CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209863Orig1s000

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:	May 23, 2018
Application Type and Number:	NDA 209863
Product Name and Strength:	Xyosted (testosterone enanthate) injection 100 mg/mL, 150 mg/mL, 200 mg/mL
Total Product Strength:	50 mg/0.5 mL, 75 mg/0.5 mL, 100 mg/0.5 mL
Product Type:	Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Antares Pharma, Inc.
Panorama #:	2018-21991669
DMEPA Safety Evaluator:	Denise V. Baugh, PharmD, BCPS
DMEPA Team Leader:	Lolita G. White, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Xyosted, 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 that was previously reviewed[a].

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, [(b) (4)]*** on March 27, 2015 under IND 116022. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, [(b) (4)]*** unacceptable [(b) (4)] (OSE Review # [(b) (4)] dated September 15, 2015). The alternative proprietary name, [(b) (4)]*** was submitted October 28, 2015. However, it was also found to be unacceptable [(b) (4)] (OSE Review # [(b) (4)] dated March 15, 2017). The Applicant submitted the alternative proprietary name, Xyosted, for review on December 21, 2016. We found this name to be acceptable (OSE Review # 2016-12080105 dated March 15, 2017). However, NDA 209863 received a Complete Response (CR) action October 20, 2017.

Thus, the Applicant re-submitted the name, Xyosted, for review on March 29, 2018 in their Class 2 re-submission.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 29, 2018.

- Intended Pronunciation: ZYE-oh-sted
- Active Ingredient: testosterone enanthate
- Indication of Use: replacement therapy for adult males with a deficiency or absence of endogenous testosterone
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 50 mg/0.5 mL, 75 mg/0.5 mL, 100 mg/0.5 mL
- Dose and Frequency: 50 mg, 75 mg or 100 mg once weekly up to a maximum of 100 mg once weekly
- How Supplied: one carton will contain 4 single-use, auto-injector devices

---

[a] Baugh D. Proprietary Name Review for Xyosted (NDA 209863). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2017 Mar 15. Panorama No. 2016-12080105.

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

- Storage: 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). Protect from light (keep in carton until time of use).

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 would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Bone, Reproductive, and Urologic Products (DBRUP) 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[b].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Xyosted 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 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 16, 2018 e-mail, the Division of Bone, Reproductive, and Urologic Products (DBRUP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 81 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%**.** We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of

[b] USAN stem search conducted on April 4, 2018.

[c] POCA search conducted on May 4, 2018 in version 4.2.

concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 18 names not previously analyzed. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	18
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 18 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Bone, Reproductive, and Urologic Products (DBRUP) via e-mail on May 22, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DBRUP on May 23, 2018, they stated no additional concerns with the proposed proprietary name, Xyosted.

3 CONCLUSION

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Oyinlola Fashina, OSE Project Manager, at 301-796-4446.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on March 29, 2018, 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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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 DNDP. OPDP or DNDP 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 DNDP 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. [d]

[d] 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 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 55% 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 ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

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 are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[e]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information 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) may be limited when the strength or dose overlaps. DMEPA reviews 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.

[e] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% 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 or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, 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: • 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. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	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 reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

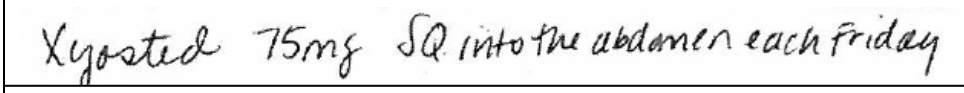
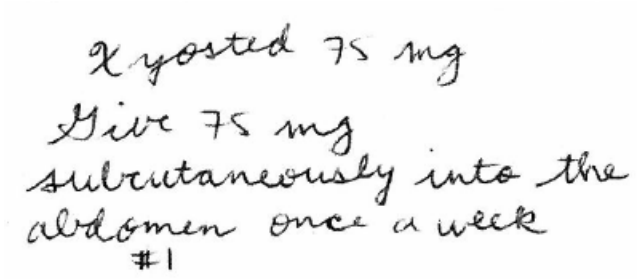
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 ≤54%).

Names with low similarity 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Xyosted Name Study (Conducted on April 13, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	"Xyosted 75 mg give 75 mg SQ into the abdomen once a week – dispense # 1"
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

299 People Received Study
80 People Responded

Study Name: Xyosted

Total	25	13	21	21	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
XIOSTED	0	0	1	0	1
XYLOSTED	0	0	1	0	1
XYOSTED	23	13	0	20	56
XYOSTID	1	0	0	1	2
XYSOTED	1	0	0	0	1
ZIOSTAD	0	0	1	0	1
ZIOSTAT	0	0	1	0	1
ZIOSTEAD	0	0	2	0	2
ZIOSTED	0	0	6	0	6
ZYALSTED	0	0	1	0	1
ZYELSTEAD	0	0	1	0	1
ZYLESTED	0	0	1	0	1
ZYOSTEAD	0	0	2	0	2
ZYOSTED	0	0	4	0	4

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

No.	**Proposed name:** Xyosted **Established name:** testosterone enanthate **Dosage form:** injection **Strength(s):** 50 mg, 75 mg, 100 mg **Usual Dose:** 50 mg, 75 mg, or 100 mg subcutaneously once a week	POCA Score (%)	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	N/A		

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
2.	Estrostep 21	56
3.	Dristan	54

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Xyosted **Established name:** testosterone enanthate **Dosage form:** injection **Strength(s):** 50 mg, 75 mg, 100 mg **Usual Dose:** 50 mg, 75 mg, or 100 mg subcutaneously once a week	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**
4.	Visken	51	This name pair has sufficient orthographic and phonetic differences.
5.	Dextrose 50 %	54	This name pair has sufficient orthographic and phonetic differences.
6.	Dextrose 60 %	54	This name pair has sufficient orthographic and phonetic differences.
7.	Dextrose 25 %	54	This name pair has sufficient orthographic and phonetic differences.
8.	Niaspan	42	This name pair has sufficient orthographic and phonetic differences.
9.	Suspen	53	This name pair has sufficient orthographic and phonetic differences.
10.	Eth-oxydose	50	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Xyosted **Established name:** testosterone enanthate **Dosage form:** injection **Strength(s):** 50 mg, 75 mg, 100 mg **Usual Dose:** 50 mg, 75 mg, or 100 mg subcutaneously once a week	**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**
11.	Xospata***	64	This name pair has sufficient orthographic and phonetic differences.
12.	(b) (4) ***	59	This name pair has sufficient orthographic and phonetic differences.

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

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
13.	N/A	

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
14.	Neoscan	54	Brand discontinued with no generic equivalents available. NDA 017655 withdrawn FR effective 05/04/2009.
15.	Xylose	52	Name found in Drugs@FDA database. Unable to find product characteristics in commonly used drug databases.
16.	Visqid	53	Name found in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	Diosmin	54	Name found in RxNorm database. Unable to find product characteristics in commonly used drug databases.
18.	Cea Scan	46	Name found in RxNorm database. Unable to find product characteristics in commonly used drug databases.
19.	Oxydose	53	Name found in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	(b) (4) ***	58	Proposed proprietary name for IND (b) (4) found to be unacceptable by DMEPA (OSE (b) (4) dated March 19, 2018). The alternative proprietary name, (b) (4) *** was submitted April 5, 2018 and is currently under review.

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

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[f].

No.	Name	POCA Score (%)
21.	N/A	

[f] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DENISE V BAUGH
05/23/2018

LOLITA G WHITE
05/23/2018

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:	March 15, 2017
Application Type and Number:	NDA 209863
Product Name and Strength:	Xyosted (testosterone enanthate) injection 100 mg/mL, 150 mg/mL, 200 mg/mL
Total Product Strength:	50 mg/0.5 mL, 75 mg/0.5 mL, 100 mg/0.5 mL
Product Type:	Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Antares Pharma, Inc.
Panorama #:	2016-12080105
DMEPA Primary Reviewer:	Denise V. Baugh, PharmD, BCPS
DMEPA Team Leader:	Lolita White, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Xyosted, 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, (b) (4) *** on March 27, 2015 under IND 116022. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, (b) (4) *** unacceptable (b) (4) (OSE Review # (b) (4) dated September 15, 2015). The alternative proprietary name, (b) (4) *** was submitted October 28, 2015. However, it was also found to be unacceptable (b) (4) (OSE Review # (b) (4) dated March 16, 2016).

Thus, the Applicant submitted the name, Xyosted, for review on December 21, 2016.

1.2 PRODUCT INFORMATION

The following product information is provided in the December 21, 2016 proprietary name submission.

- Intended Pronunciation: ZYE-oh-sted
- Active Ingredient: testosterone enanthate
- Indication of Use: replacement therapy for adult males with a deficiency or absence of endogenous testosterone
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 50 mg/0.5 mL, 75 mg/0.5 mL, 100 mg/0.5 mL
- Dose and Frequency: 50 mg, 75 mg or 100 mg once weekly up to a maximum of 100 mg once weekly
- How Supplied: one carton will contain 4 single-use, auto-injector devices
- Storage: 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). Protect from light (keep in carton until time of use).
- Reference Listed Drug: Delatestryl, NDA 009165 – 505(b)(2)

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

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 would not misbrand the proposed product. DMEPA and the Division of Bone, Reproductive and Urologic Products (DBRUP) 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[a].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Xyosted 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

Eighty-three practitioners participated in DMEPA's prescription studies. A response from one voice participant ('Diostet') sounded similar to a currently marketed product, 'Diastat'. See Appendix E for our detailed analysis.

The remaining responses did not overlap with any currently marketed products nor did the responses sound or look similar to any products in the pipeline. 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, January 13, 2017 e-mail, the Division of Bone, Reproductive, and Urologic Products (DBRUP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

[a] USAN stem search conducted on February 3, 2017.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names retrieved from our POCA search[b] and includes names identified from (b) (4) These names are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 1. Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	63
Low similarity name pair: combined match percentage score ≤54%	12

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

Our analysis of the 77 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Bone, Reproductive, and Urologic Products (DBRUP) via e-mail on March 14, 2017. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DBRUP on March 15, 2017, they stated no additional concerns with the proposed proprietary name, Xyosted.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Shawnetta Jackson, OSE Project Manager, at 301-796-4952.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 21, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

[b] POCA search conducted on February 3, 2017 in version 4.0

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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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 DNDP. OPDP or DNDP 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 DNDP 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. [c]

[c] 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 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 55% 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 ≥55% to ≤ 69%.
   - Low similarity: combined match percentage score ≤54%.

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 are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[d]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or

[d] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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) may be limited when the strength or dose overlaps. DMEPA reviews 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	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation,

	upstroke/downstroke letters present in the names?		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 ≥55% 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 or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, 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: • 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

<table>
<tr><td></td><td colspan="2">1 g, or vice versa.

• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.

• Similar sounding doses: 15 mg is similar in sound to 50 mg</td></tr>
<tr><td rowspan="2">Step 2</td><td colspan="2">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 reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td>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</td><td>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?</td></tr>
</table>

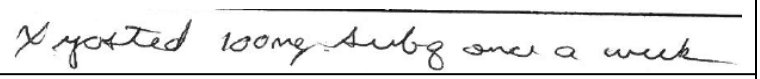
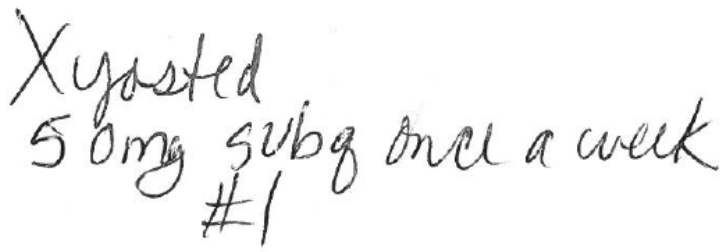
	scripted?	

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity 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.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Xyosted Name Study (Conducted on January 11, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: 	"Xyosted 50 mg subcutaneously once a week, Dispense # 1"
Outpatient Prescription: 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

297 People Received Study
83 People Responded

Study Name: Xyosted

OUTPATIENT	VOICE	INPATIENT
XYASTED (2)	DIOSTED (1)	
XYOSTED (25)	DIOSTET (1)	XYASTED (1)
	THIOSEC (1)	XYCSTED (1)
	THIOSED (1)	XYOSTED (31)
	VIAOSEPT (1)	XYOSTED ` (1)
	VIOSTEAD (1)	
	XIOFED (1)	
	XIOSTED (1)	
	XYOSTED (1)	
	ZIOFED (1)	
	ZIOSED (1)	
	ZIOSTAD (1)	
	ZIOSTED (4)	
	ZOISTEAD (1)	
	ZYLOCET (1)	
	ZYOFED (2)	
	ZYOSED (1)	
	ZYOSTED (1)	

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

No.	**Proposed name:** Xyosted **Established name:** testosterone enanthate **Dosage form:** Injection **Strength(s):** 50 mg, 75 mg, 100 mg **Usual Dose:** 50 mg, 75 mg, or 100 mg subcutaneously once per week	POCA Score (%)	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Xyosted	100	Name is the focus of this review.
2.	Lysteda	70	The prefixes and infixes of this name pair have sufficient orthographic differences. Specifically, their first letters ('L' vs. 'X') and third letters ('s' vs. 'o') look different when written. The first syllable ('Lie' vs. 'Zie'), second syllable ('sted' vs. 'o'), and third syllable ('ah' vs. 'sted') of this name pair sound different. The Name pair has the following different product characteristics: Xyosted is proposed in several strengths making it necessary to state the strength when prescribing, while Lysteda is available in single strength. The strengths do not overlap (50 mg, 75 mg, and 100 mg vs. 650 mg). The products have no overlap in doses (50 mg, 75 mg, and 100 mg vs. 1300 mg). The two products also have different routes of administration (subcutaneously vs. orally), and frequency of administration (once per week vs. three times daily).

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Zioptan	55
2.	Miostat	60
3.	Serostim	58
4.	Estrostep 21	56
5.	Dostinex	56
6.	Nystex	64
7.	Hydrostat	56

No.	Name	POCA Score (%)
8.	Austedo***	63

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Xyosted **Established name:** testosterone enanthate **Dosage form:** Injection **Strength(s):** 50 mg, 75 mg, 100 mg **Usual Dose:** 50 mg, 75 mg, or 100 mg subcutaneously once per week	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.	Diastat	58	The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences. Both Xyosted and Diastat require additional instructions to the pharmacist or caregiver to use the products as the prescriber intends. For example, Diastat is a rectal gel that is used one time 'as needed' for seizures and may be repeated within 4 to 12 hours from the time of the first dose. However, Xyosted is an auto-injector that is to be injected subcutaneously once weekly. Given the detailed instructions required for the safe and effective use of these products, we do not anticipate that a verbal order would be limited to "Xyosted 50 mg" or "Diastat 15 mg." If such a scenario did occur, it is likely that the pharmacist would need further clarification prior to dispensing given the differing product characteristics (e.g., route of administration and frequency of administration), thus, minimizing the risk of confusion between these two products.
2.	Vistide	60	The prefixes/infixes of this name pair have sufficient orthographic differences. The first/second syllables of this name pair sound different and Xyosted contains an extra syllable.

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

No.	**Proposed name:** Xyosted **Established name:** testosterone enanthate **Dosage form:** Injection **Strength(s):** 50 mg, 75 mg, 100 mg **Usual Dose:** 50 mg, 75 mg, or 100 mg subcutaneously once per week	**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**
3.	Triostat	56	The prefixes/suffixes of this name pair have sufficient orthographic differences. The first/third syllables of this name pair sound different.
4.	Tybost	56	The prefixes/infixes of this name pair have sufficient orthographic differences. The first/second syllables of this name pair sound different and Xyosted contains an extra syllable.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
1.	Savella	26
2.	Xalatan	40
3.	Xarelto	40
4.	Xeljanz	33
5.	Riastap	49
6.	Zyrtec	52
7.	Decofed	54
8.	Nasofed	54
9.	Xylamed	54
10.	Dristan	54
11.	Keftid	50
12.	Dynafed	52

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.	Prostep	64	Brand discontinued with no generic equivalent available. NDA 019983 withdrawn FR effective June 18, 2009.
2.	Feostat	67	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Cystex	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	Fostex	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Oyster D	65	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Xoten	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Cestex	60	Veterinary product
8.	Fosteum	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	Lidostat	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	Cysteine	56	Brand discontinued with no generic equivalent available. NDA 019523 withdrawn FR effective June 16, 2006.
11.	Orostat	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
12.	Xoten-C	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	Cyprostat	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	Hyospaz	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
15.	Prostap 3	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[e].

No.	Name	POCA Score (%)
1.	Systane	66
2.	Testred	65
3.	Dolsed	62
4.	Doxy-D	62
5.	Cystine	60
6.	Dysport	60
7.	Zotex-D	60
8.	Zyrtec-D	60
9.	Cytotec	59
10.	Doxatet	59
11.	Colestid	58
12.	Cycofed	58
13.	Doxytex	58
14.	(b) (4)***	58
15.	Nystop	58
16.	Prosed	58
17.	Dioctyn	57
18.	Nystan	57
19.	Vyxeos***	57
20.	Dayhist-D	56
21.	Dexophed	56
22.	Disotate	56
23.	Duo-Span	56
24.	Eye-Sed	56
25.	Kao-Spen	56
26.	Keystone	56
27.	Lohist 12D	56
28.	Lohist D	56
29.	Obestin-30	56
30.	Restone	56
31.	Syntest	56
32.	Vasaten	56
33.	Vasotec	56
34.	Vitaped	56
35.	Noctesed	55

[e] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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

No.	Name	POCA Score (%)
36.	(b) (4) ***	57

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	Not applicable.
2.	
3.	

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DENISE V BAUGH
03/15/2017

LOLITA G WHITE
03/15/2017