

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**207946Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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## 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\*\*\***

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<b>Date of This Review:</b>	February 27, 2015
<b>Application Type and Number:</b>	NDA 207946
<b>Product Name and Strength:</b>	Invega Trinza (Paliperidone Palmitate) Extended-release Injectable Suspension 273 mg/0.875 mL, 410 mg/1.315 mL, 546 mg/1.75 mL, and 819 mg/2.625 mL
<b>Product Type:</b>	Single Ingredient Product
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Janssen Pharmaceuticals, Inc.
<b>Submission Date:</b>	December 18, 2014
<b>Panorama #:</b>	2014-46035
<b>DMEPA Primary Reviewer:</b>	Loretta Holmes, BSN, PharmD
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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Invega Trinza, 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 did not submit an external name study for this proposed proprietary name.

### 1.1 PRODUCT INFORMATION

<b>Table 1. Relevant Product Information for Invega Trinza (paliperidone palmitate), Invega Sustenna (paliperidone palmitate), and Invega (paliperidone)</b>			
<b>Product Name</b>	<b>Invega Trinza (proposed product)</b>	<b>Invega Sustenna</b>	<b>Invega</b>
<b>Initial Approval Date</b>	N/A	July 31, 2009	December 19, 2006
<b>Active Ingredient</b>	paliperidone palmitate	paliperidone palmitate	paliperidone
<b>Proposed Pronunciation</b>	In-VEY-guh TRIN-zuh	In-VEY-guh Suss -TEN-uh	In-VEY-guh
<b>Indication</b>	Treatment of schizophrenia in adult patients who have been adequately treated with the 1-month paliperidone palmitate injectable product (Invega Sustenna) for at least four months	Treatment of schizophrenia  Treatment of schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers or antidepressants	Treatment of schizophrenia  Treatment of schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers and/or antidepressants
<b>Route of Administration</b>	Intramuscular	Intramuscular	Oral
<b>Dosage Form</b>	Extended-Release Injectable Suspension	Extended-Release Injectable Suspension	Extended-Release Tablet
<b>Strengths</b>	273 mg, 410 mg, 546 mg, and 819 mg	39 mg, 78 mg, 117 mg, 156 mg, and 234 mg	1.5 mg, 3 mg, 6 mg, and 9 mg

<b>Table 1. Relevant Product Information for Invega Trinza (paliperidone palmitate), Invega Sustenna (paliperidone palmitate), and Invega (paliperidone)</b>			
<b>Product Name</b>	<b>Invega Trinza (proposed product)</b>	<b>Invega Sustenna</b>	<b>Invega</b>
<b>Dose and Frequency</b>	273 mg, 410 mg, 546 mg, or 819 mg once, every three months	Initial dose of 234 mg (Day 1) followed by 156 mg (Day 8), followed by 39 mg to 234 mg once monthly	3 mg to 12 mg once daily  For patients with moderate to severe renal impairment (creatinine clearance $\geq$ 10 mL/min to $<$ 50 mL/min), the recommended initial dose is 1.5 mg once daily
<b>How Supplied</b>	Kits containing a prefilled syringe and two safety needles (a thin walled 22G, 1 ½-inch safety needle and a thin walled 22G, 1-inch safety needle)	Kits containing a prefilled syringe and two safety needles (a 1 ½-inch 22 gauge safety needle and a 1-inch 23 gauge safety needle)	30-count bottles
<b>Storage</b>	Store at room temperature (25°C, 77°F); excursions between 15°C and 30°C (between 59°F and 86°F) are permitted	Store at room temperature (25°C, 77°F); excursions between 15°C and 30°C (between 59°F and 86°F) are permitted.	Store up to 25°C (77°F); excursions permitted to 15 – 30°C (59 – 86°F)

## 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 Psychiatry Products (DPP) 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<sup>1</sup>.

### 2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Invega Trinza, in their submission. This proprietary name is comprised of the root name “Invega” and the modifier “Trinza”. The root name “Invega” does not contain any components (i.e., route of administration, dosage form, etc.) that are misleading or can contribute to medication error. Our evaluation of the modifier is discussed in Section 2.2.9.

### 2.2.3 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving Invega.

<b>Table 2. FAERS Search Strategy</b>	
<b>Date</b>	January 30, 2015
<b>Drug Name(Product Name)</b>	Invega Intuniv
<b>MedDRA Event Search</b>	Medication Errors-HLGT Product Label Issues-HLT Product Packaging Issues-HLT Product Quality Issues NEC-HLT
<b>Time/Date Limits</b>	August 2, 2014 <sup>2</sup> to January 30, 2015

Our search identified 71 US cases. Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

After individual review of the 71 identified cases, it was determined that none of the reports involved name confusion with Invega.

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<sup>1</sup>USAN stem search conducted on January 16, 2015.

<sup>2</sup> August 2, 2014 is the day after a previous FAERS search conducted for OSE Review 2014-945, see footnote #3.

We previously identified medication errors involving Invega and Intuniv and evaluated the issue in a previous DMEPA review.<sup>3</sup> In that review, our analysis indicated that the errors occurred between the Invega 3 mg and Intuniv 3 mg strengths. In the event that the modifier “Trinza” is inadvertently omitted from a prescription for Invega Trinza, the risk for confusion with Intuniv is mitigated by the fact that both products are available in multiple strengths and none of the strengths overlap between the two products. Additionally, Invega and Intuniv are on the ISMP list of confused drug names<sup>4</sup> so practitioners may be already aware of potential confusion between the two names.

#### **2.2.4 FDA Name Simulation Studies**

One hundred three (103) 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 Comments from Other Review Disciplines at Initial Review**

In response to the OSE, January 5, 2015 e-mail, the Division of Psychiatry Products (DPP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

#### **2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results**

Table 3 lists the number of names with the combined orthographic and phonetic score of  $\geq 50\%$  retrieved from our POCA search<sup>5</sup> organized as highly similar, moderately similar or low similarity for further evaluation.

<b>Table 3. POCA Search Results</b>	<b>Number of Names</b>
Highly similar name pair: combined match percentage score $\geq 70\%$	3
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	190
Low similarity name pair: combined match percentage score $\leq 49\%$	0

<sup>3</sup> Neupauer D. Intuniv and Invega Postmarketing Review [NDA 021999 (Invega) and NDA 022037 (Intuniv)]. 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); 2014 Sep 08. 6 p. OSE RCM No.: 2014-945.

<sup>4</sup> ISMP’s List of Confused Drug Names [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2014 [cited 2015 Jan 13]. Available from <http://www.ismp.org/tools/confuseddrugnames.pdf>.

<sup>5</sup> POCA search conducted on January 13, 2015.

### ***2.2.7 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength***

The proposed product, Invega Trinza will be available in strengths of: 273 mg, 410 mg, 546 mg, and 819 mg. Since these strengths are unusual and not commonly marketed, we searched the Pragmatic® Regulated Product Labeling Listing and Registration System (PR°PLLR™) database to identify any names with potential orthographic, spelling, and phonetic similarities with Invega Trinza that were not identified in POCA and found to have an overlap in strength with Invega Trinza (see Table 4).

<b>Table 4. (PR°PLLR™) Search Results</b>	<b>POCA Score</b>
No names meeting the aforementioned criteria were identified.	

### ***2.2.8 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities***

Our analysis of the 193 names contained in Table 3 determined all 193 names will not pose a risk for confusion as described in Appendices C through H.

### ***2.2.9 Safety Analysis of the Modifier “Trinza”***

Janssen proposed to use the modifier “Trinza” to represent their paliperidone palmitate extended-release injectable suspension for once every three months administration to differentiate it from their two currently marketed Invega products: Invega Sustenna (paliperidone palmitate) Extended-release Injectable Suspension and Invega (paliperidone) Extended-release Tablets.

According to Janssen, their rationale for the use of the modifier is to reduce the risk of potential medication error with Invega, Invega Sustenna, and the proposed 3-month formulation. Additionally, this will help to ensure that the dosage strengths and frequency of administration associated with the 3-month formulation will be uniquely identified via the modifier and be differentiated from the existing products Invega and Invega Sustenna. Furthermore, the rationale for using “Invega” plus a modifier is to reinforce with healthcare professionals that the active ingredient, paliperidone, is the same with the 3-month formulation and Invega Sustenna while at the same time highlighting a differentiation between the two products in terms of their frequency of administration (i.e., once a month vs. every three months).

#### **Safety assessment of the modifier**

Invega Trinza, if approved, will represent an extension of the currently marketed Invega product line. Therefore, in our evaluation of the proposed name, Invega Trinza, we considered the following:

- Whether marketing the product under a unique name is appropriate
- Whether a modifier is necessary

- Whether the modifier proposed is appropriate
1. We considered whether using a different name, a dual proprietary name (one that does not include the root name Invega), would be appropriate for this product. The use of a dual proprietary name introduces the potential for patients to be inadvertently placed on multiple paliperidone products if the proprietary names are not recognized as having the same active ingredient. This may lead to overdose and adverse drug events. Additionally, since patients should be stabilized on Invega Sustenna prior to initiating treatment with Invega Trinza, the use of a unique dual proprietary name may make it more difficult for healthcare practitioners and patients to recognize the relationship between the two products. Thus, we believe the use of a unique dual proprietary name is not appropriate for this product.
  2. We considered whether a modifier is necessary for this product. The Invega product line already contains Invega Sustenna which has a modifier to help distinguish it from Invega. The modifier Sustenna was determined to be appropriate to help distinguish the tablet formulation from the injectable formulation. Although Invega Sustenna and Invega Trinza are both extended-release injectable solutions, a modifier may help to signal that these are not the same product. We recognize there are limitations to this approach since there is postmarketing evidence that modifiers have been omitted or overlooked; however, in this circumstance we believe the addition of a modifier will add a measure of safety. If the modifier, Trinza, is dropped, we believe there is a low risk for an Invega Trinza order being filled with Invega Extended-release Tablets. Invega tablets are available in strengths of 1.5 mg, 3 mg, 6 mg, and 9 mg whereas Invega Trinza is proposed in strengths of 273 mg, 410 mg, 546 mg, and 819 mg. We also believe there is a low risk for an Invega Trinza order being filled with Invega Sustenna Extended-release Injectable Suspension. Invega Sustenna is available in strengths of 39 mg, 78 mg, 117 mg, 156 mg, and 234 mg whereas Invega Trinza is proposed in strengths of 273 mg, 410 mg, 546 mg, and 819 mg. We believe the differences in strength are sufficient to overcome the overlap in dosage form and route of administration between Invega Sustenna and Invega Trinza.
  3. We considered whether the proposed modifier is appropriate. According to the submission, the modifier has no inherent meaning. Per Janssen, *“As stated in the FDA’s Guidance for Industry: Best Practices in Developing Proprietary Names for Drugs, May 2014, to reduce the risk of medication errors associated with non-standardized modifiers in proprietary names, the FDA strongly encourages sponsors to, whenever possible, use an existing modifier with an established meaning that has not been a source of confusion.”* As mentioned above, the Applicant stated that adding Trinza to the root name Invega will help ensure that the dosage strengths and frequency of administration associated with the 3-month formulation will be uniquely identified via the modifier. While we do not have sufficient evidence to determine that the proposed modifier can convey strength and frequency differences as suggested by the Applicant, we believe that the use of this unique modifier to signal this is a different product is appropriate.

Given the totality of factors considered above, we believe that the use of a modifier is appropriate for this name and that the proposed modifier, “Trinza” is acceptable.

#### ***2.2.10 Communication of DMEPA’s Analysis at Midpoint of Review***

DMEPA communicated our findings to the Division of Psychiatry Products (DPP) via e-mail on February 12, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DPP on February 19, 2015, they stated no additional concerns with the proposed proprietary name, Invega Trinza.

### **3 CONCLUSIONS**

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Vasantha Ayalasomayajula, OSE Project Manager, at 240-402-5035.

#### **3.1 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your December 18, 2014 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

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

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

3. **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](http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological)).

4. **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#>).

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.

## APPENDICES

### Appendix A

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

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
  - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2\*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.<sup>6</sup>

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<sup>6</sup> 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.
<b>Y/N</b>	<b>Is the proposed name obviously similar in spelling and pronunciation to other names?</b>
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
<b>Y/N</b>	<b>Are there medical and/or coined abbreviations in the proprietary name?</b>
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
<b>Y/N</b>	<b>Are there inert or inactive ingredients referenced in the proprietary name?</b>
	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)).
<b>Y/N</b>	<b>Does the proprietary name include combinations of active ingredients?</b>
	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)).
<b>Y/N</b>	<b>Is there a United States Adopted Name (USAN) stem in the proprietary name?</b>
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
<b>Y/N</b>	<b>Is this proprietary name used for another product that does not share at least one common active ingredient?</b>
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
<b>Y/N</b>	<b>Is this a proprietary name of a discontinued product?</b>
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

- b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
- Highly similar pair: combined match percentage score  $\geq 70\%$ .
  - Moderately similar pair: combined match percentage score  $\geq 50\%$  to  $\leq 69\%$ .
  - Low similarity: combined match percentage score  $\leq 49\%$ .

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

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

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

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

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

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

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

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

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

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

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

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

**Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is  $\geq 50\%$  to  $\leq 69\%$ ).**

<p>Step 1</p>	<p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> <li>○ 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.</li> <li>○ Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.</li> <li>○ Similar sounding doses: 15 mg is similar in sound to 50 mg</li> </ul>
<p>Step 2</p>	<p>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 <b><u>with</u></b> overlapping or similar strengths or doses.</p>

<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names begin with different first letters?</li> </ul> <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> <li>• Are the lengths of the names dissimilar* when scripted?</li> </ul> <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> <li>• Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names?</li> <li>• Is there different number or placement of cross-stroke or dotted letters present in the names?</li> <li>• Do the infixes of the name appear dissimilar when scripted?</li> <li>• Do the suffixes of the names appear dissimilar when scripted?</li> </ul>	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names have different number of syllables?</li> <li>• Do the names have different syllabic stresses?</li> <li>• Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?</li> <li>• Across a range of dialects, are the names consistently pronounced differently?</li> </ul>
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**Table 5: Low Similarity Name Pair Checklist (i.e., combined score is  $\leq 49\%$ ).**

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

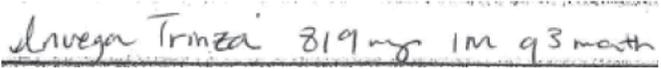
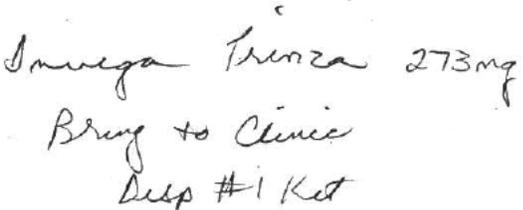
**Appendix A1: Description of FAERS**

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm>.

**Appendix B: Prescription Simulation Samples and Results**

**Figure 1. Invega Trinza Study (Conducted on January 5, 2015)**

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Invega Trinza 273 mg Bring to clinic</p>
<p><u>Outpatient Prescription:</u></p> 	<p>Dispense: 1 kit</p>

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

				252 People Received Study
				103 People Responded
<b>Study Name: Invega Trinza</b>				
<b>Total</b>	<b>36</b>	<b>34</b>	<b>33</b>	
<b>INTERPRETATION</b>	<b>OUTPATIENT</b>	<b>VOICE</b>	<b>INPATIENT</b>	<b>TOTAL</b>
ENVAGA TRENZA	0	1	0	1
ENVAGATRINZA	0	1	0	1
ENVEGA TRENZA	0	2	0	2
ENVEGATRINZA	0	2	0	2
INVEGATRIENZA	1	0	0	1
IMVEGA TRIENZA	1	0	0	1
IMVEGA TRINZA	2	0	0	2
INVEGA PRINZA	2	0	0	2
INVEGA TRENAS	0	1	0	1
INVEGA TRENIZA	1	0	0	1
INVEGA TRENZA	0	1	0	1
INVEGA TRENZA	0	1	0	1
INVEGA TRIMZA	1	0	1	2
INVEGA TRINSA	0	7	0	7
INVEGA TRINZA	21	0	28	49
INVEGA TRIVIZA	1	0	0	1
INVEGA TRIZA	0	0	1	1
INVEGAR TRINZA	0	0	1	1
INVEGATRANZA	0	1	0	1
INVEGATRENZA	0	5	0	5
INVEGATRINSA	0	2	0	2
INVEGATRINZA	0	5	0	5
INVEGOR TRINZA	0	0	1	1
INVIGA PRINZA	1	0	0	1

INVIGA TRINZA	3	0	0	3
IRIVEGA TRINZA	0	0	1	1
MEGATRINSA	0	1	0	1
SNVEGA TRIENZA	1	0	0	1
SNVIGATRINZA	1	0	0	1
VAGATRENZA	0	1	0	1
VEGATRANSA	0	1	0	1
VEGATRENZA	0	1	0	1
VEGATRINZA 273MG	0	1	0	1

**Appendix C: Highly Similar Names (e.g., combined POCA score is  $\geq 70\%$ )**

No.	<p><b>Proposed name:</b> Invega Trinza (Paliperidone Palmitate)</p> <p><b>Dosage form:</b> Extended-Release Suspension for Injection</p> <p><b>Strengths:</b> 273 mg, 410 mg, 546 mg, and 819 mg</p> <p><b>Usual Dose:</b> 273 mg, 410 mg, 546 mg, or 819 mg, once every three months</p>	POCA Score (%)	<p><b>Orthographic and/or phonetic differences in the names sufficient to prevent confusion</b></p> <p><b>Other prevention of failure mode expected to minimize the risk of confusion between these two names.</b></p>
1.	Trinza***	100	This modifier is part of the proprietary name that is the subject of this review.
2.	Trinessa	77	<p>The suffixes of the modifier Trinza and the name Trinessa have sufficient orthographic differences.</p> <p>The second syllables of the modifier Trinza and the name Trinessa sound different, and Trinessa contains an extra syllable, which helps this name pair sound different when spoken.</p> <p>The products do not have any overlapping product characteristics.</p> <p>Trinza is unlikely to be prescribed without the root name, Invega, minimizing the risk for confusion between Invega Trinza and Trinessa.</p>
3.	Treanda	72	<p>The suffixes of the modifier Trinza and the name Treanda have sufficient orthographic differences.</p> <p>The second syllables of the modifier Trinza and the name Treanda sound different and Treanda contains an extra syllable which helps this name pair sound different when spoken.</p> <p>Trinza is unlikely to be prescribed without the root name, Invega, minimizing the risk for confusion.</p>

**Appendix D:** Moderately Similar Names (e.g., combined POCA score is  $\geq 50\%$  to  $\leq 69\%$ ) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Trental	68
2.	Triam-A	68
3.	Atreza	68
4.	Tri-Nasal	67
5.	Trivora-21	65
6.	Trivora-28	65
7.	Trivora	65
8.	Trumenba	64
9.	(b) (4)	63
10.	Suprenza	62
11.	Tremin	62
12.	Trital	62
13.	Tritan	62
14.	Avinza	61
15.	Triaz	61
16.	Tri-Zel	61
17.	Zolinza	60
18.	Tresiba***	60
19.	Benza	60
20.	Trimo San	60
21.	Emtriva	59
22.	Qutenza	59
23.	Relenza	59
24.	Truvada	59
25.	Triveen	59
26.	Atripla	58
27.	Simbrinza	58
28.	Trandate	58

No.	Name	POCA Score (%)
29.	Tribenzor	58
30.	Tri-LUMA	58
31.	Trinalin	58
32.	Trovan	58
33.	Trivase	58
34.	(b) (4)	57
35.	Twynsta	57
36.	Tranmep	56
37.	Threda	56
38.	Triam	56
39.	Tripedia	56
40.	Trypsin	56
41.	Prinzide	54
42.	Trexall	54
43.	Triad	54
44.	Tritec	54
45.	Daklinza***	54
46.	Trokendi	54
47.	Trancot	54
48.	Tricosal	54
49.	Tussin V	54
50.	Tradjenta	53
51.	Tri-Linyah	53
52.	Tenivac	53
53.	Hytrin	52
54.	Motrin	52
55.	Tanzeum	52
56.	Trezix	52
57.	Triacin	52
58.	Triphed	52

No.	Name	POCA Score (%)
59.	Trivaris	52
60.	(b) (4)	52
61.	Fetrin	52
62.	Tetra 500	52
63.	Ting AF	52
64.	Tretin X	52
65.	Trimal DH	52
66.	Trioxin	52
67.	Trituss ER	52
68.	Tru-Micin	52
69.	Pronto	52
70.	Triesence	51
71.	Trizivir	51
72.	Twirla***	51
73.	Benzac	51
74.	Tri-Sudo	51
75.	Striant	50
76.	Triavil 2-10	50
77.	Triavil 2-25	50
78.	Triavil 4-10	50
79.	Triavil 4-25	50
80.	Triavil 4-50	50
81.	Triazolam	50
82.	Triostat	50
83.	(b) (4)	50
84.	Translarna***	50
85.	(b) (4)	50
86.	Tudorza	50
87.	Tencet	50
88.	Tin-Ben	50

No.	Name	POCA Score (%)
89.	Trianex	50
90.	Triavil	50
91.	Tri-K	50
92.	Triotann	50
93.	Triotann-S	50
94.	Tronolane	50
95.	Twin-K	50

**Appendix E:** Moderately Similar Names (e.g., combined POCA score is  $\geq 50\%$  to  $\leq 69\%$ ) with overlap or numerical similarity in Strength and/or Dose

No.	<p><b>Proposed name:</b> Invega Trinza</p> <p><b>Established name:</b> Paliperidone Palmitate</p> <p><b>Dosage form:</b> Extended-release Injectable Suspension</p> <p><b>Strengths:</b> 273 mg, 410 mg, 546 mg, and 819 mg</p> <p><b>Usual Dose:</b> 273 mg, 410 mg, 546 mg, or 819 mg once, every three months</p>	<p><b>POCA Score (%)</b></p>	<p><b>Prevention of Failure Mode</b></p> <p><b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b></p>
1.	Tridil	58	<p>The infixes/suffixes of the modifier Trinza and the name Tridil have sufficient orthographic differences.</p> <p>The second syllables of the modifier Trinza and the name Tridil sound different.</p>
2.	Trimox	54	<p>The suffixes of the modifier Trinza and the name Trimox have sufficient orthographic differences.</p> <p>The second syllables of the modifier Trinza and the name Trimox sound different.</p>
3.	Tretten	54	<p>The infixes/suffixes of the modifier Trinza and the name Trimox have sufficient orthographic differences.</p> <p>The second syllables of the modifier Trinza and the name Trimox sound different.</p>
4.	(b) (4)		

No.	<b>Proposed name:</b> <b>Invega Trinza</b>  <b>Established name:</b> <b>Paliperidone Palmitate</b>  <b>Dosage form:</b> <b>Extended-release Injectable Suspension</b>  <b>Strengths:</b> <b>273 mg, 410 mg, 546 mg, and 819 mg</b>  <b>Usual Dose:</b> <b>273 mg, 410 mg, 546 mg, or 819 mg once, every three months</b>	<b>POCA Score (%)</b>	<b>Prevention of Failure Mode</b>  <b>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</b>
5.	Tiazac	50	<p>The infixes/suffixes of the modifier Trinza and the name Tiazac have sufficient orthographic differences.</p> <p>The first/second syllables of the modifier Trinza and the name Tiazac sound different and Tiazac contains an extra syllable which helps this name pair sound different when spoken.</p>
6.	Tirilazad	50	<p>The prefixes/infixes/suffixes of the modifier Trinza and the name Tirilizad have sufficient orthographic differences.</p> <p>The first/second syllables in the modifier Trinza and the name Tirilazad sound different and Tirilazad contains two extra syllables which help this name pair sound different when spoken.</p>

**Appendix F:** Low Similarity Names (e.g., combined POCA score is  $\leq 49\%$ )

No.	Name	POCA Score (%)
1.	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
1.	Trituss A	68	The product characteristics were not found in commonly used (or external) databases.
2.	Tindal	62	This is a discontinued product. No generics are available. The product characteristics were not found in commonly used (or external) databases.
3.			(b) (4)
4.	Tri-Med	62	Name identified in RxNorm database. The product characteristics were not found in commonly used (or external) databases.
5.	Triban	61	This product was a suppository that contained trimethobenzamide. It was withdrawn from the market because drugs containing trimethobenzamide in suppository form lack evidence of effectiveness.
6.	Trituss	61	Dosage information was not found in commonly used (or external) databases.
7.			(b) (4)
8.			(b) (4)
9.			(b) (4)
10.			(b) (4)
11.	Triumph	59	The product characteristics were not found in commonly used (or external) databases.
12.	Trintex	58	This product contained phenylpropanolamine which was withdrawn from the marketplace for safety reasons.
13.	Trexima	57	The product characteristics were not found in commonly used (or external) databases.

No.	Name	POCA Score (%)	Failure preventions
14.	Tridane	56	The product characteristics were not found in commonly used (or external) databases.
15.	Tridrane	56	The product characteristics were not found in commonly used (or external) databases.
16.	Tri-Dec	56	The product characteristics were not found in commonly used (or external) databases.
17.	Traxam	55	The product characteristics were not found in commonly used (or external) databases.
18.	Trynate	55	The product characteristics were not found in commonly used (or external) databases.
19.			(b) (4)
20.			(b) (4)
21.			(b) (4)
22.			(b) (4)
23.	Prinize	54	The product characteristics were not found in commonly used (or external) databases.
24.	Tena	54	This is a family trade name under which feminine hygiene and male hygiene products and underwear are marketed. Tena is not a drug.
25.	Tritop	53	This is a veterinary product.
26.			(b) (4)
27.			(b) (4)
28.	Tija	52	Name identified in RxNorm and Red Book databases. Unable to find dosage information in these or other commonly used (or external) databases.

No.	Name	POCA Score (%)	Failure preventions
29.	Trimazide	52	This product was a suppository that contained trimethobenzamide. It was withdrawn from the market because drugs containing trimethobenzamide in suppository form lack evidence of effectiveness.
30.	Tri-Pase	52	The product characteristics were not found in commonly used (or external) databases.
31.	Tuinal	52	The product characteristics were not found in commonly used (or external) databases.
32.	Strix	51	Name identified in RxNorm and Red Book databases. Unable to find dosage information in these or other commonly used (or external) databases.
33.	Tri-Tex	51	This product contained phenylpropanolamine which was withdrawn from the marketplace for safety reasons.
34.	Trancopal	50	This product is discontinued. There are no generics available. The product was withdrawn effective 2009.
35.	Trandide	50	The product characteristics were not found in commonly used (or external) databases.
36.	Tranilast	50	This is a powder used for pharmaceutical compounding. It is also the name of an orphan drug (Rizaben™). The product characteristics were not found in commonly used (or external) databases.
37.	Westrim LA	50	This product contained phenylpropanolamine which was withdrawn from the marketplace for safety reasons.
38.	Trobicin	50	Product withdrawn from the market and is available for veterinary use only. No generics available.
39.	Otrivin	50	Product was discontinued. There are no generics available. The NDA was withdrawn FR effective 09/25/1997.
40.	Tri-Nefrin	50	This product was withdrawn from the market for safety reasons.

**Appendix H:** Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	Kariva	64
2.	Renova	64
3.	Cyramza	60
4.	Rynesa	60
5.	(b) (4)	58
6.	Rynessa	58
7.	Prolensa	57
8.	Afrezza	56
9.	(b) (4)	56
10.	(b) (4)	56
11.	Vienva***	56
12.	Prenexa	56
13.	Prantal	54
14.	(b) (4)	54
15.	Brilinta	53
16.	Cerenia	53
17.	Cimzia	52
18.	Intron A	52
19.	Orencia	52
20.	Pindac	52
21.	Vidaza	52
22.	(b) (4)	52
23.	(b) (4)	52
24.	Atryn	52
25.	Pretz	52
26.	Profen LA	52
27.	Prandin	51

No.	Name	POCA Score (%)
28.	Prozac	51
29.	Renvela	51
30.	Binora	51
31.	Drontal	51
32.	Ryna-12	51
33.	Butrans	50
34.	Frova	50
35.	Kinevac	50
36.	Mirena	50
37.	Spiriva	50
38.	Stendra	50
39.	Ultresa	50
40.	Ampriva***	50
41.	Bu Trans***	50
42.	(b) (4)	50
43.	(b) (4)	50
44.	(b) (4)	50
45.	Benz-All	50
46.	Inova	50
47.	Inova 4-1	50
48.	Inova 8-2	50
49.	Progynova	50

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