

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

202008Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review--Final

Date: February 24, 2012

Reviewer(s): Kevin Wright, PharmD
Division of Medication Error and Prevention Analysis

Team Leader Todd Bridges, RPh.
Division of Medication Error and Prevention Analysis

Drug Name(s) and Strength(s): Amyvid (Florbetapir F 18) Injection
37 MBq/mL to 1900 MBq/mL (1 mCi/mL to 50 mCi/mL)

Application Type/Number: NDA 202008

Applicant: Avid Radiopharmaceuticals

OSE RCM #: 2011-4215

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Amyvid is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Amyvid, acceptable in OSE Review 2010-2074 dated December 9, 2010.

2 METHODS AND RESULTS

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review RCM# 2010-2074. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded one new name (b)(4) thought to sound similar to Amyvid and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with (b)(4) and lead to medication errors. This analysis determined that the name similarity between Amyvid and the identified name was unlikely to result in medication error for the reasons presented in Appendix A.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of January 23, 2012.

The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on January 5, 2012, and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

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

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

If you have further questions or need clarifications, please contact Sandra Griffith, OSE project manager, at 301-796-2445.

4 REFERENCES

1. Baugh, D, OSE Review #2010-2074, Proprietary Name Review Final of Amyvid, December 10, 2010.
2. **Drugs@FDA** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)
Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.
3. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>)
USAN Stems List contains all the recognized USAN stems.
4. **Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request**
Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

Appendix A: Proprietary name not likely to be confused or not used in usual practice settings for the reasons described.

<u>Proposed name:</u>	<u>Strength:</u>	<u>Usual Dose:</u>
Amyvid (Florbetapir F 18) injection	37 MBq/mL to 1900 MBq/mL (1 mCi/mL to 50 mCi/mL)	370 mBq (10 mCi) administered as an intravenous bolus dose
Failure mode: Incorrect product ordered/selected;dispensed or administered because of name confusion	Causes	Prevention of Failure Mode (name confusion)

(b) (4)

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/s/

KEVIN WRIGHT
02/24/2012

TODD D BRIDGES
02/24/2012



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

Date: December 9, 2010

Application Type/Number: NDA# 202008

Through: Todd Bridges, RPh, Team Leader
Denise Toyer, PharmD, Deputy Director
Division of Medication Error Prevention and Analysis (DMEPA)

From: Denise V. Baugh, PharmD, BCPS, Safety Evaluator
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Amyvid
(Florbetapir F 18) Injection
37 MBq/mL to 1900 MBq/mL (1 mCi/mL to 50 mCi/mL) per
Unit Dose vial or syringe at the time of calibration

Applicant/sponsor: Avid Radiopharmaceuticals

OSE RCM #: 2010-2074

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EXECUTIVE SUMMARY

This review summarizes the Division of Medication Error Prevention and Analysis' evaluation for the proposed proprietary name Amyvid for Florbetapir F 18 Injection (NDA 202008). Our evaluation identified no concerns from a safety and promotional perspective that would render the name unacceptable. Thus, DMEPA finds the proposed proprietary name, Amyvid, acceptable for this product. The Applicant will be notified of these findings via letter.

The proposed proprietary name, Amyvid, must be re-reviewed 90 days before approval of the NDA. If any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

1 BACKGROUND

1.1 INTRODUCTION

The Applicant, Avid Radiopharmaceuticals, requested an assessment of the proposed proprietary name in a submission dated September 28, 2010. Within this submission, the Applicant submitted an external study in support of their proposed proprietary name.

The Division of Medication Error Prevention and Analysis (DMEPA) assesses a proposed proprietary name regarding its potential for name confusion with other proprietary or established drug names in the usual practice settings. Additionally, DMEPA considers the Division of Drug Marketing, Advertising and Communications' (DDMAC's) promotional assessment of the name.

1.2 PRODUCT INFORMATION

Amyvid is the proposed proprietary name for Florbetapir F 18 injection. It is a diagnostic radiopharmaceutical agent indicated for positron emission tomography (PET) imaging of beta amyloid aggregates in the brain. A negative florbetapir-PET scan is clinically useful in ruling out the presence of *B*-amyloid, a defining pathology of Alzheimer's disease (AD). The recommended dose is 10 mCi (370 MBq) which is given as a single intravenous bolus dose in a total volume not exceeding 10 mL. It should not be diluted prior to administration. The dose is followed by a (b)(4) flush of 0.9% Sodium Chloride Injection to ensure full delivery of the dose. Amyvid is supplied in 10 mL vials and in (b)(4) syringes containing 37 MBq/mL to 1900 MBq/mL (1 mCi/mL to 50 mCi/mL) Florbetapir F 18 per vial or syringe at the time of calibration. Each vial or syringe is enclosed in a shielded container of appropriate thickness to minimize external radiation exposure. Store Amyvid at (b)(4) 25°C; excursions are permitted to 15°C- 30°C. The product should be stored within the original container or equivalent radiation shielding.

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Amyvid.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter ‘A’ when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.^{1,2}

To identify drug names that may look similar to Amyvid, the DMEPA safety evaluators also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (six letters), upstrokes (two, capital letter A and lower case letter d), down strokes (one, lower case letter y), cross strokes (none), and dotted letters (one, lower case letter i). Additionally, several letters in Amyvid may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Amyvid.

When searching to identify potential names that may sound similar to Amyvid, the DMEPA safety evaluators search for names with similar number of syllables (three), stresses (AM-y-vid or am-y-VID), and placement of vowel and consonant sounds. (See Appendix B) Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary, such as the letters ‘amy-’ may be interpreted as ‘ami-’ or ‘vid’ may be interpreted as ‘veed-’. The Sponsor’s intended pronunciation (a mee vid) was also taken into consideration, as it was included in the Proprietary Name Review Request. However, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

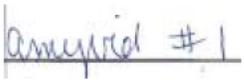
2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following two inpatient medication orders and verbal prescription were communicated during the FDA prescription studies.

¹ Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

² Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

Figure 1. Amyvid Prescription Study (conducted August, 2010)

MEDICATION ORDER and HANDWRITTEN PRESCRIPTION	VERBAL INPATIENT ORDER
<u>Inpatient Medication Order:</u> 	“Amyvid #1”
<u>Inpatient Medication Order:</u> 	

2.3 EXTERNAL PROPRIETARY RISK ASSESSMENT

For this product, the Applicant submitted a summary of an external evaluation of the proposed proprietary name, conducted by the Drug Safety Institute, Inc. (DSI). The Division of Medication Error Prevention and Analysis conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in DMEPA’s database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator’s Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings.

After the Safety Evaluator has determined the overall risk associated with the proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Applicant. The Safety Evaluator then determines whether the Division’s risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

3 RESULTS

The following sections describe DMEPA’s findings from the database searches, CDER Expert Panel Discussion, FDA prescription analysis studies, and the external proprietary name study.

3.1 DATABASES AND INFORMATION SOURCES

The DMEPA safety evaluator searches yielded a total of nineteen names as having some similarity to the name Amyvid.

Twelve of the names were thought to look like Amyvid. These include: Amytal, Angeliq, Avalide, Avandia, (b) (4)***, Ansaid, Amykal, Amytril, E-mycin, Amdry-D, Amaryl, and

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Amoxil. Three names (Amitid, Amyben, and Amevive) were thought to sound like Amyvid. The four remaining names, Amyvid, Amibid, Enovid, and Ambifed were thought to look and sound similar to Amyvid.

Additionally, DMEPA safety evaluators did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of November 19, 2010.

3.2 CDER EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Amyvid.

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

3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of 41 practitioners responded and three of the responses looked similar to existing names, 'Amifed' (n = 1) and 'Amibid' (n = 2). Amifed is similar to the marketed name, Ambifed which is a name included in our evaluation. Amibid is the root name for the names Amibid DM and Amibid LA which are also evaluated in this review.

Fifteen participants interpreted the name correctly as 'Amyvid', with the correct interpretation occurring only in written prescription studies. Misinterpretations in the written studies included misinterpretation of the letter 'v' for the letter 'b' and misinterpretation of the letter 'd' for the letters 'al' or 'el'. In the verbal studies, most responses were misspelled phonetic variations of the proposed name, Amyvid, including the misinterpretation of the letter 'y' for the letters 'a', 'i', or 'o' and the misinterpretation of the letters in the suffix ('vid') for the letters '-fed-', '-fid', '-phid', and '-fiz'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

In the proposed name risk assessment submitted by the Sponsor, the Drug Safety institute (DSI) found the proposed name acceptable.

DSI evaluated several names for their potential similarity to Amyvid. Of these names, DMEPA's primary safety evaluator found 15 names which were orthographically and/or phonetically similar to the proposed proprietary name, Amyvid. Seven of the fifteen names (Amaryl, Amevive, Amibid, Amoxil, Amdry-D, Ambifed and Enovid) were previously identified in the DMEPA safety evaluator searches. The remaining eight names (Amikin, Amiloride, Amitriptyline, Amyl Nitrite, Axid, Mavik, Ovide, and Paremyd) were thought to have orthographic and/or phonetic similarity to Amyvid and thus determined to present some risk of confusion. We considered these eight names in the assessment.

3.5 SAFETY EVALUATOR RISK ASSESSMENT

The primary safety evaluator performed an independent search for names that would represent a potential source of drug name confusion. The search identified no additional names thought to look similar to Amyvid and represent a potential source of drug name confusion.

As such, a total of 27 names were further analyzed to determine if the drug names could be confused with Amyvid and if the drug name confusion would likely result in a medication error in the usual practice setting. Nineteen names were identified from the database searches and eight names were identified by the external name study.

3.6 COMMENTS FROM THE DIVISION OF MEDICAL IMAGING PRODUCTS (DMIP)

3.6.1 Initial Phase of Review

In response to the OSE September 22, 2010, email the Division of Medical Imaging Products did not object to the proposed proprietary name, Amyvid.

3.6.2 Midpoint of Review

On December 7, 2010, DMEPA notified DMIP via email that we find the name Amyvid acceptable. Per email correspondence from DMIP on December 8, 2010, they agreed with our recommendation and had no objections to the proposed trade name.

4 DISCUSSION

This proposed name, Amyvid, was evaluated from a safety and promotional perspective. Furthermore, input from pertinent disciplines involved with the review of this application was considered accordingly.

4.1 PROMOTIONAL ASSESSMENT

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name. The Division of Medical Imaging Products and DMEPA concurred with the promotional assessment.

4.2 SAFETY EVALUATOR RISK ASSESSMENT

DMEPA identified twenty-seven names for their potential similarity to the proposed name, Amyvid. We did not identify other aspects of the name that would function as a source of error.

Twelve of the 27 names were eliminated from further evaluation for the following reasons: seven names lacked convincing orthographic and/or phonetic similarity to the proposed proprietary name (Appendix D), one name was the subject of this review (Appendix E) and four names were found not to be used in the usual practice settings for the reasons described in Appendix F.

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining fifteen (n = 15) names and lead to medication errors. This analysis determined that the name similarity between Amyvid and all 15 names identified was unlikely to result in medication errors for the reasons presented in Appendices G.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Amyvid, is not promotional nor is it vulnerable to name confusion that could lead to medication errors. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) have no objection to the proprietary name, Amyvid, for this product at this time. Our analysis is consistent with the external risk assessment conducted by Drug Safety Institute (DSI) that was provided by the Applicant. The Applicant will be notified via letter.

We are willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Sandra Griffith, OSE project manager, at 301-796-2445.

6 REFERENCES

6.1 DATABASES

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

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

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

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

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

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

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

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

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

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

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

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

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

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

USPTO provides information regarding patent and trademarks.

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

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

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

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

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

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

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

Stat!Ref contains full-text information from approximately 30 texts; it includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology, and Dictionary of Medical Acronyms Abbreviations.

13. USAN Stems (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)

USAN Stems List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

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

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

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

16. Medical Abbreviations Book

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

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. 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

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.⁴ DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA staff considers the potential for confusion throughout the entire U.S. medication use

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

⁴ Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.⁵ DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., “T” may look like “F,” lower case ‘a’ looks like a lower case ‘u,’ etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. If provided, DMEPA will consider the Sponsor’s intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice.

⁵ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 1. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

Type of similarity	Considerations when searching the databases		
	Potential causes of drug name similarity	Attributes examined to identify similar drug names	Potential Effects
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down-strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, the DMEPA staff also considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA staff conducts searches of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

3. Comments from the OND review Division or Generic drugs

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or 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 concur/not concur with DMEPA's final decision.

4. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.⁶ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section one. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?”

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Risk Assessment:

- a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that

could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

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

The threshold set for objection to the proposed proprietary name may seem low to the Sponsor. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and a preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. . (See Section 4 for limitations of the process).

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

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

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in Name, Amyvid	Scripted may appear as	Spoken may be interpreted as
Capital 'A'	Cl, O, Ci	O, 'Ah-'
lower case 'm'	h, n, r, u, or v	'n'
lower case 'y'	g, j	Any vowel
Lower case 'v'	n, o, r, s, or u	'b' or 'f'
lower case 'i'	e, l,	Any vowel
lower case 'd'	'el', 'cl'	

Appendix C: FDA Prescription Study Responses for Amyvid.

Inpatient Prescription I	Inpatient Prescription II	Verbal Prescription
Amyviel	Amyird	Amavid
Amyvid #1	Amyuid	Amavid #1
Amybid#1	Amyvid	Amavid #1
Amyvid	Amyvid	Amavid
Amyvid	Amyvid	Amifed, #1 – could not find this drug or any that sounded similar
Amybid #1	Amyvid - none.	Amavid #1
Amybid #1	Amyvid #1	Amifid #1
Amyvial #1	Amyvid #1	Amiphid #1
Amybid #1	Amyvid #1	Amafiz #1
Amyloid	Amyvid #1	Amibid #1
Amyvial	Amyvid (none)	Amibid #1
Amyvial	Amyvid, #1	Amovid
Amyvid	Amyvid, dispense 1	Amvobid
Amybid	Sonyvid # 1	

Appendix D: Proprietary names that lack convincing orthographic and/or phonetic similarities

Proprietary Name	Similarity to Amyvid
Avandia	Look
Amiloride (DSI)	Look and/or Sound
Amitriptyline (DSI)	Look and/or Sound
Axid (DSI)	Look and/or Sound
Mavik (DSI)	Look and/or Sound
Ovide (DSI)	Look and/or Sound
Paremyd (DSI)	Look and/or Sound

Appendix E. Proprietary Name which is the subject of this review.

Proprietary Name	Source
Amyvid	USPTO, Saegis

Appendix E: Proprietary names not used in usual practice settings for the reasons described.

Proprietary Name (active ingredient)	Strength	Similarity to	Failure preventions
Enovid (mestranol and norethynodrel) Oral Tablet	0.075 mg/5 mg, 0.15 mg/9.85 mg	Look and Sound	Applicant discontinued distributing and/or marketing of the drug as of July, 1992 due to (b) (4)
(b) (4)			
Amykal (Terbinafine) Oral Tablets	250 mg, 500 mg	Look	Marketed in Austria (source: Micromedex) and not available in the U.S.
Amyben (amiodarone) Injection	150 mg/3 mL, 900 mg/18 mL	Sound	Marketed in United Kingdom (source: Micromedex)

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

Appendix G: Risk of name confusion minimized by prevention listed.

Product name with potential for confusion	Similarity to proposed proprietary name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Amyvid (Florbetapir F18) Injection		37-1900 MBq/mL (1-50 mCi/mL) with up to 10 mL of solution containing 370 MBq (10 mCi) Florbetapir F 18 at the time of calibration	370 MBq (10 mCi) by intravenous bolus injection as a single dose	
Avalide (Irbesartan/ Hydrochlorothiazide) Oral Tablet Used to treat hypertension	Look	12.5 mg/150 mg, 12.5 mg/300 mg, 25 mg/300 mg	Initial dose: Irbesartan 150 mg/hydrochlorothiazide 12.5 mg once daily	<p>Orthographic difference: Avalide has no down strokes and two up strokes compared to one down stroke ('y') and a terminal upstroke ('d') in Amyvid. These features give these names different shapes and may differentiate the names from each other.</p> <p>Product characteristics differ such as route of administration (oral vs. intravenous), frequency of administration (once daily vs. once) and strengths (12.5 mg/150 mg, 12.5 mg/300 mg, or 25 mg/300 mg vs. 10 mCi (370 MBq)).</p> <p>There is no numerical overlap.</p>
Amikin (amikacin) Injection (DSI) (Amikin is no longer marketed but generic equivalents exist)	Look and/or Sound	50 mg/mL, 250 mg/mL	15 mg/kg intramuscularly or intravenously divided into 2 or 3 equally divided doses (e.g., 7.5 mg/kg every 12 hours or 5 mg/kg every 8 hours)	<p>Orthographic differences include the presence of a down stroke ('y') and terminal up stroke ('d') in the proposed name, Amyid compared to upstroke ('k') at the beginning of the suffix for 'Amikin'. These features give these names different shapes and may assist in minimizing confusion between the names.</p> <p>Product characteristics which differ include the frequency of administration (every 12 hours or every 8 hours vs. one time).</p> <p>Finally, because Amyvid is a radiopharmaceutical, regulatory control of this product necessitates a closed distribution system in which the medication would be acquired and stored separate from traditional drug products in the usual practice settings.</p>

Amytal (amobarbital) for Injection	Look	500 mg <i>Strength may be omitted since single strength and not required to dispense product.</i>	65 mg to 200 mg intramuscularly as a single dose 1 to 2 hours before surgery	Orthographic differences include the presence of a cross-stroke ('t') as the fourth letter in Amytal compared to a down stroke ('y') and an upstroke as a terminal letter in the proposed name, Amyvid. These features give the names differing shapes and may minimize the likelihood for confusion between this name pair.
Amytril (amitriptyline) Oral Tablet	Look	10 mg, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg	50 mg to 100 mg orally 1 to 3 times per day	Orthographic differences include the upstroke letter 't' in Amytril. Product characteristics differ such as route of administration (oral vs. intravenous), frequency of administration (once to three times daily vs. once) and strengths (10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg vs. 10 mCi (370 MBq)). Because of the availability of more than one strength for Amytril, this information would have to be stated by the prescriber to dispense/administer the medication.
Amdry-D (methscopolamine and pseudoephedrine) Extended Release Tablet	Look	2.5 mg/120 mg <i>Strength may be omitted since single strength and not required to dispense product.</i>	One tablet every 12 hours	Orthographic differences include the reverse locations of the upstroke and down stroke within the names (Amdry-D vs. Amyvid) as well as the inclusion of a modifier (upper case 'D') in the marketed name, Amdry-D. These features give the names a different shape and are likely to help differentiate them from each other. Product difference the route of administration (oral vs. intravenous) and frequency of administration (once vs. every twelve hours).
Amaryl (glimeperide) Tablet	Look	1 mg, 2 mg, 4 mg	1 mg to 4 mg orally once daily to a maximum of 8 mg per day	Orthographic differences include the different positions of the down stroke letter (Amaryl vs. Amyvid) which give these names a different shape. Product differences include the route of administration (oral vs. intravenous, dose (1 mg, 2 mg, 4 mg, vs. 10 mCi (370 MBq) and frequency of administration (once daily vs. one time).

Amoxil (amoxicillin) Tablet	Look	250 mg, 500 mg, 875 mg	250 mg to 500 mg orally every 8 hours or 875 mg twice daily	<p>Orthographic differences include the lack of a down stroke in the marketed name Amoxil compared to Amyvid which gives these names different shapes.</p> <p>Product characteristics that differ include the route of administration (oral vs. intravenous, dose (250 mg, 500 mg, 875 mg vs. 10 mCi (370 MBq) and frequency of administration (every 8 hours or twice daily vs. one time).</p>
Amitid (amitriptyline) Tablet	Sound	10 mg, 25 mg, 50 mg, 75 mg, 100 mg, 150 mg	50 mg to 100 mg orally 1 to 3 times per day	<p>Phonetic difference includes the hard sound of ‘t’ in Amitid vs. the soft sound of ‘v’ in Amyvid. Enunciation of these letters requires the use of different parts of the mouth and may differentiate these names from each other.</p> <p>Product characteristics that differ include the frequency of administration (one to three times daily vs. once), route of administration (oral vs. intravenous), and strengths (10 mg, 25 mg, 50 mg, 75 mg, 100 mg, and 150 mg vs. 10 mCi (370 MBq)).</p> <p>Furthermore, preliminary drug use data suggests that the name Amitid is rarely utilized. This may decrease the opportunity for confusion between this name pair.</p>
Amevive (alefacept) Injection	Sound	7.5 mg, 15 mg	15 mg intramuscularly once weekly	<p>No numerical overlap in dose.</p> <p>Amyvid is a radiopharmaceutical that requires regulatory control and a closed distribution system in which the medication would be acquired and stored separate from traditional drug products.</p> <p>Furthermore, preliminary drug use data suggests that the name Amevive is rarely utilized. This may decrease the opportunity for confusion between this name pair.</p>

<p>Amibid (marketed as Amibid DM or Amibid LA):</p> <p>Amibid DM (dextromethorphan and guaifenesin) Extended Release Tablet</p>	<p>Look and Sound</p>	<p>30 mg/600 mg</p> <p><i>Strength may be omitted since single strength and not required to dispense product.</i></p>	<p>1 tablet orally every 12 hours</p>	<p>Orthographic difference includes the presence of two upstrokes in Amibid compared to one down stroke and one upstroke in Amyvid which gives these names different shapes and may help to differentiate them from each other.</p> <p>Product characteristic differences include dosage form (tablet vs. injection), dose (1 tablet, 600 mg or 1200 mg vs. 10 mCi (370 MBq), route of administration (oral vs. intravenous), and frequency of administration (every 12 hours vs. one time). Additionally, the prescriber would have to designate the modifier (LA or DM) in order for the medication to be dispensed/administered as intended.</p>
<p>Amibid LA (guaifenesin) Extended Release Tablet</p> <p>Both products are no longer marketed but generic equivalents exist</p>		<p>600 mg</p> <p><i>Strength may be omitted since single strength and not required to dispense product</i></p>	<p>600 mg to 1200 mg orally every 12 hours</p>	<p>There is no numerical overlap in dose.</p> <p>Amyvid is a radiopharmaceutical that requires regulatory control and a closed distribution system in which the medication would be acquired and stored separate from traditional drug products.</p> <p>Additionally, preliminary drug usage data suggests that the opportunity for confusion between Amibid and Amyvid would be low.</p>
<p>Angeliq (drospirenon/estradiol) Oral Tablet</p>	<p>Look</p>	<p>0.5 mg/1 mg</p> <p><i>Strength may be omitted since single strength and not required to dispense product</i></p>	<p>One tablet daily</p>	<p>Orthographic differences include the presence of one upstroke sandwiched between two down strokes in the marketed name, Angeliq which contrasts with one down stroke ('y') and a terminal upstroke ('d') in the proposed name, Amyvid. These differences give these names different shapes and will likely differentiate them from each other.</p> <p>Product characteristic differences include dosage form (tablet vs. injection), route of administration (oral vs. intravenous), and frequency of administration (daily vs. one time).</p>

<p>Ansaid (flurbiprofen) Oral Tablet</p>	<p>Look</p>	<p>50 mg, 100 mg</p>	<p>200 mg to 300 mg per day given 2, 3, or 4 times a day</p>	<p>Orthographic difference stems from the presence of a down stroke ('y') in the proposed name Amyvid compared to the lack of such a feature in Ansaid. This gives these names different shapes and will likely differentiate these names from each other.</p> <p>Product characteristics which differ include dosage form (tablet vs. injection), route of administration (oral vs. intravenous), and frequency of administration (2, 3, or 4 times per day vs. one time)</p>
<p>Ambifed (guaifenesin and pseudoephedrine) Tablet</p>	<p>Look and Sound</p>	<p>400 mg/30 mg <i>Strength may be omitted since single strength and not required to dispense product.</i></p>	<p>1 tablet orally every 4 to 6 hours, up to 6 tablets in 24 hours</p>	<p>Orthographic differences include the presence of four upstrokes in Ambifed compared to one downstroke and one up stroke in the proposed name, Amyvid. This difference gives these names different shape and may be likely to reduce the potential for confusion between them.</p> <p>Product characteristics which differ include dosage form (tablet vs. injection), route of administration (oral vs. intravenous), and frequency of administration (every 4 to 6 hours vs. one time).</p>
<p>Amyl Nitrite Inhalant (DSI)</p>	<p>Look and/or Sound</p>	<p>0.3 mL covered glass capsule</p>	<p>Two to 6 inhalations of the vapors from the capsule are usually sufficient to produce therapeutic effects. May repeat the dose in 3 to 5 minutes.</p>	<p>Orthographic differences include the length of the name, Amyl Nitrite (11 letters and one space) compared to the proposed name Amyvid (6 letters). This difference will likely decrease the potential for confusion between this name pair</p> <p>Product differences include dosage form (capsule vs. injection), route of administration (nasal inhalation vs. intravenous), and dose (2 to 6 inhalations vs. 10 mCi (370 MBq)).</p>
<p>E-mycin Oral delayed release tablet Brand discontinued from market, but generic equivalents exist</p>	<p>Look</p>	<p>250 mg, 333 mg</p>	<p>250 mg to 1000 mg orally every 6 hours</p>	<p>Orthographic differences include the fact that the first letters ('E' vs. 'A') are not similar when written. Additionally, the last letter in Amyvid represents an upstroke ('d') which gives these names different shapes. These characteristics will likely differentiate these names from each other.</p>

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/s/

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