CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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PROPRIETARY NAME REVIEW(S)

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

Date:	April 18, 2008
To:	Donna Griebel, MD, Director Divison of Gastroenterology Products
Thru:	Linda Kim-Jung, Pharm D., Team Leader Denise Toyer, Pharm D., Deputy Director Carol Holquist, R.Ph., Director Division of Medication Error Prevention
From:	Walter Fava, R.Ph., Safety Evaluator Division of Medication Error Prevention
Subject:	Proprietary Name Review for Asacol 800
Drug Name(s):	Asacol 800 (Mesalamine)
Application Type/Number:	21-830
Applicant:	Procter & Gamble Pharmaceuticals, Inc.
OSE RCM #:	2007-2438

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EXECUTIVE SUMMARY

Based on recent information pertaining to the bioequivalency difference between Asacol 400 mg and Asacol 800, our analysis indicates that the proposed proprietary name, Asacol 800, appears vulnerable to confusion that could lead to medication errors. Errors in product substitution are likely to occur because healthcare practitioners will be led to believe the 800 mg tablet is simply a higher strength of the currently marketed Asacol 400 mg. However, the two products are not bioequivalent and have different indications of use, and it is likely that errors between the two products will occur due to overlapping names, product strengths, and frequency of administration. Based on the results of our Failure Modes and Effects Analysis, we conclude that using the proprietary name, Asacol 800, is more likely to result in more medication errors than approving the product using a different name .

The results of our Label and Labeling Risk Assessment also found that the presentation of the proposed container labels and carton labeling for Asacol 800, are vulnerable to confusion due to look-alike similarities with the currently marketed Asacol 400 mg product. In addition to identifying concerns with the presentation of the container labels and carton labeling, we also found that the statement of dose under the Dosage and Administration section of the package insert should include more information to tell prescribers that the usual adult dose is two tablets three times a day.

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, along with labels and labeling, be resubmitted for review. Additionally, if the product approval is delayed beyond 90 days from the signature date of this review, the proposed name must be resubmitted for re-evaluation.

1 BACKGROUND

1.1 INTRODUCTION

This consult was written in response to a request from the Division of Gastroenterology Products for a re-review of the name Asacol 800, for its potential to contribute to medication errors. Additionally, the container labels, carton labeling, and package insert labeling are evaluated to identify areas that could lead to medication errors.

1.2 REGULATORY HISTORY

Asacol 800 is an extension of the Asacol product line which currently consists of Asacol 400 mg tablets. Asacol 400 mg (NDA 19-651) was approved in January 1992 for the treatment of mild to moderate ulcerative colitis and maintenance of remission of ulcerative colitis.

Th proposed proprietary name, Asacol 800, was previously reviewed by the Division of Medication Error Prevention (Consult #: 02-0208, dated December 2002 and 02-0208-1, dated July 2005). Initially, we objected to the use of the numeric modifier "800" in conjunction with the proprietary name "Asacol". Our primary concerns related to the possibility of omission of the "800" modifier; that the use of the "800" modifier does not convey that two 400 mg tablets are not equivalent to one 800 mg tablet; and that these two products have different indications of use. Subsequent to that review, the Applicant submitted additional information to support the use of the name Asacol 800, along with a comprehensive communication and education plan. In conjunction with reviewing these submissions, we met with members of the Division of Gastroenterology Products to discuss issues concerning the name and the pharmacokinetics of Asacol 800. The Division stated that despite the fact that one tablet of Asacol 800 is 25% less effective than two tablets of Asacol 400 mg, there would be no safety issue with this substitution. Conversely, if one 800 mg tablet of Asacol 800 was substituted for two tablets of Asacol 400 mg, there might be diminished efficacy for mild to moderate ulcerative colitis. However, it was

further explained that the product is locally acting, and is dosed based on clinical response, so it is generally safe and well tolerated, therefore there is no safety risk. Members of the meeting concurred that the use of the modifier "800", did not distinguish the new product from Asacol 400 mg and that using a different modifier, such as DS or ER, would also not convey the bioequivalence differences between the products. We also acknowledged at the meeting that if the name Asacol 800 were approved, medication errors involving substitution with Asacol 400 mg would occur, however, the Division reiterated the fact that there were no safety concerns with this substitution and patients who did not respond would have their doses adjusted accordingly. Therefore, we rescinded our objection to the name Asacol 800 at that time.

Subsequently, on April 10, 2008, we met with the Division at their request to discuss potential errors which may occur as a result of approving the proprietary name, Asacol 800. During this meeting, the Division concurred with our assessment that there is greater potential for more medication errors to occur if the name Asacol 800 is approved. Therefore, we agreed that the least error prone option would be to ask the Applicant to propose a different name for the product.

1.3 PRODUCT INFORMATION

Asacol 800 is a delayed-release aminosalicylate indicated for the treatment of moderately active ulcerative colitis. The recommended dose of Asacol 800 in adults is 4.8 grams/day in divided doses (two 800 mg tablets three times a day). Asacol 800 will be available in bottles of 180 tablets each. For reference purposes, the product characteristics for both Asacol and Asacol 800 are summarized in the table below:

Product (Proprietary Name)	Asacol	Asacol 800
Established name	mesalamine	mesalamine
Strength	400 mg	800 mg
Dosage Form	Delayed Release Tablet	Delayed Release Tablet
Indication(s)/Usual Adult Dose	Treatment of mildly to moderately active ulcerative colitis *Two tablets by mouth three times a day* and Maintenance of remission of ulcerative colitis *1.6 grams daily in divided doses*	Treatment of moderately active ulcerative colitis *Two tablets by mouth three times a day*

2 METHODS AND MATERIALS

This section consists of two sections which describe the methods and materials used by the Division of Medication Error Prevention, medication error 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 Label and 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. 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]

We reviewed container labels and carton labeling forwarded by the Applicant as an attachment to an electronic mail message sent to Project Manager, Kristen Everett, on February 28, 2008. As part of this review, we referenced the currenly approved container labels and carton labeling for Asacol 400 mg (NDA 19651) found in the 2006 Annual Report. In addition, we also reviewed the package insert labeling.

2.1 PROPRIETARY NAME RISK ASSESSMENT

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name, Asacol 800, 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.

For the proprietary name, Asacol 800, the medication error staff of the Division of Medication Error Prevention searched 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 2.1.1.2). Division of Medication Error Prevention also conducts internal CDER prescription analysis studies (see 2.1.2), and, when provided, external prescription analysis studies results are considered and incorporated into the overall risk assessment (see detail 2.1.4).

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 2.1.4). 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 this case, our FMEA evaluated possible confusion resulting from the use of the '800' modifier in terms of how it may be interpreted. Specifically, we tried to assess the potential for the '800' modifier to be interpreted as other numbers, dosing instructions, or medical abbreviations. We also considered the potential for confusion if the modifier was to be omitted from orders for Asacol 800.

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 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

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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.

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 'A' 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.[45]

To identify drug names that may look similar to Asacol 800, the Staff also consider the other orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (6 letters), upstrokes (2, capital letter 'A', and lower case letter 'l'), downstrokes (none), cross-strokes (none), and dotted letters (none). Additionally, several letters in Asacol may be vulnerable to ambiguity when scripted, including the capital letter 'A' which may appear as the letters 'O', "Cl", 'e', or 'U'; the lower case letter 'a' may appear as a lower case 'o', 'e', or 'u'; and likewise, the lower case letter 'o' can appear as a lower case 'a', 'e', or 'u': the lower case letter 's' may appear like the lower case letter 'r'. As such, the Staff also consider these alternate appearances when identifying drug names that may look similar to Asacol 800.

When searching to identify potential names that may sound similar to Asacol 800, the Medication Error Staff search for names with similar number of syllables (3), stresses (AS-a-col or AS-a-COL), and placement of vowel and consonant sounds. In addition, several letters in Asacol 800 may be subject to interpretation when spoken, including the letter combination 'As" which may be pronounced as 'Ayz', 'Az', 'Auz', 'Aus', 'Os', 'Oz ', 'Es', 'Ez', 'Us', or 'Uz',. Likewise, the letter combination 'acol' may be interpreted as 'ickol', 'ukol', 'akol', 'acole', 'ickole', or 'ukole'. The Sponsor's intended pronunciation of the proprietary name could not be expressly taken into consideration, as this was not provided with the proposed name submission.

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 (Asacol 800), the established name (mesalamine), proposed indication (active ulcerative colitis), strength (800 mg), dose (4.8 grams daily in divided doses of two 800 mg tablets three times a day), frequency of administration (three times a day), route (oral) and dosage form of the product (tablet). Appendix A provides a more detailed listing of the product characteristics the Medication Error Staff generally 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

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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)

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.

2.1.1.1 Database and information sources

The proposed proprietary name, Asacol 800, 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 Asacol 800 using the criteria outlined in 2.1.1. A standard description of the databases used in the searches is provided in Section 7. 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 Staff review the United States Adopted Name (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.

2.1.1.2 CDER Expert Panel Discussion

An Expert Panel Discussion is held by Division of Medication Error Prevention to gather CDER professional opinions on the safety of the product and the proprietary name, Asacol. Potential concerns regarding drug marketing and promotion related to the proposed names are also discussed. This group is composed of Division of Medication Error 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.

2.1.2 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 Asacol 800 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 misinterepreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of Asacol 800 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 the medication error staff. The study for Asacol 800 inadvertently included the directions, '3 tabs po BID x 6 wks' instead of '2 tabs po TID x 6 wks', however, it is not likely that this influenced the interpretation of the name.

Figure 1. Asacol 800 Study (conducted on December 10, 2007)

HANDWRITTEN PRESCRIPITON AND MEDICATION ORDER	VERBAL PRESCRIPTION
Outpatient Prescription: Asacol 800 #180 3 tabs PO BID x 6wks	Asacol 800 #180 Take three tablets by mouth twice a day for 6 weeks.
Inpatient Medication Order : Asacol 800 3 tablets by mouth bid x 6 weeks	

2.1.3 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 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 Asacol 800 convincing similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?" An

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

affirmative answer indicates a failure mode and represents a potential for Asacol 800 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 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.

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. The Division of Medication Error Prevention 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 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 name and another drug product.

In the event that the Division of Medication Error Prevention objects 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 will object to the use of the proprietary name. The threshold set for the Division of Medication Error Prevention's 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, the World Helath Organization, the Joint Commission of Accreditation of Healthcare Organizations, and the Institute of

Safe Medication Practices, 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 Prevention 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 Applicants 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, the Division of Medication Error Prevention 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 limitations of the process).

If the Division of Medication Error Prevention 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. The Division of Medication Error Prevention is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for the Division of Medication Error Prevention to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name, and so the Division of Medication Error Prevention 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 container labels and carton labeling 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 have 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 Medication Error 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 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.

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

For this product the Sponsor submitted the following labels and insert labeling for the Division of Medication Error Prevention review (see Appendix H, I, J, and K for images):

- b(4)
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- Retail Container: 800 mg (180 tablet container)
- Package Insert Labeling (no image)

We also reviewed the carton labels and container labeling for Asacol 400 mg from the 2006 Annual Report to compare with the Asacol 800 labels and labeling listed above (Appendix L).

2.2.1 Adverse Event Reporting System (AERS) Selection of Cases

The Division of Medication Error Prevention conducted a search of the Adverse Event Reporting System (AERS) database of the currently marketed Asacol product, to determine if any medication errors are associated with the product labels and labeling and/or sound-alike or look-alike confusion with other proprietary or established drug names.

The MedDRA High Level Group Term (HLGT), "Medication Errors", active ingredient "mesalamine" and the verbatim terms "Asa%" and "mesal%" were used as search criteria. 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 error were categorized by the type of error. The Division of Medication Error Prevention 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 proprietary name, Asacol 800.

3 RESULTS

3.1 PROPRIETARY NAME RISK ASSESSMENT

3.1.1 Database and information sources

The Division of Medication Error Prevention conducted a search of the internet, several standard published databases and information sources (see Section 7 References) for existing drug names which sound-alike or look-alike to Asacol 800 to a degree where potential confusion between drug names could occur and result in medication errors in the usual clinical practice settings. In total, 14 names were identified as having some similarity to the name, Asacol 800.

Eight of the 14 names that were thought to look like Asacol 800 include: Ascarel, Asagal, Asadol, Azasan, Azasite, Asacolon, Visicol, and Asacolitin. Two additional names (Aquasol A and Aquasol E) were thought to sound like Asacol 800 and four names (Alacol, Asacol 800, Asacol, and Asacor), were thought to look and sound similar to Asacol 800.

The previous review, OSE Review #: 02-0208, identified the names Os-cal and Avelox as having look-alike and sound-alike similarities with Asacol to a degree where potential confusion between the names could occur and result in medication errors in the usual clinical practice settings.

A search of the United States Adopted Name (USAN) stems did not identify any USAN stems for the proposed proprietary name, Asacol 800.

3.1.2 Expert panel discussion

The Expert Panel reviewed the pool of names identified by the Division of Medication Error Prevention staff (see section 3.1.1. above), and noted an additional three names, Oscal, Avelox, and Ansaid, that were thought to have orthographic similarity to Asacol 800. The panelists also recommended looking at drug names beginning with the letters 'O', 'U', and 'e'.

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

3.1.3 CDER Prescription analysis studies

A total of 36 practitioners responded, but none of the responses overlapped with any existing or proposed drug names. Approximately 70% of the participants (n=26) interpreted the name correctly as "Asacol 800," or "Asacol". The remainder of the responses misinterpreted the drug name. The majority of misinterpretations occurred in the inpatient and phonetic prescription studies, with the letter 's'in Asacol reported as 'z', and 'j' instead of 's'. Also, in the phonetic prescription studies, the letter 'p' was included by two respondents, and one respondent in the written studies interpreted the letters 'col' as 'jel' from the inpatient writing sample. See Appendix A for the complete listing of interpretations from the verbal and written prescription studies.

3.1.4 Modifier Safety Concerns

Our assessment of the modifier '800' found it to be vulnerable to confusion which may contribute to medication errors. Issues of concern include omission of the modifier from orders for Asacol 800, which would likely result in the dispensing and administration of Asacol 400 mg; interpretration of the '800' as being equivalent to two 400 mg tablets of Asacol; and misinterpretation of '800' as '500' when scripted, which increases the potential for medication errors involving name confusion with the proprietary name Os-Cal which is available as a 500 mg tablet. The aforementioned safety issues are all based on the intended presentation of the modifier in conjunction with the root name. We did not identify any safety concerns for the '800' modifier by itself in relation to the usual practice setting. However, omission or misinterpretation of the '800' modifier may potentially result in patients receiving the wrong medication.

3.1.5 Adverse Event Report System

The AERS search identified a total of six medication errors resulting from confusion with proprietary drug names which look similar to Asacol. All six of the medication errors resulted in the wrong drug being dispensed to patients. These cases provided limited insight into potential name confusion errors with Asacol 800 because we evaluated the entire proposed name 'Asacol 800' and not just the 'Asacol' portion of the name in our analysis. The medication errors are summarized in Appendix M.

3.1.6 Safety evaluator risk assessment

Independent searches by the primary Safety Evaluator identified two additional names, Asmakol, thought to sound similar to Asacol 800, and Anusol, thought to look similar to Asacol 800. Careful evaluation was afforded to drug names beginning with the letters 'O' and 'Cl' in accordance with the Expert Panel's recommendations, but no additional drug names beginning with these letters were thought to have the potential for confusion with Asacol 800. As such, a total of 19 names were analyzed to determine if the drug names could be confused with Asacol 800 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 Asacol 800, and thus determined to present some risk of confusion. However, subsequent failure modes

and effects analysis determined that the name similarity between Asacol 800 and the following 18 identified names was unlikely to result in medication errors for the following reasons:

Asacol 800, available in Canada, is the same product as the proposed proprietary name, Asacol 800, and has the same indication of use.

Aquasol A, Aquasol E, Azasan, and Azasite, lack convincing look-alike and sound-alike similarities to Asacol 800 (See Appendix C).

Asacolon, Asacolitin, Asadol, Asacor, and Asagal are all foreign drug products and therefore have a low risk of confusion with Asacol 800 (See Appendix D).

Asmakol was considered to have a low risk of confusion with Asacol 800 because it is a discontinued, over-the-counter product, and there are no generic equivalents available (See Appendix E).

Ascarel, Anusol, Alacol, were considered to have a low risk of confusion with Asacol 800 due to a lack of overlapping strengths and doses (See Appendix F). Although, Ansaid and Visicol do not have overlapping strengths and doses (See Appendix F), these two names have been confused with Asacol (400 mg). A prescription for Visicol was dispensed as Asacol (2005) and a prescription for Ansaid 100 mg was dispensed with Asacol NE (2003). The Division of Medication Error Prevention completed a postmarketing medication error safety analysis of name confusion cases involving Visicol shortly after it was approved. The applicant for Visicol instituted a education plan and no further cases of confusion with Visicol have been identified. The case involving Ansaid and Asacol did not provide any causality as to why the medication occurred. However, these two names may look similar to each other because they both contain the letters, 'A', 's', and 'a', and both names end with an upstroke letter, 'l' vs 'd'.. The orthographic differences between the two names include the letters 'n', 'i' and 'd' in Ansaid which Asacol does not have, and the letters 'o' and 'l' in Asacol which Ansaid does not have. The endings of both names also look different when scripted, 'aid' vs 'col'. Considering the orthographic differences between the names, in addition to the lack of overlapping strengths, the potential for confusion between the names is sufficiently minimized.

Os-Cal presents convincing orthographic similarities with the root name 'Asacol', however, the two products do not have overlapping strengths (500 mg vs 800 mg). We also gave consideration to the possibility of the similar appearance between numbers '5' and '8' when scripted. Despite the lack of overlapping strengths between Asacol and Os-cal, there have been three cases of medication errors involving confusion between these two names. The most recent case involved an order for Asacol 400 mg being transcribed as Os-Cal 400 mg, but the order was clarified prior to administration to the patient (2003). The second case (1999) resulted from a prescription for Os-Cal being filled with Asacol 400 mg. The third case (1993) involved a verbal order for Asacol 400 mg being transcribed as Os-Cal 500 mg. The third case involved a verbal order for Asacol 400 mg being transcribed as Os-Cal 500 mg (1993). These cases did not include enough information to determine causality and outcomes were not provided. Our FMEA determined that even though orthographic confusion is possible, Os-Cal is an over-the-counter product which minimizes the potential for confusion with Asacol 800 leading to medication errors in the usual practice setting (See Appendix G).

Avelox was also noted as having orthographic similarities with the root portion of the name, Asacol 800. One medication error involving name confusion between Avelox 400 mg and Asacol 400 mg occurred in 2001 when a prescription for Avelox 400 mg was filled with Asacol 400 mg. It is also noted that Avelox has an achievable dose with Asacol 800, however, the potential for confusion between the names is minimized by the different frequency of administration and lack of convincing orthographic similarities between the two names (See Appendix G).

The FMEA determined that the remaining name, Asacol 400 mg, is vulnerable to confusion and medication errors because they share the same root name and the proposed modifier '800' does not

communicate to practitioners that these two products are not interchangeable (see section 4 below for full discussion).

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3.3 ADVERSE EVENT REPORTING SYSTEM

4 DISCUSSION

When evaluating the proposed name, Asacol 800, our primary concern was the potential for practitioners to substitute two Asacol (400 mg) tablets for one Asacol 800 tablet. These two products are not bioequivalent and this important difference will not be communicated to practitioners with the modifier '800'. It is intuitive for practitioners to think that Asacol 800 is twice the strength of Asacol 400 mg, and

that the two products are interchangeable. This makes it highly probable that substitution errors will occur and that these two products cannot safely co-exist in the marketplace.

4.1 PROPRIETARY NAME RISK ASSESSMENT

The root name of the proposed name is identical in Asacol and Asacol 800. Additionally, there is similarity between the indications of use (e.g., both treat moderately active ulcerative colitits) with similar dosing regimens (e.g., two tablets three times a day). However, Asacol 800 is between 25% and 36% less bioavailable than Asacol (400 mg). Thus, Asacol 800 and Asacol (400 mg) are not interchangeable on a milligram per milligram basis. Use of the modifier '800' with the identical root name Asacol will not communicate this substantial difference to practitioners. Our FMEA analysis determined that Asacol 800 is vulnerable to medication errors involving substitution with Asacol 400 mg.

Postmarketing evidence has shown that modifiers are often omitted by prescribers, leading to medication errors. In this case if a prescriber omits the modifier, '800' on orders for Asacol 800, it is likely that Asacol 400 mg tablets will be dispensed. Even if the modifier is not omitted, a Asacol 800 order could be substituted with Asacol 400 mg and the comparable number of tablets dispensed. Conversely an order written for Asacol 400 mg, with the directions, 'Take 2 tablets by mouth three times a day' could undergo substitution with Asacol 800 with the directions, 'Take 1 tablet by mouth three times a day'. Siince Asacol 800 is between 25% and 36% less bioavailable than Asacol 400 mg; substituting the 800 mg tablet for two 400 mg tablets or vice versa may not result in the expected outcome.

Although the applicant may educate practitioners about the differences in these two drugs, we believe an education campaign would have limited impact upon this common pharmacy practice of substitution. Thus, using the shared root name and modifier, Asacol 800, for this product will increase the potential for substitution errors between these two products.

4.2 LABEL AND LABELING RISK ASSESSMENT

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

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5 CONCLUSIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Asacol 800, appears to be vulnerable to name confusion that could lead to medication errors. We anticipate that substitution errors between Asacol 800 and Asacol 400 mg, will occur if the name Asacol 800 is approved. Substitution errors will occur despite any education or label/labeling references explaining the difference between the two products. We do not believe that a modifier used in conjunction with the root name 'Asacol', would convey to practitioners that Asacol 400 mg is not bioequivalent to Asacol 800. We acknowledge that objecting to the proposed name Asacol 800, would create dual trade names, however, in this case, our FMEA determined that a different name for this product presents the lowest risk for potential medication errors. Therefore, the Division of Medication Error Prevention objects to the use of the proprietary name, Asacol 800, for this product. The Applicant should submit two alternate proprietary names and identify their primary and secondary choice.

The Label and Labeling Risk Assessment findings indicate that the presentation of information and design of the proposed carton and container labels introduces vulnerability to confusion that could lead to medication errors. 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 5.3 that aim at reducing the risk of medication errors.

6 RECOMMENDATIONS

6.1 COMMENTS TO THE DIVISION

Based upon our risk assessment of the proposed proprietary name, Asacol 800, we object to the proposed name because of the potential for substitution errors with Asacol 400 mg.

The Division of Medication Error Prevention would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. Please copy the Division of Medication Error Prevention on any communication to the sponsor 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

The findings of our Proprietary Name Risk Assessment indicates that the proposed name, Asacol 800, has similarity to Asacol and appears vulnerable to name confusion that could lead to medication errors as described below in section 5.2.1.

6.2.1 Proprietary name

The root name of the proposed name is identical in Asacol and Asacol 800. Additionally, there is similarity between the indications of use (e.g., both treat moderately active ulcerative colitits) with similar dosing regimens (e.g., two tablets three times a day). However, Asacol 800 is between 25% and 36% less bioavailable than Asacol (400 mg). Thus, Asacol 800 and Asacol (400 mg) are not interchangeable on a milligram per milligram basis. Use of the modifier '800' with the identical root name Asacol will not communicate this substantial difference to practitioners. Our FMEA analysis determined that Asacol 800 is vulnerable to medication errors involving substitution with Asacol 400 mg.

Postmarketing evidence has shown that modifiers are often omitted by prescribers, leading to medication errors. In this case if a prescriber omits the modifier, '800' on orders for Asacol 800, it is likely that Asacol 400 mg tablets will be dispensed. Even if the modifier is not omitted, a Asacol 800 order could be substituted with Asacol 400 mg and the comparable number of tablets dispensed. Conversely an order written for Asacol 400 mg, with the directions, 'Take 2 tablets by mouth three times a day' could undergo substitution with Asacol 800 with the directions, 'Take 1 tablet by mouth three times a day'. Since Asacol 800 is between 25% and 36% less bioavailable than Asacol 400 mg; substituting the 800 mg tablet for two 400 mg tablets or vice versa may not result in the expected outcome.

Although the applicant may educate practitioners about the differences in these two drugs, we believe an education campaign would have limited impact upon this common pharmacy practice of substitution. Thus, using the shared root name and modifier, Asacol 800, for this product will increase the potential for substitution errors between these two products.

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7 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 the Division of Medication Error Prevention, 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 Error Prevention proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention 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. The Division of Medication Error Prevention 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, the Division of Medication Error Prevention will consider the Sponsor's intended pronunciation of the proprietary name. However, because the Sponsor has little control over how the name will be spoken in practice, the Division of Medication Error Prevention 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 Upstokes Downstrokes	• Names may look similar when scripted, and lead to drug name confusion in written communication

		Cross-stokes Dotted letters 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

Appendix B:

CDER Prescription Study Responses

Outpatient Prescription	Voice Prescription	Inpatient Medication Order
Asacol	Asacol 800	Asacol
Asacol	Acechol 800	Asacol 800
Asacol 800	Aspecol 800	Azadel 800
Asacol 800	Asacol 800	Asacol 800
Asacol 800	Aspercol 800	Asacol 800
Asacol	Asacol 800	Asacol 800
Asacol	Asacol 800	Ajacol 800
	Asacol 800	Asacol 800
	Asacol 800	Asacol
	Asacol 800	Asacol
		Asacol 800
		Asacol 800
		Azacol 800
		Ajavel
		Asacol 800
		Asacol 800
		Asacol 800
		Aracol 800

Appears This Way
On Original

Appendix C: Names lacking convincing look-alike or sound-alike similarity

Proprietary Name	Similarity to Asacol 800
Aquasol A	Sound
Aquasol E	Sound
Azasan	Look
Azasite	Look

Appendix D: Proprietary names used only in Foreign Countries

Proprietary Name	Similarity to Asacol 800	Country
Asacolon	Look	Ireland
Asacolitin	Look	Germany
Asadol	Look	Canada
Asacor	Look and Sound	Taiwan
Asagal	Look and Sound	Belgium
Asacol 800	Look and Sound	Canada

Appendix E: Discontinued products

Proprietary Name	Similarity to Asacol 800	Reason Not Evaluated Further
Asmakol	Sound	Discontinued

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On Original

Appendix F: Products with no numerical overlap in strength and dose.

Asacol 800 (mesalamine)		Strengths: 800 mg	Usual dose: Two 800 mg tablets by mouth three times a day for 6 weeks
Product name with potential for confusion	**Similarity to Proposed Proprietary Name**	**Strength**	**Usual Dose (if applicable)**
Ascarel	Look	144 mg/mL	One time single dose
Anusol	Look	0.5% Zinc sulfate ointment 10 mg Zinc sulfate suppository	Apply to anal area every 4 hours as needed Insert one suppository rectally twice a day
Alacol	Look and Sound	0.4 mg/mL and 1 mg/mL drops 2 mg/5 mL and 5 mg/5 mL syrup	2.5 mL po q4h up to 15 mL/day 10 mL q4h up to 60 mL/day (age >12)
Ansaid	Look	50 mg and 100 mg tablets	200 mg to 300 mg po daily in two, three or four divided doses
Visicol (Sodium Phosphate dibasic anhydrous and Sodium Phosphate monobasic monohydrate)	Look	0.398 grams/1.102 grams	Take 3 tablets (the last dose will be 2 tablets) with 8 ounces of clear liquids every 15 minutes for a total of 20 tablets the evening before procedure. In the morning, 3-5 hours prior to the procedure, take 3 tablets (the last dose will be two tablets) with 8 ounces of clear liquid every 15 minutes for a total of 20 tablets.

Appendix G: Potential confusing name with acheivable dose or overlapping frequency of administration with Asacol 800

Asacol (mesalamine)	**800 mg tablets**	**2 tablets po three times a day**
Failure Mode: Name confusion	**Causes (could be multiple)**	**Effects**
Avelox	Acheivable dose: (2 x 400 mg = 800 mg)	Orthographic differences in the name minimize the likelihood of medication errors in the usual practice setting *Rationale:* Two of the three overlapping letters in the names, 'A', 'l', and 'o', do not appear in the same position or pattern between the names Avelox vs Asacol Avelox is also administered once a day compared to the frequency of Asacol which is administered three times a day.
Os-Cal	Orthographic similarities include 'Os' vs 'As' at the beginning of both names and 'cal' vs 'col' at the end of both names. Overlapping frequency of administration: 1 tablet three times a day vs 2 tablets three times a day The modifier '800' may appear as '500' when scripted.	Orthographic similarities are minimized by the prescription status vs the over-the-counter status of the two products. *Rationale:* It is unlikely in an outpatient setting that pharmacists will receive orders for over-the-counter Os-cal. Different dosing: Asacol 800 is usually ordered as 2 tablets three times a day and Os-Cal 500 mg is ordered as one tablet three times a day.
Asacol	Orthographic similarities include overlapping root names, 'Asacol' Overlapping frequency of	Orthographic similarities along with overlapping product characteristics will likely lead to medication errors in the usual

	administration – three times a day Acheivable dose: 2 X 400 mg = 800 mg	practice setting. Concerns include omission of the modifier '800' which would result in the wrong drug, Asacol 400 mg being dispensed; misinterpretation of the modifier '800' as 500, which increases likelihood of confusion with Os-Cal 500mg; substitution errors by practitioners dispensing 2 x 400 mg Asacol for 1 Asacol 800 mg and conversely, 1 Asacol 800 being dispensed for two 400 mg Asacol. These potential areas of confusion are likely to result in confusion that will lead to medication errors in the usual practice setting.

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Appendix M : Summary of AERS cases

AERS Case #	Date Received	Type of Error	Narrative
5861058	08/08/05	Wrong Drug	Prescription for Visicol filled and dispensed with Asacol. Patient discovered the error before consuming any of the wrong medication.
4051828	12/29/03	Wrong Drug	Order transcribed as OsCal 400 mg tid. Pharmacist clarified the strength to be 500 mg tid. When dose to be given, patient found that drug was Asacol 400 mg tid. No outcome provided.
4004943	09/23/03	Wrong Drug	Prescription for Ansaid 100 mg filled and dispensed with Asacol NE. No outcome provided.
3210853	10/05/01	Wrong Drug	Prescription for Avelox 400 mg filled with Asacol 400 mg. Patient noticed error before consuming any of the incorrect medication.
3218106	03/01/99	Wrong Drug	Prescription for OsCal filled and dispensed with Asacol 400 mg. No outcome provided.
5745425	10/26/93	Wrong Drug	Verbal order for Asacol 400 mg transcribed as Oscal 500 mg tid. No outcome provided.

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/s/

Walter Fava
4/18/2008 04:56:56 PM
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