

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-100

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE
DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; White Oak 22; Mail Stop 4447)

DATE RECEIVED: 07/24/2007

DESIRED COMPLETION DATE: 08/20/2007

OSE REVIEW #:

DATE OF DOCUMENT: 04/09/2007

PDUFA DATE: 9/27/2007

2007-1579

TO: Norman Stockbridge, MD
 Director, Division of Cardiovascular and Renal Products
 HFD-110

THROUGH: Linda Y. Kim-Jung, PharmD, Team Leader
 Denise Toyer, PharmD, Deputy Director
 Carol Holquist, RPh, Director
 Division of Medication Errors and Technical Support, HFD-420

FROM: Denise V. Baugh, PharmD, BCPS, Safety Evaluator
 Division of Medication Errors and Technical Support, HFD-420

PRODUCT NAME:

Azor™
 (Amlodipine Besylate and Olmesartan Medoxomil)
 Tablets
 5 mg/20 mg, 10 mg/20 mg, 5 mg/40 mg, and
 10 mg/40 mg

SPONSOR: Daiichi Sankyo, Inc.**NDA #:** 22,100**RECOMMENDATIONS:**

1. DMETS has no objection to the use of the proprietary name, Azor. We consider this a final review. However, if the approval of the NDA is delayed beyond 90 days from the date of this review, the name must be re-evaluated. A re-review of the name before NDA approval will rule out any objections based upon approvals of other proprietary/established names from this date forward.
2. DMETS recommends implementation of the label and labeling revisions outlined in section III of this review in order to minimize potential errors with the use of this product.
3. DDMAC finds the proprietary name, Azor, acceptable from a promotional perspective.

DMETS 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 DMETS on any correspondence to the sponsor pertaining to this review. If you have further questions or need clarifications, please contact Darrell Jenkins, OSE Project Manager, at 301-796-0558.

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Division of Medication Errors and Technical Support
Office of Surveillance and Epidemiology
HFD-420; WO22; Mail Stop 4447
Center for Drug Evaluation and Research

PROPRIETARY NAME, LABEL, AND LABELING REVIEW

DATE OF REVIEW: August 1, 2007

NDA #: 22,100

NAME OF DRUG: **Azor™**
(Amlodipine Besylate/Olmesartan Medoxomil) Tablets
5/20 mg, 10/20 mg, 5/40 mg, and 10/40 mg

NDA SPONSOR: Daiichi Sankyo, Inc.

I. INTRODUCTION

This consult was written in response to a request from the Division of Cardiovascular and Renal Products (HFD-110), for a re-assessment of the proprietary name "Azor" regarding potential name confusion with other proprietary or established drug names. The name was found acceptable in the initial review dated May 16, 2007 (OSE# 2007-1167). Container labels, carton and insert labeling were provided for re-review and comment.

PRODUCT INFORMATION

Azor is a combination product containing a calcium channel blocker (amlodipine besylate) and an angiotensin receptor blocker (olmesartan medoxomil) for the indication of hypertension. Azor will be available as oral tablets in strengths of 5/20 mg, 10/20 mg, 5/40 mg, and 10/40 mg. The recommended dose is individualized based upon whether it is a replacement, add-on, or initial therapy. For initial therapy in patients requiring blood pressure reduction of $\geq 20/10$ mmHg, the recommended starting dose is 5/20 mg once daily. The dose may be increased after 2 weeks in patients requiring further reduction in blood pressure to goal, to a maximum dose of 10/40 mg once daily. Azor is supplied as 10 blisters of 10 tablets and in bottles of 30, 90 and 1000 tablets.

II. RISK ASSESSMENT

The medication error staff of DMETS conducted a search of the internet, several standard published drug product reference texts^{1,2} as well as several FDA databases^{3,4} for existing drug names which sound-alike or look-alike to Azor to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online

¹ MICROMEDEX Integrated Index, 2007, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

² Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.

³ AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-07, and the electronic online version of the FDA Orange Book.

⁴ Phonetic and Orthographic Computer Analysis (POCA)

version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted⁵. The Saegis⁶ Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient orders) and a verbal prescription study involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name. Following completion of these initial components, an overall risk assessment is conducted that does not evaluate the name alone. The assessment considers the findings from above and more importantly integrates post-marketing experience in assessing the risk of name confusion, product label/labeling, and product packaging. Because it is the product that is inserted into the complex and unpredictable U.S. healthcare environment, all product characteristics of a drug must be considered in the overall safety evaluator risk assessment.

1. EXPERT PANEL DISCUSSION (EPD)

1. DDMAC finds the proprietary name, Azor, acceptable from a promotional perspective.
2. Since the previous review (OSE # 2006-1167 dated 09/18/2006) the Expert Panel has identified one additional name, Ogen, that may have potential for confusion with Azor.

2. SAFETY EVALUATOR RISK ASSESSMENT

In re-review of the proprietary name, one name, Ogen was identified as a name with similar appearance to Azor.

Table 1 lists the dosage forms available and usual dosage of Ogen.

Product Name	Established name, Dosage form(s)	Usual adult dose*	Other**
Azor	Amlodipine Besylate/Olmesartan Medoxomil Tablets: 5/20 mg, 10/20 mg, 5/40 mg, 10/40 mg	Individualized to patient Maximum does of 10/40 mg once daily	N/A
Ogen	Estropipate Vaginal cream: 1.5 mg/gm Oral tablet: Ogen 0.625 (0.75 mg estropipate); Ogen 1.25 (1.5 mg estropipate); Ogen 2.5 (3 mg estropipate); Ogen 5 (6 mg estropipate)	Treatment of moderate to severe vasomotor symptoms associated with menopause: 0.75 mg to 6 mg estropipate daily Female hypogonadism; female castration or primary ovarian failure: 1.5 mg to 9 mg daily for the first 3 weeks, followed by a rest period of 8 to 10 days Osteoporosis prophylaxis: 0.75 mg estropipate daily for 25 days of a 31 day cycle	L/A

*Frequently used, not all-inclusive.
**LA (look-alike), SA (sound-alike)

⁵ WWW location <http://www.uspto.gov/tmdb/index.html>.

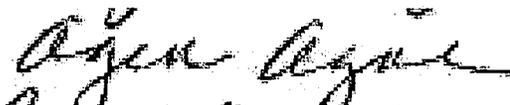
⁶ Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at www.thomson-thomson.com

Ogen is an estrogen derivative indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause; treatment of vulvar and vaginal atrophy; hypoestrogenism; and prevention of osteoporosis. The dosage of Ogen is individualized to the patient diagnosis and ranges from 0.75 mg to 9 mg daily for up to 25 days. It is also available as generic.

Ogen and Azor have look-alike similarities when written because their first letters – ‘O’ in Ogen and ‘A’ in Azor look similar orthographically. Additionally, the downstroke of the letter ‘g’ and ‘z’ also look similar in appearance when the name is scripted.

Both products have overlapping routes of administration (oral) and frequency (daily). However, most of their strengths do not overlap (0.625, 1.25, 2.5 vs. 5 mg/20 mg, 5 mg/40 mg, 10 mg/20 mg, 10 mg/40 mg). Ogen 5 has an overlapping number with Azor 5 mg/20 mg and 5 mg/40 mg. Azor is a combination product, thus both strengths would likely specified on an order which may minimize confusion between this name pair. This difference may help distinguish the two products.

Although this name pair exhibits some similarities orthographically, differences in strength require the prescriber to clarify this information in order to dispense and administer the intended dose. As a result, DMETS considers the potential for confusion in the marketplace to be minimal with this name pair.



III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES

In the review of the container labels, carton and insert labeling of Azor, DMETS focused on safety issues relating to medication errors and have identified several areas for improvement. These recommendations apply to container labels, carton and insert labeling submitted April 9, 2007 and September 14, 2007.

A. GENERAL COMMENTS

1. DMETS notes that while container labels were submitted for 30 count and 90 count bottles, there is no submission of carton labeling for these sizes. Additionally, we received carton labeling for the 100 count bottle but no container label. The package insert refers to a 1000 count bottle. No container label or carton labeling was submitted for this size. These discrepancies should be addressed with the sponsor. Recommendations for improvement apply to all proposed containers.

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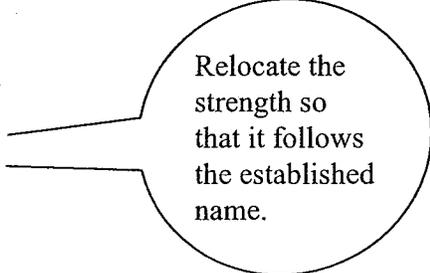
2. The colors used to identify the various strengths on the container labels and carton labeling look similar and do not provide sufficient differentiation.

These colors are not significantly different from each other and as a result may cause product selection errors especially when stored side by side on a pharmacy shelf. DMETS recommends choosing a significantly different color scheme using boxing or some other means to differentiate these 4 strengths from one another.

b(4)

3. Please ensure that the established name is at least ½ the font size of the proprietary name in accordance with 21 CFR 201.10(g)(2).
4. Relocate the strength away from the net quantity so that they are not mistaken for one another. We recommend relocating the strength so that it follows the established name and appears above the solid line that separates the name from the manufacturer's logo.

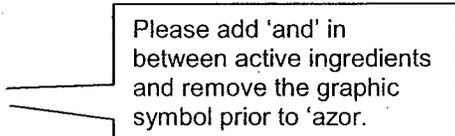
b(4)



Relocate the strength so that it follows the established name.

5. Please remove the graphic symbol prior to 'Azor' to minimize distractions and confusion and to increase the prominence of important information.
6. Please insert the word "and" between the active ingredients on the container label, carton labeling and wherever it appears throughout the package insert. For example, the label should read amlodipine besylate and olmesartan medoximil.

b(4)



Please add 'and' in between active ingredients and remove the graphic symbol prior to 'azor.

7. The established name of the product contains salts "besylate" and "medoxomil." Please clarify if the strengths and dose are based on salt or active moiety. If based on active moiety, the salts should be removed from the established name (i.e. Azor (amlodipine and olmesartan) or a statement of equivalency to active moiety should follow the established name (i.e. Each tablet contains amlodipine besylate and olmesartan medoximil equivalent to XX mg of amlodipine and XX mg of olmesartan).

Additionally, please be consistent in the presentation of the established name throughout the labeling. For further guidance, DMETS recommends that the Division consult Richard Lostritto, Chair of the CDER Labeling and Nomenclature Committee (LNC), Karl Stiller (The Project Manager Assigned to the LNC) and the assigned ONDQA Chemist regarding the proper designation of the established name. DMETS notes that at the time of writing this review DMETS researched and found out that the division plans a meeting with the sponsor to discuss this aspect of the labeling. Please notify DMETS of this upcoming meeting.

8. "Tablets" is printed above the letter 'R' in AZOR. Delete this statement as it is redundant and unnecessary.

B. BLISTER LABEL

1. See General Comments A2, A3, and A8.
2. Please delete the vertical line separating the active ingredients and the corresponding strengths of each respective active ingredient.
3. Consider establishing a color scheme for the different strengths that is consistent with the container label and carton labeling.

b(4)

Delete vertical line separating active ingredients from strength.

C. CONTAINER LABEL (30 count, 90 count and 100 count) b(4)

1. See General Comments A2 through A8.
2. For the unit-of-use bottles (e.g., 30 and 90 tablets), please ensure they comply with Poison Prevention Packaging Act, which denotes the necessity for child-resistant closure.

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D. CARTON LABELING (30 count, 90 count, 100 count)

1. See comments A1 through A7.
2. Please ensure that the carton labeling for the blister packs correctly reflect the net quantity (e.g., "10 blister packs of 10 tablets each")

E. PACKAGE INSERT LABELING

See General Comments A6 and A7.

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/s/

Denise Baugh
9/20/2007 02:27:05 PM
DRUG SAFETY OFFICE REVIEWER

Linda Kim-Jung
9/20/2007 02:31:21 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
9/20/2007 03:01:08 PM
DRUG SAFETY OFFICE REVIEWER

REQUEST FOR CONSULTATION

TO (Division/Office):

**Director, Division of Medication Errors and
Technical Support (DMETS), HFD-420
WO22, RM 4447**

FROM: Denise Hinton

Division of Cardiovascular and Renal Products
(301) 796-1090

DATE
July 18, 2007

IND NO.
IND 70, 410

NDA NO.
22-100

TYPE OF DOCUMENT
Tradename Request

DATE OF DOCUMENT
April 9, 2007

NAME OF DRUG
CS-8663 (olmesartan
medoxomil and amlodipine
besylate)

PRIORITY CONSIDERATION
Standard

CLASSIFICATION OF DRUG
Fixed dose combination
CCB/Angiotensin II
receptor antagonists

DESIRED COMPLETION DATE
August 18, 2007

NAME OF FIRM: Daiichi Sankyo Pharma Development

REASON FOR REQUEST

I. GENERAL

- | | | |
|--|--|---|
| <input type="checkbox"/> NEW PROTOCOL | <input type="checkbox"/> PRE-NDA MEETING | <input type="checkbox"/> RESPONSE TO DEFICIENCY LETTER |
| <input type="checkbox"/> PROGRESS REPORT | <input type="checkbox"/> END OF PHASE II MEETING | <input type="checkbox"/> FINAL PRINTED LABELING |
| <input type="checkbox"/> NEW CORRESPONDENCE | <input type="checkbox"/> RESUBMISSION | <input type="checkbox"/> LABELING REVISION |
| <input type="checkbox"/> DRUG ADVERTISING | <input type="checkbox"/> SAFETY/EFFICACY | <input type="checkbox"/> ORIGINAL NEW CORRESPONDENCE |
| <input type="checkbox"/> ADVERSE REACTION REPORT | <input type="checkbox"/> PAPER NDA | <input type="checkbox"/> FORMULATIVE REVIEW |
| <input type="checkbox"/> MANUFACTURING CHANGE/ADDITION | <input type="checkbox"/> CONTROL SUPPLEMENT | <input checked="" type="checkbox"/> OTHER (SPECIFY BELOW): Trade name review |
| <input type="checkbox"/> MEETING PLANNED BY | | |

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH

STATISTICAL APPLICATION BRANCH

- | | |
|--|---|
| <input type="checkbox"/> TYPE A OR B NDA REVIEW | <input type="checkbox"/> CHEMISTRY REVIEW |
| <input type="checkbox"/> END OF PHASE II MEETING | <input type="checkbox"/> PHARMACOLOGY |
| <input type="checkbox"/> CONTROLLED STUDIES | <input type="checkbox"/> BIOPHARMACEUTICS |
| <input type="checkbox"/> PROTOCOL REVIEW | <input type="checkbox"/> OTHER (SPECIFY BELOW): |
| <input type="checkbox"/> OTHER (SPECIFY BELOW): | |

III. BIOPHARMACEUTICS

- | | |
|--|---|
| <input type="checkbox"/> DISSOLUTION | <input type="checkbox"/> DEFICIENCY LETTER RESPONSE |
| <input type="checkbox"/> BIOAVAILABILITY STUDIES | <input type="checkbox"/> PROTOCOL-BIOPHARMACEUTICS |
| <input type="checkbox"/> PHASE IV STUDIES | <input type="checkbox"/> IN-VIVO WAIVER REQUEST |

IV. DRUG EXPERIENCE

- | | |
|--|--|
| <input type="checkbox"/> PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL | <input type="checkbox"/> REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY |
| <input type="checkbox"/> DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES | <input type="checkbox"/> SUMMARY OF ADVERSE EXPERIENCE |
| <input type="checkbox"/> CASE REPORTS OF SPECIFIC REACTIONS (List below) | <input type="checkbox"/> POISON RISK ANALYSIS |
| <input type="checkbox"/> COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP | |

V. SCIENTIFIC INVESTIGATIONS

CLINICAL

PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS: Please provide a second review of the proposed proprietary name, AZOR (olmesartan medoxomil and amlodipine besylate). The sponsor submitted an NDA on November 27, 2006. The name was found acceptable in the initial review dated 16May07. The goal date for this application will be 27Sep07. Thank you.

\\Cdsub1\evsprod\NDA022100\0006\m1\us\114-label\1141-draft-label\11411-draft-cart-cont\contain-blistersrev1.pdf

\\Cdsub1\evsprod\NDA022100\0006\m1\us\114-label\1141-draft-label\11411-draft-cart-cont\carton-sampleboxesrev1.pdf

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PDUFA DATE: 27Sep07

ATTACHMENTS: Draft Package Insert, Container and Carton Labels

CC: Archival IND/NDA 70410/22100

HFD-110/Division File

HFD-110/RPM

HFD-110/Reviewers and Team Leaders

NAME AND PHONE NUMBER OF REQUESTER

Denise Hinton for Akinwale Williams, MD

METHOD OF DELIVERY (Check one)

DFS ONLY

MAIL

HAND

SIGNATURE OF RECEIVER

SIGNATURE OF DELIVERER

5/28/05

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/s/

Denise Hinton
7/18/2007 04:40:40 PM

CONSULTATION RESPONSE
DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; White Oak 22; Mail Stop 4447)

DATE RECEIVED: 12/22/2006
DATE OF DOCUMENT: 9/18/2006

DESIRED COMPLETION DATE: 3/1/2007
PDUFA DATE: 9/27/2007

OSE REVIEW #:
2006-1167

TO: Norman Stockbridge, MD
Director, Division of Cardiovascular and Renal Products
HFD-110

THROUGH: Denise Toyer, PharmD, Deputy Director
Carol Holquist, RPh, Director
Division of Medication Errors and Technical Support, HFD-420

FROM: Judy Park, PharmD, Safety Evaluator
Division of Medication Errors and Technical Support, HFD-420

PRODUCT NAME:
Azor™
(Amlodipine Besylate and Olmesartan Medoxomil)
Tablets
5 mg/20 mg, 10 mg/20 mg, 5 mg/40 mg, and
10 mg/40 mg

SPONSOR: Daiichi Sankyo, Inc.

NDA #: 22,100

RECOMMENDATIONS:

1. DMETS has no objection to the use of the proprietary name, Azor. This is considered a tentative decision and the firm should be notified that this name with its associated labels and labeling must be re-evaluated approximately 90 days prior to the expected approval of NDA. A re-review of the name prior to NDA approval will rule out any objections based upon approvals of other proprietary or established names from the signature of this document.
2. DMETS recommends implementation of the label and labeling revisions outlined in section III of this review in order to minimize potential errors with the use of this product.
3. DDMAC finds the proprietary name, Azor, acceptable from a promotional perspective.

DMETS 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 DMETS on any correspondence to the sponsor pertaining to this review. If you have further questions or need clarifications, please contact Tanya Clayton, OSE Project Manager, at 301-796-0871.

Division of Medication Errors and Technical Support
Office of Surveillance and Epidemiology
HFD-420; WO22; Mail Stop 4447
Center for Drug Evaluation and Research

PROPRIETARY NAME, LABEL, AND LABELING REVIEW

DATE OF REVIEW: February 1, 2007

NDA #: 22,100

NAME OF DRUG: **Azor™**
(Amlodipine Besylate/Olmesartan Medoxomil) Tablets
5/20 mg, 10/20 mg, 5/40 mg, and 10/40 mg

NDA SPONSOR: Daiichi Sankyo, Inc.

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

I. INTRODUCTION

This consult was written in response to a request from the Division of Cardiovascular and Renal Products, for an assessment of the proprietary name "Azor" regarding potential name confusion with other proprietary or established drug names. Container labels, carton and insert labeling were provided for review and comment. Additionally, the sponsor submitted a name evaluation conducted by Drug Safety Institute, Inc. in support of the proposed proprietary name for review and comment.

PRODUCT INFORMATION

Azor is a fixed combination product containing a calcium channel blocker (amlodipine besylate) and an angiotensin receptor blocker (olmesartan medoxomil) for the indication of hypertension. Currently, amlodipine besylate (Norvasc™) and olmesartan medoxomil (Benicar™) exist as separate drugs. Azor will be available as oral tablets in strengths of 5/20 mg, 10/20 mg, 5/40 mg, and 10/40 mg. The recommended dose is individualized based upon whether it is a replacement, add-on, or initial therapy. For initial therapy in patients requiring blood pressure reduction of $\geq 20/10$ mmHg, the recommended starting dose is 5/20 mg once daily. The dose may be increased after 2 weeks in patients requiring further reduction in blood pressure to goal, to a maximum dose of 10/40 mg once daily. Azor is supplied as 10 blisters of 10 tablets and in bottles of 30, 90 and 1000 tablets.

II. RISK ASSESSMENT

The medication error staff of DMETS conducted a search of the internet, several standard published drug product reference texts^{1,2} as well as several FDA databases^{3,4} for existing drug

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² Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.

³ AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-07, and the electronic online version of the FDA Orange Book.

⁴ Phonetic and Orthographic Computer Analysis (POCA)

names which sound-alike or look-alike to Azor to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted⁵. The Saegis⁶ Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient orders) and a verbal prescription study involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name. Following completion of these initial components, an overall risk assessment is conducted that does not evaluate the name alone. The assessment considers the findings from above and more importantly integrates post-marketing experience in assessing the risk of name confusion, product label/labeling, and product packaging. Because it is the product that is inserted into the complex and unpredictable U.S. healthcare environment, all product characteristics of a drug must be considered in the overall safety evaluator risk assessment.

A. EXPERT PANEL DISCUSSION

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name, Azor. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. DDMAC finds the proprietary name, Azor, acceptable from a promotional perspective.
2. The Expert Panel identified a total of twenty proprietary names that were thought to have potential for confusion with Azor.

B. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

Three separate studies were conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Azor 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. These studies employed a total of 123 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process. An inpatient order and outpatient prescriptions were written, each consisting of a combination of marketed and unapproved drug products and a prescription for Azor (see page 4). These prescriptions were optically scanned and one prescription was delivered to a random sample of the participating health professionals via e-mail. In addition, the outpatient orders were recorded on voice mail. The voice mail message was then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription order, the participants sent their interpretations of the orders via e-mail to the medication error staff.

⁵ WWW location <http://www.uspto.gov/tmdb/index.html>.

⁶ Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at www.thomson-thomson.com

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
<p>Outpatient RX:</p> <p><i>azor 5mg/20mg</i> <i>1 tablet po daily #30</i></p>	<p>Azor 5 mg plus 20 mg #30 Take 1 tablet by mouth daily</p>
<p>Inpatient RX:</p> <p><i>Azor 5mg/20mg 1 tablet by mouth daily</i></p>	

2. Results:

None of the interpretations of the proposed name overlap, sound similar, or look similar to any currently marketed U.S. product. See appendix A for the complete listing of interpretations from the verbal and written studies.

C. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name, the following names were identified to have potential similarity in appearance and/or sound to Azor: Aceon, Oxyir, Azo Gantanol, Azo Gantrisin, Cipro, Azolid, Tazorac, Nizoral, Apri, Cozaar, Zocor, Ara-C, Ascor L-500, Azopt, Ayr product line, Azo product line, and foreign drug products, Azur (Germany), Azur (Italy), Ezor (Spain), and Azor (South Africa).

Additionally, DMETS conducted prescription studies to simulate the prescription ordering process. In this case, there was no confirmation that Azor could be confused with any of the aforementioned names. However, negative findings are not predicative as to what may occur once the drug is widely prescribed, as these studies have limitations primarily due to a small sample size. The majority of misinterpretations were misspelled/phonetic variations of the proposed name, Azor.

Of these twenty names, nine names, Aceon, Oxyir, Azo Gantanol, Azo Gantrisin, Cipro, Azolid, Tazorac, Nizoral, and Apri, were not reviewed further because they lack significant look-alike and/or sound-alike similarities to Azor in addition to having differentiating product characteristics that may include: indication for use, product strength, usual dosage, route of administration, frequency of administration, dosage form, prescriber population, patient population, storage conditions, and/or product unavailability.

Additionally, the names, Azor, Azur, and Ezor, are either exact matches orthographically and/or phonetically to the proprietary name, Azor. These products are marketed in other countries. Azor is alprazolam in South Africa, Azur is paracetamol/caffeine/codeine in Germany and fluoxetine in Italy, and Ezor is contact laxative in Spain. The similarity and exact match of Azor is most concerning. Through review of the literature and postmarketing surveillance, DMETS is aware of confusion between products marketed domestically and abroad which have similar or identical proprietary names but different active ingredients. A recent example of such confusion is the case of Palladone (U.S. – extended-release hydromorphone), vs. Pallidone (New Zealand – methadone)⁷ where the names are different by one letter. The Institute of Safe Medication Practices (ISMP) also recently published an article citing other such examples of confusion, including, Dilacor XR (U.S. - extended-release diltiazem), vs. Dilacor (Serbian – digoxin)⁸. One source of confusion is that

⁷ Safety Briefs, Foreign Influence. ISMP Safety Alert! Community/Ambulatory Care Issue. June 2005, 4(6), 2,3.

⁸ New Dangers in the Drug Re-Importation Process: Will we know what our patients are taking? ISMP Safety Alert! January 27, 2005, 10(2), 1-2.

patients and/or healthcare providers seeking information about a product (e.g., on the world wide web or through searches of electronic medical databases, e.g., Micromedex⁹), using a misspelling could find information about the wrong medication. DMETS envisions the scenario where health care providers or patients seeking information on the newly approved Azor would be confused by this information due to the exact match in the product name. We also envision the scenario where patients arriving from abroad and wishing to continue on Azor (alprazolam) are prescribed Azor (amlodipine/olmesartan). Alternatively there could be confusion for travelers seeking to get an equivalent for Azor abroad, where health care practitioners will most likely think of Azor (alprazolam). Although this does not affect the acceptability of the proposed proprietary name in this country, the sponsor should be alerted to the potential for confusion due to misinterpretation of the active ingredients of Azor. Thus, these four foreign names will not be reviewed further.

The remaining drug products are listed in Table 1 (see below and page 6), along with the dosage forms available and usual dosage. These names are discussed in detail below.

Table 1: Potential Sound-Alike/Look-Alike Names Identified by DMETS Expert Panel for Azor

Product Name	Established name, Dosage form(s)	Usual adult dose*	Other
Azor	Amlodipine Besylate/Olmesartan Medoxomil Tablets: 5/20 mg, 10/20 mg, 5/40 mg, 10/40 mg	Individualized to patient Maximum does of 10/40 mg once daily	
Cozaar	Losartan Tablets: 25 mg, 50 mg, 100 mg	Individualized to patient. Generally 25-100 mg PO QD or BID.	LA
Zocor	Simvastatin Tablets: 5 mg, 10 mg, 20 mg, 40 mg, 80 mg	Individualized to patient. Recommended usual starting dose is 20-40 mg QD.	LA
Ara-C	Cytarabine Injectable: Multiple (20 mg, 100 mg, 500 mg, 1000 mg, 2000 mg)	Varies depending on indication.	LA
Ascor L-500	Ascorbic Acid Injectable: 500 mg/mL	Varies. Generally 100-250 mg for adults QD or BID.	LA/SA
Azopt	Brinzolamide Ophthalmic Suspension: 1%	1 drop in eye(s) TID.	LA
Ayr OTC Product Line • Baby's Saline Nose Spray • Mentholated Vapor Inhaler • Saline Nasal Gel with Soothing Aloe • Saline Nasal Gel • No-Drip Sinus Spray • Saline Nasal Mist • Snore Relieving Throat Spray	Saline Intranasal Sprays/Gels	Varies depending on the product.	LA

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⁹ MICROMEDEX Integrated Index, 2007, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

Product Name	Established name, Dosage form(s)	Usual adult dose	Other
Azor	Amlodipine Besylate/Olmesartan Medoxomil Tablets: 5/20 mg, 10/20 mg, 5/40 mg, 10/40 mg	Individualized to patient Maximum dose of 10/40 mg once daily	
Azo OTC Product Line • Azo Cranberry • Azo Standard • Azo Test Strips • Azo Yeast	<u>Azo Cranberry</u> : Natural Cranberry Powder Concentrate Tablets: 900 mg <u>Azo Standard</u> : Phenazopyridine Tablets: 95 mg <u>Azo Test Strips</u> <u>Azo Yeast</u> : Boneset (eupatorium Perfoliatum) 6x, Mistletoe Leaf (Viscum album) 6x	<u>Azo Cranberry</u> : 1-4 tablets daily PO with meals. <u>Azo Standard</u> : 2 tablets PO QID. <u>Azo Test Strips</u> : Use as directed. <u>Azo Yeast</u> : 1 tablet QD to TID.	LA/SA
*Frequently used, not all-inclusive. **LA (look-alike), SA (sound-alike)			

1. Cozaar was noted to have similar appearance to Azor. Cozaar (losartan) is an angiotensin II receptor antagonist indicated for hypertension. The dosage of Cozaar is individualized to patient and ranges from 25 mg to 100 mg QD or BID. It is also available as generic. Cozaar is available in 25 mg, 50 mg, 100 mg oral tablets in bottles of 30, 90, 1000, and 10,000 tablets, and unit dose of 100 tablets.

Cozaar and Azor have beginning and ending look-alike similarities. When “Co” in Cozaar is scripted close together, it can look similar to “A” in Azor. Both names are followed by “z” which makes the first several letters of the names look-alike. Both names end in “ar” and “or”. The letters “a” and “o” are known to be mistaken for one another when scripted which increases the look-alike similarities of the ending. The differentiating characteristic is the length of the name (6 letters vs. 4 letters) which is emphasized by the extra “a” in the middle of Cozaar. Thus, Azor appears much shorter than Cozaar.

Both products have overlapping indication of use (hypertension), drug classification (angiotensin II receptor antagonist), individualized dosing, frequency of administration (once daily), route of administration (oral), prescriber population (general practitioners and cardiologists), and package size (bottles of 30, 90, 1000 tablets). However, they do not share overlapping strengths (25 mg, 50 mg or 100 mg vs. 5/20 mg, 5/40 mg, 10/20 mg, 10/40 mg). Additionally, Cozaar is a single active ingredient product and Azor is a fixed combination product of two active ingredients which requires specification of both strengths when prescribing. These differences may help distinguish the two products. Although this name pair exhibits some similarities in appearance and product characteristics exist, the length of the name will help in minimizing potential confusion between the Cozaar and Azor.

2. Zocor was found to look-alike to Azor. Zocor (simvastatin) is indicated for hypercholesterolemia. The dosage is individualized to patient according to the therapy goal and the patient's response. However, the recommended usual starting dose is 20 mg to 40 mg once a day. It is available as generic. Zocor is available in 5 mg, 10 mg, 20 mg, 40 mg, and 80 mg oral tablets in bottles of 30, 60, 90, 100, 1000, and 10,000 tablets.

Zocor and Azor look similar because they share overlapping letters (z, o, and r) and both end in "-or". Although the first letters are different, if "Z" in Zocor is crossed in the middle, it can resemble the line across the capital letter "A" in Azor. The endings (-cor vs. -zor) can also look similar when "z" is not scripted in a lower case letter. The first "o" in Zocor and the difference in first letters can help distinguish the name.



The image shows two handwritten words. The top word is 'Azor' written in a cursive style. The bottom word is 'Zocor' also written in a cursive style, with a horizontal line crossing through the middle of the 'Z'.

The overlapping product characteristics include strengths (5 mg, 10 mg, 20 mg, and 40 mg), usual dosage (individualized to patient), frequency of administration (once daily), route of administration (oral), dosage forms (tablets), and package size (bottles of 30, 90, and 1000 tablets). Although both products share the same overlapping strengths, Zocor is a single entity product and Azor is a combination product which requires specification of both strengths of the active ingredients (e.g., 10 mg vs. 10/40 mg). Thus, if a prescription for Zocor 10 mg was misinterpreted as Azor 10 mg, the dispenser would need further clarification of Azor's strength since Azor is available in two fixed 10 mg strengths (10/20 mg and 10/40 mg). DMETS believes the risk of confusion is low due to the dual strength of Azor as well as the lack of strong look-alike characteristics.

3. Ara-C was found to have look-alike similarities to Azor. Ara-C is a common name used to refer to cytarabine which is a chemotherapy agent used to treat various types of leukemia. The recommended dose is in mg/m^2 and varies depending on what type of leukemia is being treated and how it is administered (intravenous, intrathecal or subcutaneous). Ara-C is available as powder for injection which requires reconstitution (100 mg, 500 mg, 1 g, 2 g) and solutions (100 mg/5 mL). It is available as generic by multiple manufacturers.

Ara-C and Azor both have 4 letters in the name and start with the letter "A". Ara-C can look like Azor when the hyphenation in Ara-C is omitted and the name is written together without the capitalization of C (Arac). The "r" in Ara-C can look similar to "z" in Azor when "z" is not scripted. The similarity of "a" and "o" makes the first 3 letters look alike (Ara- vs. Azo-). The ending letters (-c vs. -r) can also look similar with the scripted "r".

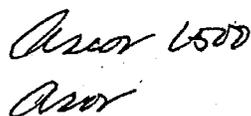


The image shows two handwritten words. The top word is 'Azor' written in a cursive style. The bottom word is 'Arac' also written in a cursive style.

Ara-C and Azor have an overlapping strength of 20 mg (20 mg/mL vs. 5/20 mg and 10/20 mg). However, since Azor is available in two fixed 20 mg strengths (5/20 mg and 10/20 mg), the prescriber would need to specify the strength of the other active ingredient, amlodipine (5 mg or 10 mg). Additionally, since Ara-C is prescribed in mg/m^2 or calculated total dose and the dosing depends on patient's body surface area (BSA) and indication, the total dose will vary and most likely not overlap. Furthermore, since Ara-C can be administered as intravenously, intrathecally or subcutaneously, the route of administration would need to be specified when prescribing. These differences, therefore, minimize the potential for confusion between Ara-C and Azor.

4. Ascor L-500 was found to look and sound similar to Azor. Ascor L-500 is an ascorbic acid injection use to treat scurvy (vitamin C deficiency). It is available in a strength of 500 mg/mL in a 50 mL vial. The usual dosage varies depending on the age of the patient and severity of the deficiency. But the general dose for adults ranges from 100-250 mg once daily.

Ascor L-500 can look like Azor when the modifier "L-500" is omitted from the prescription. Both names have the same beginning (A-) and ending (-or). The differentiating letters (-sc- vs. -z-) can look similar when "sc" is written close together and "z" is not scripted with a downstroke. They also sound similar although "c" in Ascor gives a stronger accent to the name.



Ascor L500
Azor

Ascor L-500 and Azor have overlapping frequency of administration (QD). However, they have many different product characteristics such as strength (500 mg/mL vs. 5/20 mg, 5/40 mg, 10/20 mg, 10/40 mg), dosage form (injectable vs. tablet), route of administration (intravenous vs. oral), usual dosage (100 mg to 250 mg vs. 1 tablet), and indication of use (scurvy vs. hypertension). Ascor L-500 will likely be prescribed in total dose (100 mg to 250 mg) or total volume (0.2-0.5 mL) which does not overlap in dosing with Azor. Additionally, Ascor L-500 is a single entity product and Azor is a fixed combination product of two active ingredients requiring specification of both strengths when prescribing. Thus, due to these product differences as well as orthographic differences, DMETS believes the potential confusion between Ascor L-500 and Azor is minimal.

5. Azopt was found to have similar look-alike characteristics with Azor. Azopt (brinzolamide) is an ophthalmic suspension drops used to treat glaucoma. The recommended dose is 1 drop in affected eye(s) TID. It is available in a single strength of 1% and package size of 5 mL, 10 mL and 15 mL.

Azopt and Azor start with the same 3 letters (Azo-). However, Azopt looks different from Azor in regards to the length of its name (5 letters vs. 4 letters) and the downstroke of "p" and upstroke of "t".



Azopt
Azor

Azopt and Azor do not share any overlapping product characteristics except for the number "5" in Azopt package size and the strength of one of the active ingredients in Azor (5 mL vs. 5 mg). A prescription can be written as "Azopt 5 mL" which can have potential confusion with "Azor 5/20 mg (or 5/40 mg)". However, since Azor is a fixed combination product and available in two fixed 5 mg strengths, the dispenser would need further clarification of Azor's strength (5/20 mg and 5/40 mg). Thus the likelihood of such error to occur is minimized. Due to the lack of overlapping product characteristics and the difference in look alike characteristics, DMETS believes the risk of confusion between Azopt and Azor is minimal.

6. Ayr was found to have look-alike similarities to Azor. Ayr is an over-the-counter (OTC) product line of intranasal saline products. All of the products start with the family trade name "Ayr" followed by the distinguishing product name (Ayr Baby's Saline Nose Spray, Ayr Mentholated Vapor Inhaler, Ayr Saline Nasal Gel with Soothing Aloe, Ayr Saline Nasal Gel, No-Drip Sinus Spray, Ayr Saline Nasal Mist, and Ayr Snore Relieving Throat Spray). The recommended dose varies depending on the product.

Ayr and Azor can look-alike because they both start and end with the same letter (A and r). Additionally, the downstroke of "y" and "z" (scripted) increases the look-alike similarities between the two names. However, the extra "o" in Azor may help in distinguishing the name by lengthening the name (see samples on page 9).

Ayr
Azor

Ayr and Azor do not share overlapping product characteristics. Ayr is used intranasally and Azor is an oral tablet. Additionally, Ayr products do not contain any active drug ingredients (saline primarily). Since Ayr is an OTC product, it will not likely be prescribed in writing or verbally. If a prescription is written for Ayr as a reminder for the patient, it is likely that the prescriber will include the modifier describing which product they want. Even if the modifier is omitted, the prescriber would need to be contacted for the appropriate strength before Azor is dispensed since Azor is available in 4 different strengths. Therefore, due to the dual strength of Azor and lack of overlapping product characteristics, the potential confusion between the Ayr and Azor is minimal.

7. Azo was noted to look similar to Azor. Azo is an over-the-counter (OTC) product line which starts with "Azo" followed by the distinguishing product name (Azo Cranberry, Azo Standard, Azo Test Strips and Azo Yeast). Azo Standard has the active ingredient, phenazopyridine, which is used to relieve symptoms of urinary tract infection (UTI). Azo Cranberry is made up of cranberry powder concentrate and is used to help maintain healthy urinary tract. Azo Test Strips is a home diagnostic kit to test for UTI. Azo Yeast consists of homeopathic ingredients (Boneset and Mistletoe Leaf in a natural base containing Lactobacillus Sporogenes) and is used for vaginal yeast infection prevention and symptomatic relief. All the products are oral tablets except for Azo Test Strips and the recommended dose varies depending on the product (see Table 1).

Azo and Azor have similar look-alike and sound-alike characteristics. The names look identical except for the additional "r" at the end of Azor. They also sound alike when "r" is not less pronounced.

Azo
Azor

The overlapping product characteristics are dosage form (tablet), route of administration (oral), and frequency of administration (QD). Since Azo products are OTC products, they will not most likely be prescribed in writing or verbally. However, a patient with UTI may be prescribed antibiotics and a prescriber may also write "Azo" on the prescription for the UTI pain as a reminder for the patient. But most likely, the prescriber will include the modifier describing which product they want. Even if the modifier is omitted, the prescriber would need to be contacted for the appropriate strength before Azor is dispensed since Azor is available in 4 different strengths. Due to the dual strength of Azor, the potential for confusion is decreased.

D. DRUG SAFETY INSTITUTE ASSESSMENT

(Proprietary Name Safety and Promotional Assessment for Azor™ dated August 31, 2006)

The Drug Safety Institute (DSI) conducted a study to evaluate the potential for error between Azor and currently marketed brand/generic drug products. DSI's research methodology involves four sections. For Section I the staff at DSI conducted a search of standard published and electronic drug references in order to identify sound and/or look-alike proprietary and non-proprietary names marketed in the U.S. and other countries. A DSI Internal Expert Panel then convened to discuss and review the findings from these searches. In Section II, six physicians, two pharmacists, and two nurses produce verbal and handwritten prescriptions similar to those that would be

communicated in practice. In Section III, pharmacists, physicians, and nurses interpret the multiple prescriptions collected in Section II. Each participant interprets only one of the three prescription types: handwritten inpatient, handwritten outpatient, or verbal. In addition to the test names, control names are added to the prescription studies. Once the healthcare professionals have interpreted the prescriptions, they complete self-administered questionnaires online. The healthcare professionals are asked to identify proprietary or nonproprietary drug names that may sound like and/or look like the proposed proprietary name. A total of 150 U.S. healthcare professionals interpret prescriptions and answer questions directly related to name safety. The sample includes 23 primary care physicians, 23 cardiologists, 96 pharmacists, and 8 nurses. The participants in Sections II and III do not participate in any other research section. Section IV involves the Computerized Orthographic and Phonologic Analysis (COPA) which evaluates the degree of look-alike and sound-alike similarity for all drug names identified in the research relative to Azor, including drug names originating from the DSI Internal Expert Panel discussion, the prescription interpretation studies, the similar drug name listings from surveys of healthcare professionals, and computerized searches. Section V is the DSI-Reference Comparative Safety Analysis that identifies profiles for existing drug products and compares them with the profile of the test drug to identify commonalities or overlapping characteristics.

The analysis conducted by DSI identified the following names as having significant look-alike or sound-alike similarity to Azor: Alora, Avelox, Axid, Azactam, Azolid, Azopt, Hyzaar, Nizoral, Sorine, Aceon, Actos, Advicor, Anspor, Asacol, Avelox, Avodart, Axert, Axid, Azathioprine, Azithromycin, Azmacort, Azol, Azor, Azo-Standard, Cozaar, Crestor, Ensure, K-Lor, Lipitor, Mevacor, Tazorac, Zocor, Ak-Zol, Alor, Avar, Aza-CR, Azdone, Azo-100, Eazol, Ezol, Lazer, Pazo, Vazol, and Zazole.

In the prescription studies conducted by DSI, one participant from the verbal study misinterpreted Azor as Theo-Dur and one participant from the outpatient study misinterpreted Azor as Hyzaar. However, DSI believed that the likelihood of confusion to be minimal due to differences in strength, usual dose and low COPA scores which were well-below the threshold.

Overall, the DSI study favorably supported the use of Azor as a proposed proprietary name.

DMETS comments:

Like DSI's analysis, DMETS also identified the names Azolid, Azopt, Nizoral, Aceon, Azor, Azo-Standard, Tazorac, Cozaar, and Zocor as names which could be confused in appearance and/or sound with Azor. DMETS did not find the following names that DSI identified as having look- and/or sound-alike to Azor: Alora, Avelox, Axid, Azactam, Hyzaar, Sorine, Actos, Advicor, Anspor, Asacol, Avelox, Avodart, Axert, Axid, Azathioprine, Azithromycin, Azmacort, Azol, Crestor, Ensure, K-Lor, Lipitor, Mevacor, Ak-Zol, Alor, Avar, Aza-CR, Azdone, Azo-100, Eazol, Ezol, Lazer, Pazo, Theo-Dur, Vazol, and Zazole. DMETS identified the following additional names which were not identified in the DSI evaluation as having look- and/or sound alike: Oxyir, Azo Gantanol, Azo Gantrisin, Cipro, Apri, Ara-C, Ascor L-500, Ayr product line, Azo product line, and foreign drug products, Azur (Germany), Azur (Italy), Ezor (Spain), and Azor (South Africa).

Following the review of the proprietary name analysis submitted by DSI, DMETS concurs with DSI in considering the names identified to have low potential for confusion with Azor due to a lack of convincing look-alike/sound-alike similarities with Azor in addition to numerous differentiating product characteristics such as the lack of availability of the drug. DMETS also concurs with DSI's analysis of their prescriptions studies in regards to Theo-Dur and Hyzaar.

III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES

In the review of the container labels, carton and insert labeling of Azor, DMETS focused on safety issues relating to medication errors. DMETS has identified the following areas of improvement, which will minimize potential user error.

A. GENERAL COMMENTS

1. The container label and carton labeling were submitted in black and white format. Thus, DMETS was unable to assess if there are any safety issues due to the use of color fonts especially in distinguishing different strengths. Please submit color versions when available.
2. Please ensure that the established name is at least ½ the font size of the proprietary name.
3. Please remove _____ in the established name and replace it _____ Additionally, include _____ after the first active ingredient (_____) **b(4)**
4. The established name of the product contains salts “besylate” and “medoxomil.” Please clarify if the strengths and dose are based on salt or active moiety. If based on active moiety, the salts should be removed from the established name (i.e. Azor (amlodipine and olmesartan) or a statement of equivalency to active moiety should follow the established name (i.e. Each tablet contains amlodipine besylate and olmesartan medoximil equivalent to XX mg of amlodipine and XX mg of olmesartan). Additionally, please be consistent in the presentation of the established name throughout the labeling. For further guidance, DMETS recommends that the Division consult Richard Lostritto, Chair of the CDER Labeling and Nomenclature Committee (LNC), Karl Stiller (The Project Manager Assigned to the LNC) and the assigned ONDQA Chemist regarding the proper designation of the established name.

B. BLISTER LABEL

1. See General Comments A1 through A4.
2. Remove “Tablets” after the proprietary name since the dosage form is not part of the proprietary name. Instead, relocate it after the established name.
3. As per 21 CFR 201.10 (i)(1), include the name of the manufacturer, packer or distributor of the drug.

C. CONTAINER LABEL

1. See General Comments A1 through A4.
2. Relocate the strength away from the net quantity so that they are not mistaken for one another. We recommend relocating the strength so that it follows the established name.
3. Please ensure that the company logo is not larger than the font size of the trade name and does not compete in prominence with the trade name.
4. For the unit-of-use bottles (e.g., 30 and 90 tablets), please ensure they comply with Poison Prevention Packaging Act, which denotes the necessity for child-resistant closure.

D. CARTON LABELING

1. See comments A1 through A4, and C3.
2. For the non-professional sample labels, relocate the strength away from the net quantity so that they are not mistaken for one another. We recommend relocating the strength so that it follows the established name.
3. The net quantity of the blister packs should be correctly reflected on the carton (e.g., “10 blisters packs of 10 tablets each”)

E. PRESCRIBING INFORMATION

1. See General Comments A3 and A4.

2. Under the Dosage and Administration section, i

b(4)

We recommend specifying what the next dose increase should be. For example, if a patient on Azor 5 mg/20 mg needs a further dose increase, clarify whether the next dose should be 10 mg/20 mg, 5 mg/40 mg, or 10 mg/40 mg.

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Appendix A

Azor Prescription Study Results

Written Inpatient	Written Outpatient	Verbal
Azor	Azok	Azore
Azor	Lizou	Azore
Cezor	Azor	Azor
AZOR	Uzor / Lazor	Azor
Azor	Lazor	Azor
Azor	Lazor	Azor
Azor	Azor	Azore
Azor	Azon	Azor
Pezor	Lazor	Azor
Azor	Lazor	
Cezor	Azor	
Azor	Azok	
Azor	Lizok	
Azor	Azor	
Azor	Uzor / Azor	
Azor	Azor	
Azor	Azor	
Azor	Azor	
Azor		
Azor		
Azor		
Cezor		

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