CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206494Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	November 25, 2014
Application Type and Number:	NDA 206494
Product Name and Strength:	Avycaz (ceftazidime/avibactam) for injection, 2000 mg/ 500 mg
Product Type:	Single Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Cerexa
Submission Date:	September 23, 2014
Panorama #:	2014- 35116
DMEPA Primary Reviewer:	Justine Harris, RPh
DMEPA Acting Team Leader:	Tingting Gao, PharmD
Associate Director:	Irene Z. Chan, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Avycaz, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by (b) (4), for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Cazavi, on June 16, 2014 and June 25, 2014. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, Cazavi, unacceptable due to orthographic similarities and shared product characteristics with the proprietary name Cozaar in OSE reviews #2014-25619 and 2014-25965 dated August 27, 2014.

Thus, the Applicant submitted the name, Avycaz, for review on September 23, 2014.

1.2 PRODUCT INFORMATION

The following product information is provided in the September 23, 2014 proprietary name submission.

- Intended Pronunciation: AV-ee-kaz
- Active Ingredient: ceftazidime/avibactam
- Indication of Use: Treatment of complicated urinary tract infections (cUTI), including acute pyelonephritis, and treatment of complicated intra-abdominal infections (cIAI)
- Route of Administration: intravenous
- Dosage Form: powder for injection
- Strength: 2000 mg ceftazidime/500 mg avibactam
- Dose and Frequency: 2000 mg/ 500 mg every 8 hours; maximum daily dose is 6000 mg/1500 mg
- How Supplied: single clear glass vial; 10 vials per carton
- Storage: Unconstituted vial stored at 25°C; excursion permitted between 15°C and 30°C.
- Container and Closure Systems: 20 mL clear glass vial with rubber stopper and aluminum flip-off overseal

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name does not misbrand the proposed product. DMEPA and the Division of Anti-Infective Products (DAIP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Avycaz, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Ninety-eight practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products; however, seven participants in the voice study misinterpreted the proposed name as 'Avitaz', which is a close variation to the currently marketed product Avita. This misinterpretation is further evaluated in Section 2.2.6 and Appendix E.

Of the 98 practitioners in the study, 31 interpreted the name correctly, and they were all in the written prescription studies. In the written prescription study, 28 participants misinterpreted the ending letter string '-caz' for '-coz' and 25 participants misinterpreted the letter '-v-'for the letter '-u-'. In the verbal prescription study, 11 participants misinterpreted the ending letter string '-caz' for '-taz' and 25 participants misinterpreted the letter '-y-' for '-i-'.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 14, 2014 e-mail, the Division of Anti-Infective Products (DAIP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar,

[1]USAN stem search conducted on October 3, 2014.

[2] POCA search conducted on September 25, 2014.

or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation or by (b) (4).

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	42
Low similarity name pair: combined match percentage score ≤49%	25

2.2.6 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 68 names contained in Table 1 determined the names will not pose a risk for confusion as described in Appendices C through H.

We evaluated the potential for confusion between Avycaz and Avita in detail due to the responses generated from the FDA Prescription Stimulation Study. Seven participants in the voice study misinterpreted the proposed name as 'Avitaz', which is a close variation to the currently marketed product Avita. (See Section 2.2.3 and Appendix B). We evaluated the phonetic similarity to the marketed product, Avita, and determined that the risk of confusion with Avycaz is mitigated by the fact this name pair have significant product characteristic differences. Although both products are available in single strengths, which may be omitted on the prescription, they have differing doses and instructions for use (e.g., apply to affected area or UAD vs, 2.5 g IVPB q 8 hours).

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Anti-Infective Products (DAIP) via e-mail on November 6, 2014. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAIP on November 7, 2014, they stated no additional concerns with the proposed proprietary name, Avycaz.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Karen Townsend, OSE project manager, at 301-796-5413.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 23, 2014 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

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

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment**:** We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [3]

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

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion, which is an area of concern (See Table 3).
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders, which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

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/s/

JUSTINE HARRIS
11/25/2014

IRENE Z CHAN
11/26/2014

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review:	August 27, 2014
Application Type and Number:	IND 101307 and NDA 206494
Product Name and Strength:	Cazavi (ceftazidime/avibactam) Injection, 2.5 grams
Product Type:	Multi-ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Cerexa Inc.
Submission Date:	June 16, 2014 and June 25, 2014
Panorama #:	2014-25619 and 2014-25965
DMEPA Primary Reviewer:	Danielle Neupauer, RPh
DMEPA Acting Team Leader:	Tingting Gao, PharmD
DMEPA Acting Director:	Kellie Taylor, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Cazavi, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by [redacted] (b) (4), for this proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the June 16, 2014 proprietary name submission.

- Intended Pronunciation: kaz-AV-ee
- Active Ingredient: ceftazidime-avibactam
- Indication of Use: The proposed indication is for the treatment of complicated urinary tract infections (cUTI), including acute pyelonephritis, and treatment of complicated intra-abdominal infections (cIAI)
- Route of Administration: Intravenous
- Dosage Form: Solution for Injection
- Strength: 2.5 grams (2000 mg ceftazidime/500 mg avibactam)
- Dose and Frequency: 2.5 grams every 8 hours. The maximum daily dose is 7.5 grams.
- How Supplied: Product will be available in single clear glass vial; 10 vials per carton.
- Storage: 25°C; excursion permitted between 15°C and 30°C.

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Anti-Infective Products (DAIP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Cazavi, is derived from ceftazidime and avibactam. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

One hundred practitioners participated in DMEPA's prescription studies. One inpatient study interpretation overlapped with one currently marketed product, Cozaar. Additionally, two participants commented that this name looks similar to Cozaar. This misinterpretation is evaluated in Section 3.1.

None of the other interpretations overlapped with any currently marketed product nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline.

In the outpatient study, 23 of 38 participants correctly interpreted the name Cazavi. Common misinterpretation was in the suffix '-avi' which was misinterpreted as '-ari' by 10 of 38 participants.

In the voice study, 1 of 28 participants correctly interpreted the name Cazavi. Common misinterpretations were in the prefix 'Caz-' which was misinterpreted as 'Kas-', 'Tiz-' and 'Kas-'.

In the inpatient study, 1 of 34 participants correctly interpreted the name Cazavi. Common misinterpretation was in the prefix 'Caz-' which was misinterpreted as 'Coz-' by 21 of 34 participants.

Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, June 25, 2014 e-mail, the Division of Anti-Infective Products (DAIP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation Study and by (b) (4).

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[1]USAN stem search conducted on June 30, 2014.

[2] POCA search conducted on June 30, 2014.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	121
Low similarity name pair: combined match percentage score ≤49%	3

2.2.6 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

We determined 125 of the 126 of names will not pose a risk for confusion as described in Appendix C through G. However, the proposed name could be confused with Cozaar. The rationale for the risk of confusion is described in Section 3.1.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Anti-Infective Products (DAIP) via e-mail on August 5, 2014. Per e-mail correspondence from the DAIP on August 11, 2014, they stated no additional concerns with the proposed proprietary name, Cazavi.

3 CONCLUSIONS

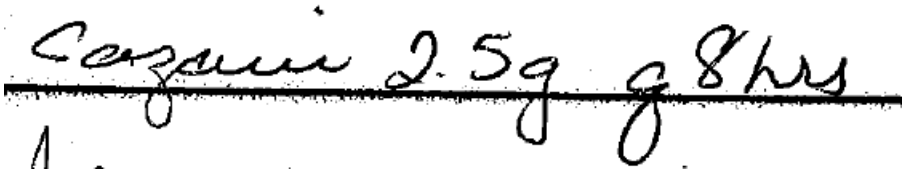
The proposed proprietary name is acceptable from a promotional perspective but not acceptable from a safety perspective. The proposed name, Cazavi, is vulnerable to name confusion with Cozaar. Therefore, the decision to deny the name will be communicated to the Applicant/Sponsor via letter (See ***Section 3.1).***

If you have further questions or need clarifications, please contact Karen Townsend, OSE project manager, at 301-796-5413.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Cazavi, and have concluded that this name is unacceptable for the following reasons:

Your proposed name, Cazavi, may be confused with the currently marketed product, Cozaar. We identified this safety concern based upon the misinterpretation of Cazavi as Cozaar in our written prescription simulation study. Because the likelihood of observing an error in a small study is low, we consider this finding to be an important predictor of errors that could occur in actual use if the proposed name were to be approved and marketed. On this basis, we have concern that the name Cazavi is likely to lead to errors with Cozaar in actual use. The sample below was used in the FDA written prescription simulation study.



We also note that the Cazavi Safety Analysis prepared by (b) (4) and submitted as part of the request for proprietary name review identified Cozaar as having similar sound and similar appearance in the Prescription Interpretation and Safety Survey. The survey participants were all healthcare professionals which further supports the potential for confusion between the two names.

(b) (4) concluded that Cazavi and Cozaar had sufficient distinctions to alleviate the potential for confusion because they do not share any identical letter strings longer than two letters. However, both names have the same length (6 letters), start with same letter 'C', have the letter string 'za' in the 3rd and 4th positions, and have similar shape when scripted. Furthermore, FDA's Phonetic and Orthographic Computer Analysis (POCA) calculates a 61% orthographic match for this name pair, which suggests that Cazavi and Cozaar look similar to each other.

In addition to their orthographic similarity, these products also share overlapping product characteristics. Cazavi and Cozaar have numerical similarities in strength and dose (2.5 grams vs. 25 mg). Oversight of decimals is a wide known factor in medication errors, and post-marketing surveillance of other wrong drug errors due to numerical similarity in dose and strength demonstrates this risk. For example, the Institute for Safe Medication Practices (ISMP) describes a case of medication confusion where prescriptions written for Microzide (hydrochlorothiazide) 12.5 mg were misinterpreted as Micronase (glyburide) 1.25 mg due to their look-alike names.[3]

We note that Cazavi and Cozaar have a single route of administration and dosage form, which may be omitted from a prescription without prompting a clarification. However, we find that these differences are insufficient to prevent and error due to overwhelming orthographic similarity between Cazavi and Cozaar as evident in our prescription simulation study where full characteristics were provided yet misinterpreted. For example, ISMP describes a case of medication confusion where a written order for Celebrex was misinterpreted as Cerebyx since no route of administration was noted.[4]

Therefore, based upon the orthographic similarity of the names and overlapping product characteristics, we conclude there is a risk of wrong drug errors if your proposed name were to be approved. We find the proposed proprietary name, Cazavi unacceptable..

[3] Institute for Safe Medication Practices, Oral antidiabetic therapy: Not as easy as it used to be (part 2). ISMP Med Saf Alert Community/Ambulatory 2004; 3(9) 2-4

[4] Institute for Safe Medication Practices, Safety Briefs. ISMP Med Safe Alert Acute Care 1999; 4(3) 2

REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name.

1. **Promotional Assessment**: For prescription drug products, the promotional review of the proposed name is conducted by OPDP. For over-the-counter (OTC) drug products, the promotional review of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [5]

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Affirmative answers to these questions indicate a potential area of concern.
Y/N	Does the name have obvious Similarities in Spelling and Pronunciation to other Names?
Y/N	Are there Manufacturing Characteristics in the Proprietary Name?
Y/N	Are there Medical and/or Coined Abbreviations in the Proprietary Name?
Y/N	Are there Inert or Inactive Ingredients referenced in the Proprietary Name?
Y/N	Does the Proprietary Name include combinations of Active Ingredients
Y/N	Is there a United States Adopted Name (USAN) Stem in the Proprietary Name?
Y/N	Is this the same Proprietary Name for Products containing Different Active Ingredients?
Y/N	Is this a Proprietary Name of a discontinued product?

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

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. Based on our root cause analysis of post marketing experience errors, we find the expression of strength and dose, which is often located in close proximity to the drug name itself on prescriptions and medication orders, is an important factor in mitigating or potentiating confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion is limited (e.g., route, frequency, dosage form, etc.).

- For highly similar names, there is little that can mitigate a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are likely to be rejected by FDA. (See Table 3)
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics (e.g., route, frequency, dosage form, etc.) to mitigate confusion may be limited when the strength or dose overlaps. FDA will review these names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4)
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist (See Table 5).

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair do not share a common strength or dose (see Step 1 of the Moderately Similar Checklist).			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths have a higher potential for confusion and should be evaluated further (see Step 2). For single strength products, also consider circumstances where the strength may not be expressed. For any combination drug products, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: o Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion between moderately similar names **with** overlapping or similar strengths or doses.

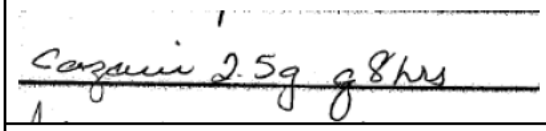
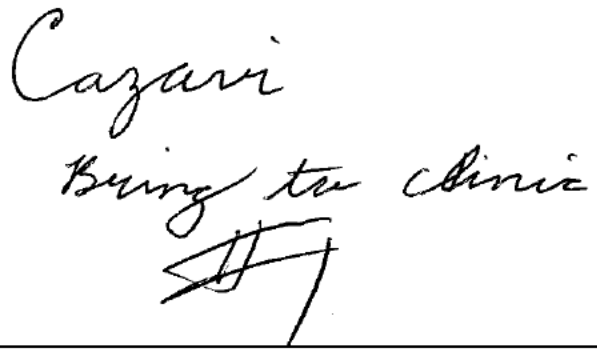
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where there are data that suggest a name with low similarity might be vulnerable to confusion with your proposed name (for example, misinterpretation of the proposed name as a marketed product in a prescription simulation study). In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Cazavi Study (Conducted on June 27, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: 	Cazavi Bring to clinic #1
Outpatient Prescription: 	

FDA Prescription Simulation Responses

Study Name: Cazavi

265 People Received Study

100 People Responded

Total	38	28	34	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
CAJAVI	1	0	0	1
CARZIN	0	0	1	1
CASAVI	0	1	0	1
CAZAIR	2	0	0	2
CAZALVI	0	1	0	1
CAZARI	10	0	0	10
CAZARRI	1	0	0	1
CAZARVI	1	0	0	1
CAZAUI	0	0	2	2
CAZAUIR	0	0	1	1
CAZAUIS	0	0	1	1
CAZAVI	23	1	1	25
CAZAVIS	0	0	1	1
CAZCUIC	0	0	1	1
CAZCUIR	0	0	1	1
CAZCUIS	0	0	1	1
CAZSEUI	0	0	1	1
CORZAIN	0	0	1	1
CORZAVIR	0	0	1	1
COZ???	0	0	1	1
COZAAR	0	0	1	1
COZAIN	0	0	3	3
COZAIN?	0	0	1	1
COZAIR	0	0	2	2

COZAIRE	0	0	2	2
COZARIA	0	0	1	1
COZAUI	0	0	1	1
COZAVI	0	0	2	2
COZAVIN	0	0	1	1
COZAVIR	0	0	4	4
COZSIVI	0	0	1	1
COZUIR	0	0	1	1
KASAVEE	0	1	0	1
KASAVI	0	4	0	4
KAZABI	0	2	0	2
KAZADIE	0	1	0	1
KAZAVI	0	6	0	6
KESOVI	0	1	0	1
KISAVI	0	2	0	2
KIZAVI	0	1	0	1
KUZABEE	0	1	0	1
PISANVI	0	1	0	1
PISSAVI	0	1	0	1
QIZABI	0	1	0	1
TIZABY	0	1	0	1
TIZAVI	0	2	0	2

Appendix C: Highly Similar Names (i.e., combined POCA score is ≥70%)

No.	Proposed name: Cazavi Strength(s): 2.5 grams Usual Dose: 2.5 grams IV every 8 hours	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Or Failure prevention reasons
1.	Cazavi	100	Proposed name is subject of this review.
2.	(b) (4) ***	74	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-3624). Product approved under established name (ANDA 91325).

Appendix D: Moderately Similar Names (i.e., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	KAZANO	68
2.	CLARAVIS	62
3.	KARIVA	62
4.	(b) (4) ***	60
5.	CAFCIT	56
6.	CALAN	56
7.	Covera	56
8.	Nazarin	56
9.	(b) (4) ***	55
10.	(b) (4) ***	54
11.	CAMILA	54
12.	Capzasin-P	54
13.	Coraz	54
14.	Corzall	54
15.	Cosamin	54
16.	Panafil	54
17.	Atazanavir	52
18.	CAMBIA	52
19.	Claris	52

20.	COBAVITE	52
21.	GADAVIST	52
22.	Kaon-CI	52
23.	KAPVAY	52
24.	KAVA ROOT	52
25.	(b) (4)***	52
26.	Cafatine	51
27.	Cevi-Bid	51
28.	Codar AR	51
29.	(b) (4)***	51
30.	AVAGE	50
31.	Calagel	50
32.	Cala-Gen	50
33.	Capsaicin	50
34.	CARDIZEM	50
35.	CARDURA	50
36.	Cartia	50
37.	CONZIP	50
38.	COTAZYM	50
39.	C-SOLVE-2	50
40.	KADIAN	50
41.	Phenazo	50
42.	Prazosin	50
43.	VIDAZA	50

Appendix E: Moderately Similar Names (i.e., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name: Cazavi** **Strength(s): 2.5 grams** **Usual Dose: 2.5 grams IV every 8 hours**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	CANASA	64	The suffix of this name pair have sufficient orthographic differences The second syllables of this name pair sound different
2.	GAZYVA	63	The infix of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different
3.	CO-LAV	60	The infix of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different
4.	COLAZAL	58	The prefix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
5.	ARAVA	56	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
6.	CARAC	56	The suffix of this name pair have sufficient orthographic differences. Cazavi contains an extra syllable.
7.	(b) (4) ***	56	The infix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
8.	CLOZARIL	56	The prefix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.

9.	Cotab A	56	The infix of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different.
10.	Kabiven***	54	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
11.	Capsin	52	The suffix of this name pair have sufficient orthographic differences. Cazavi contains an extra syllable.
12.	Capacet	52	The suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
13.	JAKAFI	52	The prefix and suffix of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different.
14.	LOVAZA	52	The suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
15.	SITAVIG	52	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
16.	SOVALDI	52	The infix and suffix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
17.	Kerasal	51	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
18.	SAVELLA	51	The infix and suffix of this name pair have sufficient orthographic differences. Cazavi contains an extra syllable.

19.	CANTIL	50	The infix and suffix of this name pair have sufficient orthographic differences. Cazavi contains an extra syllable.
20.	KAFOCIN	50	The prefix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
21.	Pannaz	50	The prefix and suffix of this name pair have sufficient orthographic differences. Cazavi contains an extra syllable.
22.	Sarapin	50	The infix of this name pair have sufficient orthographic differences. The prefix and suffix of this name pair have sufficient orthographic differences.
23.	VIDAZA	50	The infix and suffix of this name pair have sufficient orthographic differences. The prefix and suffix of this name pair have sufficient orthographic differences.

Appendix F: Low Similarity Names (i.e., combined POCA score is ≤49%)

No.	Name	POCA Score (%)
1.	Tarceva	49
2.	Tazicef	47
3.	Tyvaso	42

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	52	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2013-668). Product approved under pending proprietary name (b) (4) ***.
2.	(b) (4) ***	52	Proposed name withdrew by the Applicant. (OSE# 2013-1145). NDA (b) (4) received Complete Response on (b) (4).
3.	(b) (4) ***	68	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2009-1620). Product approved under proprietary name Moxeza.
4.	(b) (4) ***	67	This is a secondary proposed proprietary name and the product was approved under proprietary name Elinest.
5.	(b) (4) ***	62	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-3812). Product approved under established name.
6.	(b) (4) ***	62	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-3812). Product approved under established name.
7.	(b) (4) ***	62	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-3812). Product approved under established name.
8.	Calanif	61	International product marketed in United Kingdoms
9.	(b) (4) ***	61	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2010-1630). Product approved under proprietary name Philith.

10.	(b) (4) ***	61	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2010-1186). No new proprietary name submitted.
11.	C20-40 ACID	60	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
12.	(b) (4) ***	60	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2010-2629). Product approved under proprietary name Jakafi.
13.	(b) (4) ***	58	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-3814). Product approved under proprietary name Yaz.
14.	(b) (4) ***	58	Proposed proprietary name found unacceptable by DMEPA (OSE # 2011-3141). Product conditionally approved under new proprietary name (b) (4) ***
15.	Calazem	56	International product marketed in United Kingdom
16.	(b) (4) ***	56	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2010-1236). Product approved under proprietary name Safyral.
17.	(b) (4) ***	56	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2007-2012). No new proprietary name submitted.
18.	Kefadim	56	International product marketed in United Kingdom, Brazil, and China.
19.	Carace	55	International product marketed in United Kingdom and Ireland.
20.	(b) (4) ***	55	Proposed proprietary name found unacceptable by DMEA (OSE 2008-1370). Product approved under proprietary name Orsythia.
21.	Aviva	54	Product is not a drug. It is the name of a non-PVC IV bag.
22.	Calcid	54	International product marketed in India

23.	Ca-Rezz	54	Product is not a drug. It is a skin disinfectant.
24.	CariFree	54	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
25.	(b) (4)***	54	Secondary proposed proprietary name and the product was approved under established name Tacrolimus (ANDA 065461).
26.	Paraffin	54	Product is not a drug. It is a wax.
27.	(b) (4)***	54	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2008-1122). Product approved under established name.
28.	(b) (4)***	53	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-47). Product approved under proprietary name Absorica.
29.	C10-36 OLEFIN	52	Product is not a drug. It is a surfactant.
30.	C24-28 Olefin	52	Product is not a drug. It is a surfactant.
31.	C30-45 OLEFIN	52	Product is not a drug. It is a surfactant.
32.	(b) (4)***	52	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-3935). No new proprietary name submitted.
33.	Catosal	52	Veterinary product.
34.	Claradin	52	International product marketed in United Kingdoms and Ireland.
35.	Clario	52	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
36.	(b) (4)***	52	Proposed proprietary name found unacceptable by DMEPA (OSE# 2011-1221). No new proprietary name submitted.
37.	Kapvey***	52	Secondary proposed proprietary name. Product was approved under new proprietary names Kapvay and Jenloga (NDA 22331).

38.	Ketaved	52	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
39.	Koate DVI	52	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
40.	(b) (4) ***	52	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2011-181). Product approved under proprietary name Sitavig.
41.	(b) (4) ***	52	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2010-2282). Product approved under proprietary name Trokendi.
42.	Calazime	51	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
43.	carvone	51	Product is not a drug. It is an isomer used as flavoring and in perfumes.
44.	Chigarid	51	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
45.	(b) (4) ***	51	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2013-1502). Product approved under established name.
46.	Captan	50	Product is not a drug. It is an insecticide.
47.	(b) (4) ***	50	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2006-466). Product conditionally approved under proprietary name (b) (4) ***
48.	Covace	50	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
49.	(b) (4) ***	50	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2008-1300). Product approved under proprietary name Zirgan.

50.	[redacted] ***	50	This is a secondary proposed proprietary name and the product was deemed acceptable under proprietary name [redacted] ***.
51.	[redacted] ***	50	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-1271). Product approved under proprietary name Khedezla.
52.	Laviv	50	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases.
53.	[redacted] ***	50	This is a secondary proposed proprietary name and the product was approved under proprietary name Pradaxa.
54.	[redacted] ***	50	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2009-2410). Application (NDA [redacted]) was withdrawn by the Applicant on July 6, 2012.
55.	Tanabid	50	International product marketed in Puerto Rico.

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/s/

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