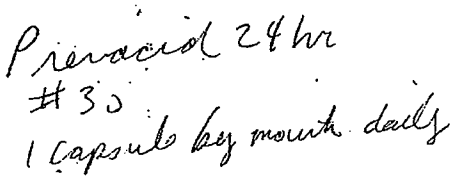
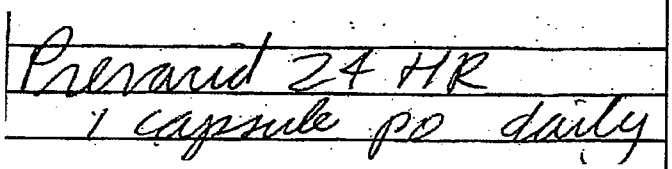
2.1.2 FDA Prescription Analysis Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Prevacid 24HR 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 Prevacid 24HR 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 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 DMEPA. It is noted that the prescription studies included the frequency of twice daily in error rather than once daily.

Figure 1. Prevacid 24HR Study (conducted on 12/18/2008)

HANDWRITTEN PRESCRIPITON AND MEDICATION ORDER	VERBAL PRESCRIPTION
Outpatient Prescription  	Prevacid 24HR Number 30 One capsule by mouth QD
Inpatient Medication Order :  	

2.1.3 Comments from the Office of New Drugs

DMEPA requests the regulatory division in the Office of New Drugs 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 the Division of Drug Marketing, Advertising and Communication decision on the name. Any comments or concerns are addressed in the safety evaluator's assessment.

The 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 regulatory division is requested to concur/not concur with DMEPA's final decision.

2.1.4 Safety Evaluator Risk Assessment of the Proposed Proprietary Name

Based on the criteria set forth in Section 2.1, the Safety Evaluator Risk Assessment applies his/her individual expertise gained from evaluating medication errors reported to FDA to conduct 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 as a result of the 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 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 A. 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 Prevacid 24HR 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 Prevacid 24HR 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 posses similarity that would cause confusion at any point in the medication use system, then 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 not ultimately 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; for example, 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.

DMEPA 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

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

through a PROPRIETARY name or otherwise. [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

2. 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)].
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 (United States Adopted Names) stem, particularly in a manner that is contradictory to the USAN Council's definition.
5. 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.

In the event 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 is awarded approval first has the right to the use the name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

If none of these criteria are met, then DMEPA will not object to the use of the proprietary name. If any of these criteria are met, then DMEPA will object to the use of the proposed 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 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), who 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, 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, 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 and other post-approval efforts are low-leverage strategies that have proven to have limited effectiveness at alleviating 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 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).

If DMEPA objects 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. 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.

2.1.5 Prevacid OTC Name Evaluation Study

Novartis Consumer Health, Inc. sponsored a Name Evaluation Study conducted by ——— to identify an appropriate proprietary name for over-the-counter Lansoprazole Delayed-Release Capsules. They surveyed a U.S. sample of adult males and females selected from — U.S. Online Panel who were not employed in a competitive occupation/industry, and who were at least six month heartburn, indigestion or acid reflux sufferers. Panelists were tested based on a 'Round the Clock Heartburn Relief' concept description provided. In developing the proposed tradename, Novartis tested several potential tradenames to determine the optimal means of communicating the product's use and benefits. Fifteeen names were developed and subsequently tested amongst the consumer panelists. Panelists were exposed to the fifteen selected names and were tested based on criteria including overall appeal of the name, appropriateness, how they would describe the product to a friend, uniqueness, ranking of name, as well as reasons names were liked best or least, name imagery statements, and preference ranking versus 'Prevacid'. Results of the report were compiled and submitted in Novartis' Prevacid OTC Name Evaluation Final Report dated June 2007. b(4)

2.2 ADVERSE EVENT REPORTING SYSTEM (AERS)

On October 1, 2008, the Division of Medication Error Prevention and Analysis conducted a search of the FDA Adverse Event Reporting System (AERS) database to identify post-marketing reports of medication errors associated with the currently marketed product, Prevacid (Lansoprazole) Delayed-Release Capsules. The following criteria were used: MedDRA High Level Group Term (HLGT) 'Medication Errors' and the Preferred term (PT) 'Pharmaceutical Product Complaint' with the active ingredient (Lansoprazole), trade name (Prevacid), and verbatim term 'Prevacid%'.

The cases were manually reviewed to determine if medication errors occurred involving the label/labeling and/or nomenclature. Those cases that did not describe a medication error were excluded from further analysis. The cases that did describe a medication error were categorized by type of error. We reviewed the cases within each category to identify contributing factors.

3 RESULTS

3.1 PROPRIETARY NAME RISK ASSESSMENT

3.1.1 Database and Information Sources

The searches yielded 17 names as having some similarity to Prevacid 24HR.

Thirteen names were thought to look like Prevacid 24HR. They include: Duricef, Pravachol, Prevail, Prevalin, Prevask, Prevident, Previfem, Prezista, Prialt, Prinivil, Prinzide, Proventil and Provera. b(4)

One name, ——— was thought to sound like Prevacid 24HR.

Three names were thought to look and sound like Prevacid 24HR. They include: Prevacid, Prevacid I.V. and Prevacid Naprapapac.

Additionally, DMEPA did not identify any United States Adopted Names (USAN) stems in Prevacid 24HR as of March 3, 2009.

3.1.2 Expert Panel Discussion

The Expert Panel reviewed the pool of names identified by the staff (see section 3.1.1. above) but did not identify any additional names with similarity to Prevacid 24HR.

Although the Agency does not maintain regulatory authority for promotional aspects related to over-the-counter drug products, DDMAC provided comments on the proposed proprietary name, stating "Prevacid 24 HR" overstates the efficacy of the drug product. They acknowledge that "Prevacid" is currently on the market. However, the term "24 HR" easily evokes the term "24 Hour", and misleadingly implies that the drug is guaranteed to be effective in the treatment of frequent heartburn for a full 24 hours. In the absence of substantial evidence to support such a treatment duration (i.e., that once-daily dosing equates to consistent efficacy over a 24-hour time period), and that the proposed trade name is misleading.

3.1.3 FDA Prescription Analysis Studies

A total of 24 practitioners responded to the FDA prescription analysis studies but none of the responses overlapped with any existing or proposed drug names. Only two of the participants interpreted the name correctly as "Prevacid 24HR" with misinterpretations dispersed equally between both the written and verbal studies. Fifteen respondents interpreted the name as "Prevacid 24" without the 'HR' modifier, and an additional five respondents interpreted the name as "Prevacid" only without a modifier. See Appendix B for the complete listing of interpretations from the verbal and written prescription studies.

3.1.4 Prevacid OTC Name Evaluation Study

The Applicant reported that of the fifteen names tested with consumer panelists, Prevacid 24HR ranked highest overall in most categories across all key subgroups of the study. The Applicant proposes that the tradename 'Prevacid 24HR' communicates to consumers that the product is effective over a 24-hour period when taken once a day, as directed, for a fourteen-day course of treatment. They also proposed that this tradename differentiates the OTC product from prescription Prevacid and precludes potential confusion with the current OTC proton pump inhibitor, Prilosec OTC. Both Prevacid 24HR and ——— — rated highest in the study. The main reasons that the "24HR" and — names were preferred according to consumers tested was the names communicated the 24 hour relief the product provides ——— works 24 hours all day). Secondarily, consumers reported that they liked that the names communicate a clear, concise, positive description of the product, "what the product does and what you get from it". (See Appendix C for complete list of names evaluated in the study). b(4)

3.1.5 Adverse Event Reporting System (AERS)

Our Adverse Event Reporting System database search retrieved five relevant cases of medication errors associated with nomenclature, labels or labeling for the prescription strength Prevacid product.

Four cases involved reports of 'potential' medication error due to name confusion. Three of the four cases involved Prevacid versus Pravachol name confusion and in all cases, reporting pharmacists cited 'potential' for confusion between Prevacid and Pravachol due to orthographic and phonetic similarities between the two names. No medication error occurred for these three cases but the reporters emphasized the potential for medication error or delay of treatment occurring due to the similarities. One of the four cases involved potential name confusion between Prevacid and Prinivil. A pharmacist reported a potential medication error due to illegible prescription making 'Prevacid' look alike 'Prinivil'. No actual medication error occurred.

The fifth case retrieved involved a medication error due to name confusion between Prevacid and Prilosec. The pharmacist received a prescription for the compounded form of Prevacid (Lansoperazole) oral suspension and incorrectly labeled and filled the prescription with Omeperazole oral suspension (Prilosec). The medication reached the patient and the error was discovered by the patient after

approximately one month with no adverse outcomes reported. The pharmacist cited 'look-alike' quality of the names as a contributing factor for the medication error occurrence but specified 'Omeprazole' versus 'Lansoperazole' as the names of confusion, not the brand names 'Prevacid' and 'Prilosec'.

3.1.6 Safety Evaluator Risk Assessment

Independent searches by the primary Safety Evaluator identified five additional names thought to both look like Prevacid 24HR and represent a potential source of drug name confusion: Paremyd, Pediapred, Pepcid, Prilosec and Prilosec OTC. As such, a total of 22 names were analyzed to determine if the drug names could be confused with Prevacid 24HR, and if the drug name confusion would likely result in a medication error.

Two names lacked orthographic and/or phonetic similarity and were not evaluated further (See Appendix D).

Failure mode and effect analysis (FMEA) was then applied to determine if the potential name could potentially be confused with any of the remaining 20 names and lead to medication errors. This analysis determined that the name similarity between Prevacid 24HR and the identified names was unlikely to result in medication errors with any of the 20 products identified for the reasons presented in Appendices E through K.

3.1.7 Comments from the Office of New Drugs

On October 6, 2008, DMEPA requested that the Division of Gastroenterology Products and the Division of Non-Prescription Clinical Evaluation provide comments on any potential clinical issues related to the Applicant's proposed proprietary name, Prevacid 24 HR. Additionally, the Divisions were asked to comment on the DDMAC comments provided regarding proposed proprietary name, Prevacid 24HR.

On December 2, 2008, DMEPA met with representatives of both the Division of Gastroenterology Products (DGP) and the Division of Non-Prescription Clinical Evaluation (DNCE) to discuss potential clinical concerns of the proposed proprietary name, Prevacid 24HR. Both Divisions expressed concerns with the Applicant's proposed proprietary name, Prevacid 24HR. Specifically, there was concern that the modifier '24HR' implies a use (night-time heartburn relief) beyond the supported indication (frequent heartburn). Prevacid 24HR has not been adequately studied for night-time heartburn relief. Additionally, the clinical review team expressed concerns that the '24HR' modifier could be misinterpreted by consumers as relating to the product's duration of action (1 day) or course of treatment (1 day). The proposed label states that optimal relief of frequent heartburn may be achieved after one to four days of consecutive use for full effect, and the recommended course of therapy is 14 days.

On March 3, 2009, DMEPA met with DNCE and DGP to further discuss the proposed proprietary name, Prevacid 24HR, in order to formulate guidance to provide to the Applicant for their product name. Options included proposing a completely different proprietary name, considering an alternative modifier or adding clarifying language to product labels and labeling aimed to inform the consumer about the duration of action and course of treatment. On March 17, 2009, DMEPA, DNCE and DGP staff met again in a teleconference with the Applicant to discuss concerns and evaluated alternatives. On April 6, 2009, the Applicant submitted revised labels and labeling that include the statement *"Make take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours"*, which DNCE, DGP and DMEPA found acceptable (See Appendix J for proposed container labels and labeling).

4 DISCUSSION

4.1 PROPRIETARY NAME RISK ASSESSMENT

Twenty-one names were evaluated for their potential similarity to the proposed name, Prevacid 24HR. The FMEA indicates that the proposed name is not likely to result in name confusion that could lead to medication errors.

As identified by both the Divisions of Gastroenterology Products and the Division of Non-Prescription Clinical Evaluation, the modifier '24HR' could be misinterpreted by consumers as relating to the product's duration of action (1 day) or course of treatment (1 day). The proposed label states that optimal relief of frequent heartburn may be achieved after one to four days of consecutive use for full effect, and the recommended course of therapy is 14 days. DMEPA, along with DGP and DNCE agreed that the Applicant's proposal to add the statement *"Make take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours"* to the principal display panel of container labels, carton labeling, as well as package insert labeling would help inform consumers about the product's duration of action and frequency of use. The addition of this statement alleviated DNCE and DGP promotional concerns with the proposed proprietary name.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Prevacid 24HR, does not appear to be vulnerable to name confusion that could lead to medication errors. Additionally, DMEPA, DNCE and DGP agree that the acceptability of the name from a promotional perspective is contingent upon the Sponsor's proposal to add the statement *"Make take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours"* to Prevacid 24HR container labels, carton labeling and package insert labeling. This statement is necessary to provide clarification to the consumer about the duration of action and course of treatment.

6 RECOMMENDATIONS

6.1 COMMENTS TO THE DIVISION

We would be willing to meet with the Division for further discussion, if needed. Please copy us on any communication to the applicant with regard to this review. If you have further questions or need clarifications, please contact Cherye Milburn, Project Manager, at 301-796-2084.

6.2 COMMENTS TO THE APPLICANT

6.2.1 Proprietary Name

We have completed our review of the proposed proprietary name, Prevacid 24HR and have concluded that it is acceptable with the provision that the additional language be added to the principal display panel of container labels and carton labeling, as well as package insert labeling as follows: *"Make take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours"* as proposed in your April 6, 2009 submission (NDA 22-327, Amendment 13).

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, call Cherye Milburn, Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (301) 796-2084. For any other information regarding this application contact the Division of Nonprescription Clinical Evaluation Regulatory Project Manager, Mary Vienna at (301) 796-4150.

7 REFERENCES

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

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

2. Phonetic and Orthographic Computer Analysis (POCA)

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

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

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

4. AMF Decision Support System [DSS]

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

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

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

9. Clinical Pharmacology Online (www.clinicalpharmacology-ip.com)

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

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

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

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

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

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

Stat!Ref contains full-text information from approximately 30 texts; it 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.

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

USAN Stems List contains all the recognized USAN stems.

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

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

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

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

16. ***Medical Abbreviations Book***

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

APPENDICES

Appendix A:

DMEPA 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 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 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. DMEPA 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), along with other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, 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. 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	• 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-strokes Dotted letters	• Names may look similar when scripted, and lead to drug name confusion in written communication

		Ambiguity introduced by scripting letters Overlapping product characteristics	
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

Appears This Way
On Original

Appendix B: FDAPrescription Study Responses – Prevacid 24HR

INPATIENT STUDY	OUTPATIENT STUDY	VERBAL STUDY
Prevacid	Prevacid 24	Prevacid 24
Prevacid	Prevacid	Pervacid
Prevacid 24	Prevacid	Prevacid 24
Prevacid 24	Prevacid 14	Prevacid 24HR
Prevacid 24	Prevacid 24	
Prevacid 24	Prevacid 24	
Prevacid 24	Prevacid 24	
	Prevacid 24	
	Prevacid 24	
	Prevacid 24	
	Prevacid 24	
	Prevacid 24hr	
	Prevacol	

Appendix C: Novartis Name Evaluation Report for Prevacid 24HR

Proprietary Names Considered and Tested by Consumer Panel
[redacted]
Prevacid 24HR
[redacted]

b(4)

Appendix D: Drug names lacking convinging look or sound-alike similarities to Prevacid 24HR

Proprietary Name	Similarity to Prevacid 24HR
[redacted]	Sound-Alike
Prialt	Look-Alike

b(4)

Appendix E: Drug names that were past proposed proprietary names**

Proprietary Name	Similarity to Prevacid 24HR	Status
[redacted]	Look-Alike	Alternate Proprietary Name (Iprivask) selected – NDA approved 4/2003

b(4)

Appendix F: Drug names of New Drug Applications Withdrawn from Agency

Proprietary Name	Similarity to Prevacid 24HR	Application Status
[redacted]	Look-Alike	Withdrawn by Applicant June 29, 2005

b(4)

Appendix G: Drug names with no numerical overlap in strength and dose

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
Prevacid 24HR (Lansoprazole) Delayed-Release Capsules		**15 mg Capsule**	**Take One Capsule with a glass of water before eating in the morning once daily for fourteen days. You may repeat a fourteen-day course every four months. Do not use for more than fourteen days or more often than every four months unless directed by your doctor.**
Duricef (Cefadroxil and Cefadroxil Hemihydrate)	Look-Alike	250 mg and 500 mg Oral Capsule 125 mg, 250 mg and 500 mg Oral Suspension	Adults: 1 or 2 grams per day in a single or two divided doses. Children: 30 mg/kg/day in divided doses every twelve hours
Pepcid (Famotidine)	Look- Alike	20 mg and 40 mg Oral Tablets 40 mg/5 mL Oral Suspension 10 mg/mL Solution for Injection	40 mg once daily at bedtime or 20 mg twice daily for acute therapy of active duodenal ulcer or GERD 20 mg once daily at bedtime for maintenance 40 mg once daily at bedtime for active benign gastric ulcer Oral Suspension may be substituted for tablets 20 mg intravenously every twelve hours
Prevalin (Cromolyn Sodium)	Look-Alike	20 mcg/2 mL Inhalation Solution 4 % Ophthalmic Solution 5.2 mg/spray Metered Nasal Spray	20 mcg Nebulizer Solution four times daily 2 metered sprays (800 mcg/spray) from metered-dose inhaler four times daily One spray in each nostril three to four times daily
Prezista (Darunavir)	Look-Alike	300 mg or 600 mg tablets	600 mg twice daily with Ritonavir 100 mg
Prinzide (Hydrochlorothiazide and Lisonopril)	Look- Alike	12.5 mg/20 mg Oral Tablet 25 mg/20 mg Oral Tablet 12.5 mg/10 mg Oral Tablet	10 mg/12.5 mg to 20 mg/12.5 mg when switched from lisinopril or hydrochlorothiazide monotherapy. Further increases of either component could depend on clinical response.
Proventil* (Albuterol Sulfate) Discontinued but generics available	Look-Alike	2 mg and 4 mg Oral Tablet 2 mg/5 mL Oral Syrup 0.042 %, 0.5 % and 0.083 % Inhalation Solution	Oral Tablets and Oral Syrup: 2 mg to 4 mg every six to eight hours Oral Inhalation: 90 mcg to 180 mcg (1 to 2 inhalations) every four to six hours

Appendix H: Drug names with overlap in single strength availability but with other differentiating product characteristics

Product name with potential for confusion	**Strength**	**Usual Dose (if applicable)**	**Differentiating Product Characteristics**
Prevacid 24HR (Lansopraxole) Delayed-release Capsules	**25 mg Capsule**	**Take one capsule once daily in morning for fourteen days**	**Dose expressed 'take one capsule'** **Dosage form is capsule** **Route of administration is oral**
Paremyd (Hydroxyamphetamine Hydrobromide and Tropicamide)	1 % Hydroxyamphetamine Hydrobromide and 0.25 % Tropicamide Ophthalmic Solution	One to two drops in the conjunctival sac for Mydriasis.	Dose expressed as 'one to two drops' Dosage form is solution Route of administration is ophthalmic
Prevident (Sodium Fluoride) Dental Gel and Dental Paste	1.1 % Brush on Gel 1.1 % Brush on Paste	Brush on to teeth and rinse; avoid overuse or ingestion	Dose expressed as 'brush onto teeth' Dosage form is oral gel or oral paste Route of administration is topical

Appendix I: Drug names with potential for confusion due to single strength availability or numeric overlap in strength, dose or attainable dose

Failure Mode: Name confusion	Causes (could be multiple)	Effect
Prevacid 24HR (Lansoprazole) Delayed-Release Capsules	**15 mg Capsule**	**Take One Capsule with a glass of water before eating in the morning once daily for fourteen days. You may repeat a fourteen-day course every four months. Do not use for more than fourteen days or more often than every four months unless directed by your doctor.**
Pediapred (Prednisolone Sodium Phosphate) 5 mg/5 mL Oral Solution	Orthographic similarities: Both names begin with 'P' and end with 'd'. Both names have an 'e' similarly placed at the beginning of the name. Overlap in dose: Prevacid 24HR 15 mg and possible dosing of Pediapred 5 mg/5 mL if 15 mL given.	Orthographic differences in the names, dose form and usual dose minimize the likelihood of medication error in the usual practice setting: *Rationale:* Pediapred contains a downstroke letter 'p' not presented in Prevacid, differentiating the shapes of the two names. The '24HR' in Prevacid 24HR differentiates the name from Pediapred and minimized the risk of name confusion. Prevacid 24HR will be available over-the-counter however, Pediapred is available by prescription only therefore, cannot be self-selected by consumers in pharmacies or retail stores. However, if Prevacid 24HR is written as a prescription, dosage form and usual dose differentiate the two drugs. Pediapred is available as an oral solution, dosed in milligrams and/or milliliters (5 mL to 60 mL per day) while Prevacid 24HR is an oral capsule dosed as take one capsule. These variations are differentiated on prescription orders and would minimize the risk of confusion that could lead to medication error.
Prevacid (Lansoprazole) 15 mg and 30 mg Delayed Release Capsule 15 mg/packet and 30 mg/packet for oral suspension 15 mg and 30 mg Oral Disintegrating Tablet	Orthographic similarities: Both names contain the trade name 'Prevacid'.	Orthographic differences in the names and variations in dosage form and strengths minimize the likelihood of medication error in the usual practice setting. *Rationale:* The '24HR' in Prevacid 24HR differentiates the name from Prevacid and minimized the risk of name confusion. Prevacid 24HR is only available in a 15 mg strength while prescriptions for Prevacid are available in 15 mg and 30 mg strengths and different dosage forms.
Prevacid I.V. (Lansoprazole) 30 mg/vial for Injection	Orthographic similarities: Both names contain the trade name 'Prevacid'.	Orthographic differences in the names and variations in dosage form, clinical setting of use and route of administration minimize the likelihood of medication error in the usual practice setting. *Rationale:* The 'I.V.' looks different than the '24HR' when scripted differentiating the two drug names and minimizes the risk of name confusion. Prevacid 24HR will be available over-the-counter however, Prevacid I.V. is available by prescription only therefore, cannot be self-selected by consumers in pharmacies or retail stores. However, if Prevacid 24HR is written as a prescription, route of administration will differentiate the two drug products. Physician prescription orders would specify dose, dose form and route of administration, which would differentiate the two products and minimize the potential of medication error occurring.

Prevacid Naprapapac (Lansoprazole Delayed-Release Capsule and Naproxen Tablets) Kit 15 mg Lansoprazole Delayed-Release Capsule and 250 mg Naproxen Tablet 15 mg Lansoprazole Delayed-Release Capsule and 375 mg Naproxen Tablet 15 mg Lansoprazole Delayed-Release Capsule and 500 mg Naproxen Tablet	Orthographic similarities: Both names contain the trade name 'Prevacid'.	Orthographic differences in the names, dosing regimen and multiple combination strength availability minimize the likelihood of medication error in the usual practice setting. *Rationale:* The additional word 'Naprapapac' differentiates this drug name from Prevacid 24HR and minimized the risk of name confusion. Prevacid 24HR will be available over-the-counter however, Prevacid Naprapapac is available by prescription only therefore, it cannot be self-selected by consumers in pharmacies or retail stores. However, if Prevacid 24HR is written as a prescription, strength availability and frequency will differentiate the two drug products. Prevacid Naprapapac is available in three different combination strengths (15 mg/250 mg, 15 mg/375 mg and 15 mg/500 mg) while Prevacid 24HR is available only in a 15 mg strength. Dosing frequency for Prevacid 24HR is 15 mg once daily while Prevacid Naprapapac includes one 15 mg Lansoprazole tablet in the morning along with the specified dose of Naproxen twice daily.
Previfem (Ethinyl Estradiol and Norgestimate) 0.035 mg Ethinyl Estradiol and 0.25 mg Norgestinate Tablet	Orthographic similarities: Both names begin with 'Prev'.	Orthographic differences in the names minimize the likelihood of medication error in the usual practice setting. *Rationale:* The endings of the names vary orthographically with 'fem' containing an upstroke 'f' not present in Prevacid, and 'cid' containing an upstroke 'd' in the last letter position not present in Previfem. Additionally, the modifier '24HR' provides added distinction that differentiate the two names and make Prevacid 24HR appear longer when scripted.
Prinivil (Lisinopril) 5 mg, 10 mg, 20 mg, 40 mg Oral Tablets	Orthographic similarities: 'Pre' looks like 'Pri'; the 'v' in Prevacid 24HR can look like 'n' in Prinivil; the 'd' in Prevacid looks similar to 'l' in Prinivil Overlap in dose: Prevacid 24HR 15 mg and possible dosing of Prinivil 15 mg	Orthographic differences in the names, usual recommended dose and available strengths minimize the likelihood of medication error in the usual practice setting. *Rationale:* Although both names share orthographic similarities in the core name (Prevacid and Prinivil), the additional '24HR' differentiates Prevacid 24HR from Prinivil making the name appear longer when scripted. Additionally, the 'v' is located in the fourth letter position of Prevacid 24HR and is positioned in the sixth letter position of Prinivil. Prevacid 24HR is available in one '15 mg' strength and the dose would be written 'take one tablet' on prescription orders. Prinivil is available in four strengths while Prevacid 24HR is only available in one '15 mg' strength.
Provera (Medroxyprogesterone Acetate) 2.5 mg, 5 mg and 10 mg Oral Tablets	Orthographic similarities: 'Pro' looks like 'Pre'; 'v' similarly placed in both names; 'a' can look like 'd'. Overlap in dose: Prevacid 24HR 15 mg is attainable for Provera by dosing a 5 and 10 mg tablet or three 5 mg tablets.	Orthographic differences in the names, multiple strength availability and usual recommended dose minimize the likelihood of medication error in the usual practice setting. *Rationale:* The '24HR' differentiates Prevacid 24HR from Provera orthographically. Additionally, Prevacid contains a dotted 'i' not present in Provera and Prevacid 24HR appears longer when scripted. Prevacid 24HR will be available over-the-counter, however, Provera is available by prescription only therefore, cannot be self-selected by consumers in pharmacies or retail stores. However, if Prevacid 24HR is written as a prescription, the usual dose 'take one tablet' while the usual dose for Provera is either 5 mg or 10 mg. Because of Provera's unique dosing regimen specific to menstrual cycle, prescription orders would likely include directives such as "begin on 'X' day of menstrual cycle" which would differentiate the two products.

Appendix J: Drug names with potential for confusion due to drug class and over-the-counter availability

Failure Mode: Name confusion	Causes (could be multiple)	Effect
Prevacid 24HR (Lansoprazole) Delayed-Release Capsules	**15 mg Capsule**	**Take One Capsule with a glass of water before eating in the morning once daily for fourteen days. You may repeat a fourteen-day course every four months. Do not use for more than fourteen days or more often than every four months unless directed by your doctor.**
Prilosec (Omeprazole Magnesium) Delayed-Release Pellets 10 mg, 20 mg and 40 mg Oral Suspension 2.5 mg and 10 mg per packet	Orthographic similarities: Both names begin similarly 'Pre' and 'Pri'; 'a' can look like 'o' and are similarly positioned in the names. Both drugs are acid reducers with the same indication of treating 'heartburn', will be stored in similar locations on pharmacy shelves, and have the same limited duration of therapy.	Orthographic differences in the names, available strengths and variations in dosage form and usual dose minimize the likelihood of medication error in the usual practice setting: *Rationale:* Medication error between Prevacid 24HR and the prescription form of Prilosec is unlikely due to '24HR' which differentiate the names orthographically. Additionally, Prilosec contains an upstroke 'l' not present in the same location of Prevacid. Prevacid 24HR contains an upstroke 'd' in the last letter position not present in Prilosec 'c' further differentiating the two names when scripted. The usual dose for Prilosec ranged from 20 mg to 40 mg, depending on indication, with pediatric dosing ranging from 5 mg to 10 mg. The usual dose for Prevacid 24HR is 15 mg. Although prescribing orders for Prevacid 24HR may be written 'take one tablet' since there is only one strength, orders for Prilosec would require the strength be included since there are varying strengths for different indications, which would provide distinction between the two products. And although our AERS search did identify one case of name confusion between Prilosec and Prevacid, that case involved confusion with the established names (Lansoperazole versus Omeprazole). In the usual clinical practice setting, however, prescription orders are likely to be written using the tradename 'Prevacid 24HR' rather than the established name.
Prilosec OTC (Omeprazole Magnesium) Delayed Release Tablet 20 mg	Orthographic similarities: Both names begin similarly 'Pre' and 'Pri'; 'a' can look like 'o' and are similarly positioned in the names. Both drugs are acid reducers with the same indication of treating 'heartburn', will be stored in similar locations on pharmacy shelves, and have the same limited duration of therapy.	Orthographic differences in the names minimize the likelihood of medication error in the usual practice setting: *Rationale:* Orthographic variations in 'Prilosec OTC' versus 'Prevacid 24HR' minimize the potential for this error. 'OTC' appears considerably different than '24HR' on container labels/carton labeling, as well as on written prescriptions. Additionally, Prilosec contains an upstroke 'l' not present in the same location of Prevacid. Prevacid 24HR contains an upstroke 'd' in the last letter position not present in Prilosec 'c' further differentiating the two names when scripted. Should prescription orders for the products be written with the strength, the '20 mg' versus '15 mg' would provide additional distinction that would minimize the likelihood of medication error. And although our AERS search did identify one case of name confusion between Prilosec and Prevacid, that case involved confusion with the established names (Lansoperazole versus Omeprazole). In the usual clinical practice setting, however, prescription orders are likely to be written using the tradename 'Prevacid 24HR' rather than the established name.

Appendix K: Look-Alike Drug names with potential for confusion

Failure Mode: Name confusion	Causes (could be multiple)	Effect
Prevacid 24HR (Lansoprazole) Delayed-Release Capsules	**15 mg Capsule**	**Take One Capsule with a glass of water before eating in the morning once daily for fourteen days. You may repeat a fourteen-day course every four months. Do not use for more than fourteen days or more often than every four months unless directed by your doctor.**
Pravachol (Pravastin) 10 mg, 20 mg, 40 mg and 80 mg Oral Tablets Adults: 40 mg once daily; if results not achieved, 80 mg once daily recommended 10 mg daily for patients with history of significant renal or hepatic dysfunction Children (Ages 8 to 13 yrs): 20 mg once daily Adolescents (Ages 14 to 18 yrs): 40 mg once daily	Orthographic similarities: 'Pravac' looks like 'Prevac' and 'd' can look like 'l'.	Available strengths and usual dose variations minimize the likelihood of medication error in the usual practice setting: *Rationale:* Pravachol is available in five different strengths with usual dosing that ranges from 10 mg up to 80 mg depending on patient age and clinical profile. Prescription orders would include the strength specified as take 'X' mg once daily. Prevacid 24HR is only available in one 15 mg strength and prescription orders would either be written as '15 mg' or 'take one tablet' daily, which would differentiate the two products.

1 Page(s) Withheld

____ Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

____ Draft Labeling (b5)

____ Deliberative Process (b5)

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