

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**22-192**

**PROPRIETARY NAME REVIEW(S)**



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

Date: February 11, 2009

To: Thomas Laughren, MD, Director  
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Through: Todd Bridges, RPh, Team Leader  
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From: Diane C. Smith, PharmD, Safety Evaluator  
Division of Medication Error Prevention and Analysis (DMEPA)

Subject: Proprietary Name Review

Drug Name(s): Fanapt (Iloperidone) Tablets  
1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg

Application Type/Number: NDA # 22-192

Applicant: Vanda Pharmaceuticals

OSE RCM #: 2009-69

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

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## **EXECUTIVE SUMMARY**

The Proprietary Name Risk Assessment findings indicate that the proposed name, Fanapt, is not vulnerable to name confusion that could lead to medication errors. As such, we have no objections to the use of the proprietary name, Fanapt, for this product. The Division of Psychiatry Products concurs with this assessment.

However, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this Risk Assessment finding, and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment and, as such, the conclusions on re-review of the name are subject to change. Additionally, if the product approval is delayed beyond 90 days from the date of this review, the proposed name must be resubmitted for evaluation.

## **1 BACKGROUND**

### **1.1 INTRODUCTION**

This review is in response to a request from the Division of Psychiatry Products for assessment of the proprietary name, Fanapt, regarding potential name confusion with other proprietary or established drug names. Labels and labeling will be evaluated in a separate forthcoming review (OSE review # 2009-70). Additionally, the Applicant submitted an independent analysis of the name by \_\_\_\_\_ subsidiary of \_\_\_\_\_ for review and comment.

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### **1.2 REGULATORY HISTORY**

The Division of Medication Error Prevention and Analysis objected to the primary proposed proprietary name Fiapta in OSE Review 2007-537, dated April 14, 2008, because of orthographic similarity and overlapping product characteristics to Lipitor. Subsequently, DMEPA reviewed the Applicant's secondary name, Fanapta, in OSE Review 2007-538 dated June 3, 2008. DMEPA objected to the name Fanapta because the name had orthographic similarities and overlapping product characteristics with Lunesta. Thus, in a letter dated June 6, 2008, the Applicant was asked to submit two alternate proprietary names for review. As a result, Vanda Pharmaceuticals submitted a request for proposed proprietary name review of the proprietary name, Fanapt, on November 19, 2008.

### **1.3 PRODUCT INFORMATION**

Fanapt (Iloperidone) is an atypical antipsychotic agent indicated for the acute treatment of schizophrenia in adults. The recommended dose is 12 mg to 24 mg per day administered twice daily (BID) based on clinical response. This target dose range should be achieved through the following daily dosage adjustments until the desired maintenance dose is achieved: 1 mg BID, 2 mg BID, 4 mg BID, 6 mg BID, 8 mg BID, 10 mg BID and 12 mg BID on days 1, 2, 3, 4, 5, 6 and 7, respectively.

Fanapt will be supplied as follows:

	<b>Professional Sample Bottle of 14 tablets</b>	<b>Trade Container of 60 tablets</b>	<b>Professional Blister Cards</b>
<b>Tablet Strength</b>			
1 mg		X	X
2 mg		X	X
4 mg	X	X	X
6 mg	X	X	X
8 mg	X	X	X
10 mg	X	X	X
12 mg	X	X	X

## 2 METHODS AND MATERIALS

This section consists of the methods and materials used by the DMEPA staff conducting a proprietary name risk assessment (see 2.1 Proprietary Name Risk Assessment). The primary focus for all of the assessments is to identify and remedy potential sources of medication error prior to drug approval. Our Division 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>1</sup>

### 2.1 PROPRIETARY NAME RISK ASSESSMENT

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

For the proprietary name, Fanapt, the DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity (see section 2.1.1 for detail) and held a CDER Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (see section 2.1.3). The Division of Medication Error Prevention and Analysis also conducts internal FDA prescription analysis studies (see 2.1.2), and, when provided, external prescription analysis studies (see 2.1.5) results are considered and incorporated into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name (see detail 2.4). The overall risk assessment is based on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and is focused on the avoidance of medication errors. FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>2</sup> FMEA is used to

<sup>1</sup> National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

<sup>2</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

analyze whether the drug names identified with look- and/or sound-alike similarity to the proposed name could cause confusion that subsequently leads to medication errors in the clinical setting. The Division of Medication Error Prevention and Analysis 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>1</sup> DMEPA uses the clinical expertise of our staff to anticipate the conditions of the clinical setting that the product is likely to be used in based on the characteristics of the proposed product.

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed drug name include, but are not limited to established name of the proposed product, the proposed indication, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, we consider the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.<sup>2</sup>

### **2.1.1 Search Criteria**

DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted as outlined in Appendix A.

For this review, particular consideration was given to drug names beginning with the letter 'I' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.<sup>3,4</sup>

To identify drug names that may look similar to Fanapt, the staff also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (6 letters), upstrokes (two, capital letter 'F' and 't'), downstrokes (one, lower case 'p'), cross-strokes (two, 'F' and 't'), and dotted letters (none). Additionally, several letters in Fanapt may be vulnerable to ambiguity when scripted, including the letter 'F' may appear as the letter 'T', 'L', 'Z', 'I' or 'J'; lower case 'a' may appear as lower case 'e', 'c' and 'o'; lower case 'n' may appear as a lower case 'm', 'r'; 'h', 'u' 's', or 'v'; lower case 'p' may appear as 'x' and 'y'; lower case 't' may appear as a lower case 'f', 'r', 'l' or 'i'. As such, the DMEPA also considers these alternate appearances when identifying drug names that may look similar to Fanapt.

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<sup>1</sup> National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

<sup>2</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

<sup>3</sup> Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

<sup>4</sup> Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

When searching to identify potential names that may sound similar to Fanapt, the DMEPA staff searches for names with similar number of syllables in the name (2 syllables), stresses (FA-napt or fa-NAPT), and placement of vowel and consonant sounds. In addition, several letters in Fanapt may be subject to interpretation when spoken, including the letter 'F' may be interpreted as 'Ph', 'V', or 'Fe'; the letter 'a' may be interpreted as the letter 'e' or 'eh' and the letter 't' may be interpreted as 'te', 'teh' or 'tuh'. The Applicant's intended pronunciation of the proprietary name could not be expressly taken into consideration, as this was not provided with the proposed name submission.

The DMEPA staff also considers the product characteristics associated with the proposed drug throughout the identification of similar drug names, since the product characteristics of the proposed drug ultimately determine the use of the product in the clinical practice setting. For this review, the DMEPA staff was provided with the following information about the proposed product: the proposed proprietary name (Fanapt), the established name (Iloperidone), proposed indication (treatment of schizophrenia), strength (1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg), dose (can be respective strength), frequency of administration (twice daily), route (oral) and dosage form of the product (tablet). Appendix A provides a more detailed listing of the product characteristics DMEPA general take into consideration.

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

#### **2.1.1.1 Database and Information Sources**

The proposed proprietary name, Fanapt, was provided to the DMEPA staff to conduct a search of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to Fanapt using the criteria outlined in 2.1.1.1. A standard description of the databases used in the searches is provided in Section 6.2. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The findings of the individual Safety Evaluators were then pooled and presented to the Expert Panel.

#### **2.1.1.2 CDER Expert Panel Discussion**

An Expert Panel Discussion is held by DMEPA to gather CDER professional opinions on the safety of the product and the proprietary name, Fanapt. Potential concerns regarding drug marketing and promotion related to the proposed names are also discussed. This group is composed of DMEPA and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC).

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

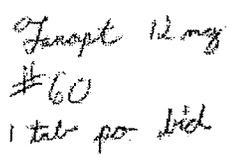
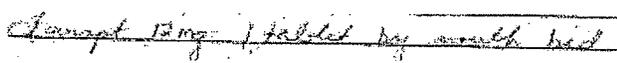
#### **2.1.2 FDA Prescription Analysis Studies**

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Fanapt 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 a total of 123 healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The results are used by the Safety Evaluator to identify any orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of Fanapt in handwriting and verbal communication of the name, inpatient medication orders and outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These prescriptions are optically scanned and one prescription is delivered to a random sample of 123 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 send their interpretations of the orders via e-mail to the medication error staff.

**Figure 1. Fanapt Study (conducted on January 23, 2009)**

HANDWRITTEN PRESCRIPTION AND MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Outpatient Prescription:</u></p> 	<p>Fanapt 12 mg # 60 1 tablet by mouth bid</p>
<p><u>Inpatient Medication Order:</u></p> 	

**2.1.3 External Proprietary Name Risk Assessment**

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

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

#### **2.1.4 Comments from the Division of Psychiatry Products (DPP)**

DMEPA requests the regulatory division in the Office of New Drugs responsible for the application for their comments and/or clinical/other concerns on the proposed proprietary name at the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with DDMAC's decision on the name. Any comments or concerns are addressed in the safety evaluator's assessment.

The Review Division is contacted a second time following our analysis of the proposed name. At this point, DMEPA conveys their decision to accept or reject the name. The regulatory division is requested to concur /not concur with DMEPA's final decision.

#### **2.1.5 Safety Evaluator Risk Assessment of the Proposed Proprietary Name**

Based on the criteria set forth in Section 2.1.1, the Safety Evaluator Risk Assessment applies their individual expertise gained from evaluating medication errors reported to FDA to conduct a Failure Mode and Effects Analysis and provide an overall risk of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>1</sup> When applying FMEA to assess the risk of a proposed proprietary name, the Division of Medication Error Prevention and Analysis seeks to evaluate the potential for a proposed name to be confused with another drug name as a result of the name confusion and cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to look- or sound-alike drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

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

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, expert panel evaluation, and studies, and identifies potential failure modes by asking: "Is the name Fanapt convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?" An affirmative answer indicates a failure mode and represents a potential for Fanapt to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system and the name is eliminated from further review.

In the second stage of the Risk Assessment, all potential failure modes are evaluated to determine the likely *effect* of the drug name confusion, by asking "Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?" The answer to this question is a central component of the Safety Evaluator's overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would ultimately not be a source of medication errors in the usual practice setting, the name is eliminated from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend that an alternate proprietary name be used. In rare instances, the FMEA findings may provide other risk-reduction

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<sup>1</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

strategies, such as product reformulation to avoid an overlap in strength or an alternate modifier designation may be recommended as a means of reducing the risk of medication errors resulting from drug name confusion.

DMEPA will object to the use of proposed proprietary name when the one or more of the following conditions are identified in the Safety Evaluator's Risk Assessment:

1. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the review Division concurs with DDMAC's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a trade name or otherwise. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n)].
2. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
3. FMEA identifies potential for confusion between the proposed proprietary name and other proprietary or established drug names, and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
4. The proposed proprietary name contains an USAN stem, particularly in a manner that is contradictory to the USAN Council's definition.
5. DMEPA staff identify a potential source of medication error within the proposed proprietary name. The proprietary name may be misleading, or inadvertently introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

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

If none of these conditions are met, then DMEPA will not object to the use of the proprietary name. If any of these conditions are met, then we will object to the use of the proprietary name. The threshold set for objection to the proposed proprietary name may seem low to the Applicant; however, the safety concerns set forth in criteria 1 through 5 are supported either by FDA Regulation or by external healthcare authorities, including the Institute of Medicine, World Health Organization, Joint Commission, and Institute for Safe Medication Practices, which have examined medication errors resulting from look- or sound-alike drug names and called for Regulatory Authorities to address the issue prior to approval.

Furthermore, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, can be identified and remedied prior to approval to avoid patient harm.

Additionally, postmarketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to remedy post-approval. Educational efforts and so on are low-leverage strategies that have proven to have limited effectiveness at alleviating the medication errors involving drug name confusion. Higher-leverage strategies, such as drug name changes, have been undertaken in the past; but at great financial cost to the Applicant, and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for the approving the error-prone proprietary name. Moreover, even after Applicant's have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioner's

vocabulary, and as such, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval (see limitations of the process).

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

### 3 RESULTS

#### 3.1 PROPRIETARY NAME RISK ASSESSMENT

##### 3.1.1 Database and Information Sources

In total, twenty-nine names were identified as having some similarity to the name Fanapt. Twenty-two of the twenty-nine names thought to look like Fanapt include: Lunesta, Panacet, Femhrt, Timoptic Trusopt, Fanaxal, Bancap, Tanafed, Tannate, Fiapta\*\*\*, Tana, Tamiflu, Panafil, Fanasal, Famopril, Farabant, Tovalt, Fablyn, Faropem and Danazol. Three names (Phanate, Penlac and Tanac) were thought to sound like Fanapt. Finally, four names (Fanapta\*\*\*, Fempatch, Finafta and Fanapt) were thought to look and sound like Fanapt.

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On January 9, 2009, the name Fanapt was searched against the United States Adopted Names (USAN) stem list and the proposed name was found to contain no USAN stems.

##### 3.1.2 CDER Expert Panel Discussion

The Expert Panel reviewed the pool of names identified by DMEPA staff (see section 3.1.1 above) and did not have any additional comments regarding the name Fanapt.

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

##### 3.1.3 FDA Prescription Analysis Studies

A total of 28 practitioners responded to the prescription analysis study, but none of the responses overlapped with any existing or proposed drug names. Approximately 28 % of the participants (n=8) interpreted the name correctly as "Fanapt," with the correct interpretation occurring most frequently in the Outpatient Prescription study. The remainder of the respondents misinterpreted the name. In the Inpatient Medication Order study most respondents misinterpreted the beginning of the name, misinterpreting the letters 'Fa' as the letters 'La' and the second 'a' as the letter 'o'. In the Outpatient Prescription study the letters 'Fa' in Fanapt was misinterpreted as the letters 'Ta', 'Za' or 'La'; and the second letter 'a' was misinterpreted as the letter 'o'. In the Verbal Prescription study the letters 'Fa' was misinterpreted as the letters 'Be', 'Bi', 'Ve', 'Me', 'Mo' and 'Fi'; the letter 't' was misinterpreted as the letter 's'. See Appendix B for the complete listing of interpretations from the verbal and written prescription studies.

### **3.1.4 Comments from the Division of Psychiatry Products (DPP)**

In response to the OSE January 15, 2009 e-mail, DPP did not forward any comments and/or clinical/other concerns on the proposed name at the initial phase of the name review.

DMEPA notified DPP via e-mail that we had found no objections to the proposed proprietary name, Fanapt, on February 10, 2009. Per e-mail correspondence from the Division of Psychiatry Products on February 11, 2009, they indicated they concur with our assessment of the proposed name, Fanapt.

### **3.1.5 External Proprietary Name Risk Assessment**

In the proposed name risk assessment submitted by the Applicant, \_\_\_\_\_ identified and evaluated a total of five drug names (Parnate, Trusopt, Lunesta, Azopt and Cosopt) thought to have some potential for confusion with the name Fanapt. \_\_\_\_\_ evaluated all the names identified for both look and sound-alike similarities. Two of the five names (Lunesta and Trusopt) were previously identified in our staff searches or Expert Panel Discussion. Three of the five names (Parnate, Azopt and Cosopt) were not previously identified in our staff searches, the Expert Panel Discussion, or FDA prescription studies.

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### **3.1.6 Safety Evaluator Risk Assessment**

Independent searches by the primary Safety Evaluator did not identify any additional names thought to look or sound similar to Fanapt and represent a potential source of drug name confusion. However, the Safety Evaluator re-reviewed the 16 names (Femara, \_\_\_\_\_ Fynefta, Synaptra, Fansidar, Timoptic, Pentora, Tinactin, Taractan, Zarnestra, FemPatch, Tanafed, Lipitor, Fareston, Sonata, and Lunesta) identified in the previous review for Fanapta (OSE review # 2007-538). Three of these names were identified in either the External Proprietary Name Risk Assessment or the Database searches.

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As such, a total of forty-five names were analyzed to determine if the drug names could be confused with Fanapt and if the drug name confusion would likely result in a medication error.

Thirty-one (31) names lacked orthographic and/or phonetic similarity and were not evaluated further (see Appendix C). Two names (Fiapta and Fanapta) were not further reviewed, as these names were the previous proposed names for this product that were found acceptable (see Appendix D).

Thus, failure mode and effect analysis (FMEA) was then applied to determine if the potential name, Fanapt, could potentially be confused with any of the twelve names and lead to medication errors.

FMEA determined that the name similarity between Fanapt and the identified names was unlikely to result in medication errors for all twelve product names for the reasons described in Appendices E through J.

## **4 DISCUSSION**

DMEPA evaluated forty-five (45) names for their potential similarity to the proposed name, Fanapt. The FMEA indicates that the proposed name, Fanapt, is not likely to result in name confusion that could lead to medication errors. This finding was consistent with and supported by an independent risk assessment of the proprietary name submitted by the Applicant.

## **5 CONCLUSIONS**

DMEPA has no objection to the use of the proprietary name, Fanapt, for this product. This decision was shared with the OND division who concurred with our findings on February 11, 2009. If any of the proposed product characteristics are altered prior to approval of the marketing application; DMEPA rescinds this Risk Assessment finding, and the name must be resubmitted for review. In the event that our Risk Assessment findings is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment and, as such, the conclusions on re-review are subject to change.

Additionally, if the product approval is delayed beyond 90 day from the date of this review, the proposed name must be resubmitted for evaluation.

## **6 RECOMMENDATIONS**

### **6.1 COMMENTS TO THE DIVISION**

We would appreciate feedback of the final outcome of this review. We would be willing to meet with the Division for further discussion, if needed. Please copy the Division of Medication Error Prevention and Analysis on any communication to the Applicant with regard to this review. If you have further questions or need clarifications, please contact Bola Adeolu, OSE Project Manager, at 301-796-4264.

### **6.2 COMMENTS TO THE APPLICANT**

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

The proprietary name, Fanapt, will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

If any of the proposed product characteristics are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

**APPEARS THIS WAY  
ON ORIGINAL**

## 7 REFERENCES

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

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

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

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

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

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

4. ***AMF Decision Support System [DSS]***

DSS is a government database used to track individual submissions and assignments in review divisions.

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

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

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

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

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

Provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

Provides information regarding patent and trademarks.

9. ***Clinical Pharmacology Online*** ([www.clinicalpharmacology-ip.com](http://www.clinicalpharmacology-ip.com))

Contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. Provides a keyword search engine.

10. **Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at ([www.thomson-thomson.com](http://www.thomson-thomson.com))**

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

11. **Natural Medicines Comprehensive Databases ([www.naturaldatabase.com](http://www.naturaldatabase.com))**

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

12. **Stat!Ref ([www.statref.com](http://www.statref.com))**

Contains full-text information from approximately 30 texts. Includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology and Dictionary of Medical Acronyms Abbreviations.

13. **USAN Stems (<http://www.ama-assn.org/ama/pub/category/4782.html>)**

List contains all the recognized USAN stems.

14. **Red Book Pharmacy's Fundamental Reference**

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

15. **Lexi-Comp ([www.lexi.com](http://www.lexi.com))**

A web-based searchable version of the Drug Information Handbook.

16. **Medical Abbreviations Book**

Contains commonly used medical abbreviations and their definitions.

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## APPENDICES

### Appendix A:

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

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

Type of similarity	Considerations when searching the databases		
	Potential causes of drug name similarity	Attributes examined to identify similar drug names	Potential Effects
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> <li>Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	Orthographic similarity	Similar spelling Length of the name Upstrokes Downstrokes Cross-strokes Dotted letters Ambiguity introduced	<ul style="list-style-type: none"> <li>Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>

		by scripting letters Overlapping product characteristics	
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>

**Appendix B: FDA Prescription Analysis Study Responses**

Inpatient Medication Order	Voice Prescription	Outpatient Prescription
Fanapt	Benapt	Fanapt
Fanapt	Menapt	Tanopt
Fanapt	Venapt	Fanapt
Fanopt	Benapt	Tanopt
Lanapt	Monaps	Zanopt
Fanapt	Menat	Lanopt
Fanapt	Venat	
Fanapt	Binapt	
Lanopt	Finapt	
	Venapt	
	Benat	
	Benapt	
	Benapt	

**Appendix C:** Names lacking convincing look-alike and/or sound-alike similarities with Fanapt

Identified Name	Similarity to Fanapt
Femhrt	Look
Timoptic —	Look
Bancap	Look
Tanafed	Look
Tannate	Look
Sonata	Look
Tamiflu	Look
Famopril	Look
Farabant	Look
Tovalt —	Look
————	Look
Fablyn	Look
Faropem	Look
Danazol	Look
Phanate	Sound
Penlac	Sound
Tanac	Sound
Fempatch	Look/Sound ✓
Parnate	Not specified
Azopt	Not specified
Cosopt	Not specified ✓
Femara	———— not specified
————	Look/Sound
Fansidar	Look
Timoptic XE	Look
Fentora	Look
Tinactin	Sound
Taractan	Look/Sound
Zarnestra	Look
Fareston	Look
Lipitor	Look

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**Appendix D:** Names that were previously found unacceptable by DMEPA for the product which is the subject of this review

Proprietary Name	Similarity to Fanapt
Fiapta***	Look
Fanapta***	Look and Sound
***This review contains proprietary and confidential information that should not be released to the public.	

**Appendix E:** Withdrawn by applicant or marketed under a different proprietary name

Proprietary Name	Similarity to Fanapt	Status
Fynefta***	Look/Sound; OSE review 2007-538	_____
_____	Sound	Approved under the proprietary name _____
***This review contains proprietary and confidential information that should not be released to the public.		

**Appendix F:** Proposed names that have not been submitted to the Agency by the Applicant.

Identified Name	Similarity to Fanapt
Fanapt : _____ AEGIS)	Look and Sound

**Appendix G:** Products approved or trademarked in a foreign country.

Identified Name	Similarity to Fanapt	Country of Approval
Fanaxal (Alfentanil)	Look	Spain
Fanasal (Naphazoline nitrate)	Look	Venezuela
Tanap	Look	Czech

**Appendix H:** Products with no additional information available

Proprietary Name	Similarity to Fanapt	Status
—	Look	Unable to locate in any other drug database

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**Appendix I:** Proprietary names with no overlapping strength or usual dose.

Product name with potential for confusion	Similarity to Fanapt	Strength	Usual Dose
Fanapt (Iloperidone)		Tablets: 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg	Titration to a maintenance dose of _____
Panacet (Hydrocodone bitartrate, Acetaminophen)	Look	Tablets Hydrocodone bitartrate 5 mg, Acetaminophen 500 mg	1 to 2 tablets every 4 to 6 hours
Panafil (Chlorophyllin Copper Complex, Papain, Urea)	Look	Ointment/Spray: _____	Apply directly to wound, cover with dressing daily or twice daily
Finafta (Ethyl Alcohol 60%, Salicylic Acid USP 1%)	Look/Sound	Topical Liquid Anesthetic/Analgesic	Apply 2 brushstrokes twice or several times daily to affected areas of mouth, gums, or mucous membranes

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**Appendix J:** Proprietary names with numerical overlap in strength or achievable dose.

Failure Mode: Name confusion	Causes: (could be multiple)	Effects:
<p style="text-align: center;"><b>Fanapt (Iloperidone)</b></p>	<p><b>Strength:</b> <b>Tablets:</b> 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg</p>	<p><b>Titrate to maintenance dose of _____ y</b></p>
<p>Lunesta (Eszopiclone)</p> <p><u>Dosage Form:</u> Tablets</p> <p><u>Strength:</u> 1 mg, 2 mg and 3 mg</p> <p><u>Usual Dose:</u> 2 mg, orally, immediately before bedtime</p>	<p>Orthographic similarities: Similar number of letters (seven vs. six), both names share 2 of the same letter in the same location ('n, t'), scripted 'L' can look like 'F', lower case 'u' looks like 'a', lower case 'e' looks like 'a', both names contain the same number of upstrokes (2) located in the same positions (1<sup>st</sup> and 6<sup>th</sup> letter).</p> <p>Overlap in dose (1 mg, 2 mg).</p>	<p>The orthographic difference in the names in addition to the difference in frequency of administration minimizes the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The orthographic differences in each name will help minimize the risk of error. Lunesta has an extra 'a' at the end which causes the name to appear longer.</p> <p>Although the strengths overlap at 1 mg and 2 mg, these strengths are prescribed for the first two days of a 4 day titration phase. Thus, these strengths are likely to only be written as part of the 4 day titration schedule, not as a single prescription. Additionally, the package insert recommends that titration occur in 4 mg increments (i.e., 6 mg BID, 8 mg BID etc.) Therefore, it is likely that prescribers would increase the dose in similar increments. Thus, if a separate order of 1 mg BID or 2 mg BID was ordered for add on therapy for a patient, the differences in the frequency (at bedtime vs. twice daily) will help to differentiate the products.</p>
<p>Trusopt (Dorzolamide Hydrochloride)</p> <p>Dosage Form: Solution</p> <p>Strength: 2 %</p> <p>Usual Dose: 1 Drop into affected eye(s) three times daily</p>	<p>Orthographic similarities: Similar first letters when scripted 'T' can look like 'F'; the middle letters 'so' when scripted can look like 'na'; both names contain the same ending 'pt'.</p> <p>Numerical overlap in strength (2 % versus 2 mg)</p>	<p>Orthographic differences in the names minimizes the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i></p> <p>The risk for medication error is minimized by the orthographic differences in the names. Although the first letters in Fanapt and Trusopt have similar first letters 'T' and 'F' when scripted and similar endings 'sopt' and 'napt'. When scripted the letters 'ru' and 'a' are orthographically different.</p> <p>Although there is a numerical overlap (2) in strength for Trusopt and Fanapt, the differences in route of administration and frequency will help differentiate the products which would help minimize errors.</p>

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/s/

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Diane Smith  
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DRUG SAFETY OFFICE REVIEWER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 22-192

**PROPRIETARY NAME REQUEST  
- CONDITIONALLY ACCEPTABLE**

Vanda Pharmaceuticals, Inc.  
Attention: John Feeney, M.D.  
Acting Chief Medical Officer  
9605 Medical Center Drive  
Suite 300  
Rockville, MD 20850

Dear Dr. Feeney:

Please refer to your New Drug Application (NDA 22-192) dated September 27, 2007, received September 27, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Iloperidone tablets 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg.

We also refer to your November 19, 2008, correspondence, received November 19, 2008, requesting review of your proposed proprietary name, Fanapt. We have completed our review of Fanapt and have concluded that it is acceptable.

The proprietary name, Fanapt will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

If **any** of the proposed product characteristics as stated in your November 19, 2008 submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you have any questions, call Abolade (Bola) Adeolu, Regulatory Project Manager, at (301) 796-4264.

Sincerely,

*{See appended electronic signature page}*

Thomas Laughren, M.D.  
Director  
Division of Psychiatry Products  
Office of New Drugs  
Center for Drug Evaluation and Research

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/s/

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

Date: June 3, 2008

To: Thomas Laughren, M.D.  
Director, Division of Psychiatry Products

Through: Todd Bridges, RPh, Team Leader  
Denise Toyer, Pharm D, Deputy Director  
Carol Holquist, RPh, Director  
Division of Medication Error Prevention

From: Diane C. Smith, PharmD, Safety Evaluator  
Division of Medication Error Prevention

Subject: Proprietary Name Review

Drug Name(s): Fanapta  
(Iloperidone) 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and  
12 mg Tablets

Application Type/Number: NDA 22-192

Applicant: Vanda Pharmaceuticals, Inc.

OSE RCM #: 2007-538

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## EXECUTIVE SUMMARY

Our analysis indicates that Fanapta appears vulnerable to name confusion that could lead to medication errors with Lunesta. See Section 4 for full discussion. As such, the Division of Medication Error Prevention objects to the use of the proprietary name, Fanapta, and recommends two alternate names be submitted for consideration.

### 1 BACKGROUND

#### 1.1 INTRODUCTION

This review was written in response to a request from the Division of Psychiatry Products, for assessment of the proprietary name, Fanapta, regarding potential name confusion with other proprietary or established names. The applicant submitted an independent analysis of the name by \_\_\_\_\_ a subsidiary \_\_\_\_\_, for review and comment. b(4)

Additionally, the applicant submitted container labels, carton and insert labeling for review and comments. The Division of Medication Error Prevention's assessment of the labels and labeling will be forwarded in a separate review.

#### 1.2 REGULATORY HISTORY

The Division of Medication Error Prevention initially reviewed the proprietary name, Fiapta, for this product (OSE Review # 2007-537, dated April 14, 2008). The Division of Medication Error Prevention found the name, Fiapta, unacceptable due to safety concerns with orthographic similarities with the existing proprietary name, Lipitor.

#### 1.3 PRODUCT INFORMATION

Fanapta (iloperidone) is a psychotropic agent indicated for the treatment of schizophrenia. The recommended target dosage range is 12 mg–24 mg daily administered twice daily during the acute phase. Titration to target dosage range should be achieved in daily dosage adjustment.

Day 1	Day 2	Day 3	Day 4
1 mg twice daily	2 mg twice daily	4 mg twice daily	6 mg twice daily

Alternately, the starting dose can begin at 2 mg twice a day. During the maintenance phase the target dose of \_\_\_\_\_ can be administered once daily or twice daily. Fanapta will be supplied in strengths of 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg tablets. Fanapta will be supplied in blister cards for dose titration in all the aforementioned strengths. Additionally, the 4 mg, 6 mg, 8 mg, 10 mg and 12 mg product strengths will be supplied in bottles of \_\_\_\_\_ 60 tablets. b(4)

### 2 METHODS AND MATERIALS

This section describes the methods and materials used by the Division of Medication Error Prevention staff conducting a proprietary name risk assessment (see 2.1 Proprietary Name Risk Assessment). The primary focus of the assessment is to identify and remedy potential sources of medication error prior to drug approval. The Division of Medication Error Prevention 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>1</sup>

## 2.1 PROPRIETARY NAME RISK ASSESSMENT

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

For the proprietary name, Fanapta, the Medication Error Prevention staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity (see Sections 2.1.1 for detail) and held an CDER Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (see 2.1.1.2). We also conduct internal CDER prescription analysis studies (see 2.1.2), and, when provided, external prescription analysis studies results are considered and incorporated into the overall risk assessment (see detail 2.1.4).

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name (see detail 2.1.4). The overall risk assessment is based on the findings of a Failure Modes and Effects Analysis (FMEA) of the proprietary name, and is focused on the avoidance of medication errors. FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>2</sup> FMEA is used to analyze whether the drug names identified with look- or sound-alike similarity to the proposed name could cause confusion that subsequently leads to medication errors in the clinical setting. The Division of Medication Error Prevention 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>3</sup> Our Division uses the clinical expertise of the medication error staff to anticipate the conditions of the clinical setting that the product is likely to be used in based on the characteristics of the proposed product.

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

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

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<sup>1</sup> National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

<sup>2</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

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

entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.<sup>4</sup>

### *2.1.1 Search Criteria*

The Medication Error Staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted as outlined in Appendix A.

For this review, particular consideration was given to drug names beginning with the letter 'F' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.<sup>56</sup>

To identify drug names that may look similar to Fanapta, the Staff also consider the other orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (7 letters), upstrokes (2, capital letter 'F' and 't'), downstrokes (one, 'p'), cross-strokes (two, 'F' and 't'), and dotted letters (none). Additionally, several letters in Fanapta may be vulnerable to ambiguity when scripted, including the letter 'F' may appear as 'L', 'T', 'Z', 'I', or 'J'; lower case 'a' appear as a lower case 'e', 'c' and 'o'; lower case 'n' may appear as 'r', 'h', 's', 'm', 'u' or 'v'; lower case 'p' may appear as 'x', and 'y'; and lower case 't' may appear as 'f', 'r', 'l' or 'i'. As such, the Staff also consider these alternate appearances when identifying drug names that may look similar to Fanapta.

When searching to identify potential names that may sound similar to Fanapta, the Medication Error Staff search for names with similar number of syllables (3), stresses (fa-NAP-ta or FA-nap-TA), and placement of vowel and consonant sounds. In addition, several letters in Fanapta may be subject to interpretation when spoken, including the letter "F" may be interpreted as 'Ph', 'V' or 'Fe'; the letter 'a' may be interpreted as 'e' or 'eh'; and the letters 'ta' may be misinterpreted as 'tuh'. The Applicant's intended pronunciation of the proprietary name could not be expressly taken into consideration, as this was not provided with the proposed name submission.

The Staff also consider the product characteristics associated with the proposed drug throughout the identification of similar drug names, since the product characteristics of the proposed drug ultimately determine the use of the product in the clinical practice setting. For this review, the Medication Error Staff were provided with the following information about the proposed product: the proposed proprietary name (Fanapta), the established name (iloperidone), proposed indication (schizophrenia), strength (1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg), dose (titrate up to 24 mg daily based on clinical response), frequency of administration (once daily to twice daily), route (oral) and dosage form the product (tablet). Appendix A provides a more detailed listing of the product characteristics the Medication Error Staff general take into consideration.

Lastly, the Medication Error Staff also consider the potential for the proposed name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. As such, these broader safety implications of the name are considered and evaluated throughout this assessment and the Medication Error Staff provide additional comments related to the safety of the proposed name or product based on their professional experience with medication errors.

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<sup>4</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

<sup>5</sup> Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

<sup>6</sup> Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

#### **2.1.1.1 Data base and information sources**

The proposed proprietary name, Fanapta, was provided to the medication error staff of the Division of Medication Error Prevention staff to conduct a search of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to Fanapta using the criteria outlined in 2.1.1. A standard description of the databases used in the searches is provided in Section 6. To complement the process, the Medication Error Staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the Medication Error Staff review the United States Adopted Names (USAN) stem list to determine if any USAN stems are present within the proprietary name. The findings of the individual Safety Evaluators were then pooled and presented to the Expert Panel.

#### **2.1.2 CDER Expert Panel Discussion**

An Expert Panel Discussion is held by the Division of Medication Error Prevention to gather CDER professional opinions on the safety of the product and the proprietary name, Fanapta. Potential concerns regarding drug marketing and promotion related to the proposed names are also discussed. This group is composed of Medication Errors Prevention Staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC).

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

#### **2.1.3 CDER Prescription Analysis Studies**

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Fanapta 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 a total of 123 healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The results are used by the Safety Evaluator to identify any orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of Fanapta in handwriting and verbal communication of the name, inpatient medication orders and outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These prescriptions are optically scanned and one prescription is delivered to a random sample of 123 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 send their interpretations of the orders via e-mail to the medication error staff.

**Figure 1. Fanapta Study (conducted on April 5, 2007)**

HANDWRITTEN PRESCRIPTION AND MEDICATION ORDER	VERBAL PRESCRIPTION
<p>Outpatient Prescription:</p> <p><i>Fanapta 12mg #60</i>  <i>1 tablet by mouth bid</i></p>	<p>Fanapta 12 mg 1 tablet bid</p>
<p>Inpatient Medication Order :</p> <p><i>Fanapta 12mg 1 tab po bid</i></p>	

**2.1.4 External Proprietary Name Risk Assessment**

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

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

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### ***2.1.5 Safety Evaluator Risk Assessment of the Proposed Proprietary Name***

Based on the criteria set forth in Section 2.1.1, the Safety Evaluator Risk Assessment applies their individual expertise gained from evaluating medication errors reported to FDA to conduct a Failure Modes and Effects Analysis and provide an overall risk of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>7</sup> When applying FMEA to assess the risk of a proposed proprietary name, the Division of Medication Error Prevention seeks to evaluate the potential for a proposed name to be confused with another drug name as a result of the name confusion and cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to look- or sound-alike drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

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

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, expert panel evaluation, and studies, and identifies potential failure modes by asking: "Is the name Fanapta convincing similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?" An affirmative answer indicates a failure mode and represents a potential for Fanapta to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system and the name is eliminated from further review.

In the second stage of the Risk Assessment, all potential failure modes are evaluated to determine the likely *effect* of the drug name confusion, by asking "Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?" The answer to this question is a central component of the Safety Evaluator's overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would ultimately not be a source of medication errors in the usual practice setting, the name is eliminated from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend that an alternate proprietary name be used. In rare instances, the FMEA findings may provide other risk-reduction strategies, such as product reformulation to avoid an overlap in strength or an alternate modifier designation may be recommended as a means of reducing the risk of medication errors resulting from drug name confusion.

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<sup>7</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

The Division of Medication Error Prevention will object to the use of proposed proprietary name when the one or more of the following conditions are identified in the Safety Evaluator's Risk Assessment:

1. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the review Division concurs with DDMAC's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a trade name or otherwise. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n)].
2. We identify that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
3. FMEA identifies potential for confusion between the proposed proprietary name and other proprietary or established drug names, and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
4. The proposed proprietary name contains an USAN stem, particularly in a manner that is contradictory to the USAN Council's definition.
5. Medication Error Staff identify a potential source of medication error within the proposed proprietary name. The proprietary name may be misleading, or inadvertently introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug another drug product.

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

If none of these conditions are met, then we will not object to the use of the proprietary name. If any of these conditions are met, then we will object to the use of the proprietary name. The threshold set for objection to the proposed proprietary name may seem low to the Applicant; however, the safety concerns set forth in criteria 1 through 5 are supported either by FDA Regulation or by external healthcare authorities, including The Institute of Medicine, The World Health Organization, The Joint Commission, and The Institute For Safe Medication Practices, have examined medication errors resulting from look- or sound-alike drug names and called for Regulatory Authorities to address the issue prior to approval.

Furthermore, the Division of Medication Error Prevention contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, can be identified and remedied prior to approval to avoid patient harm.

Additionally, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to remedy post-approval. Educational efforts and so on are low-leverage strategies that have proven to have limited effectiveness at alleviating the medication errors involving drug name confusion. Higher-leverage strategies, such as drug name changes, have been undertaken in the past; but at great financial cost to the Applicant, and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for the approving the error-prone proprietary name. Moreover, even after Applicant's have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioner's vocabulary, and as such, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, we believe that post-approval efforts at reducing name

confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval (see limitations of the process).

If we object to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the FMEA process is used to identify strategies to reduce the risk of medication errors. Our Division is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for review by our Division. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name, and so we may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error would render the proposed name acceptable.

### 3 RESULTS

#### 3.1 PROPRIETARY NAME RISK ASSESSMENT

##### 3.1.1 Database and Information Sources

We conducted a search of the internet, several standard published databases and information sources (see Section 6 References) for existing drug names which sound-alike or look-alike to Fanapta to a degree where potential confusion between drug names could occur and result in medication errors in the usual practice settings. In total, 14 names were identified as having some similarity to the name Fanapta.

Eight of fourteen names were thought to look like Fanapta, which include: Fansidar, FemPatch, Lunesta, Tanafed, Timoptic, Zarnestra\*\*\*, Fentora, and Fareston. Four names (Fynefta\*\*\*, , Sonata and Taractan) were thought to look and sound similar to Fanapta. Two names (Tinactin and ) were thought to sound similar to Fanapta.

b(4)

As of April 9, 2008, the proposed name, Fanapta, did not contain a United State Adopted Name (USAN) stem.

##### 3.1.2 CDER Expert Panel Discussion

The Expert Panel reviewed the pool of names identified by Medication Error Staff (see section 3.1.1. above), and no additional names were thought to have orthographic or phonetic similarity to Fanapta.

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

##### 3.1.3 CDER Prescription Analysis Studies

A total of 39 practitioners responded, but none of the responses overlapped with any existing or proposed drug names. About 23% of the participants (n=9) interpreted the name correctly as "Fanapta", with correct interpretation occurring more frequently in the written studies. The remainder of the responses misinterpreted the drug name. The majority of misinterpretations occurred in the phonetic prescription study, with the first vowel in Fanapta reported as 'e' instead of 'a'. Additionally, the first syllable 'Fa' was misinterpreted as 'Ve'; 'Va', 'Vi', 'Phe', 'Pe' or 'Be'. In the written prescription studies, the letter 'F' was misinterpreted as by 'T' by ten respondents. See Appendix B for the complete listing of interpretations from the verbal and written prescription studies.

### **3.1.4 External Proprietary Name Risk Assessment**

The Applicant submitted a Trademark Evaluation conducted by, \_\_\_\_\_, a subsidiary of \_\_\_\_\_, which identified and evaluated the look-alike and sound-alike characteristics of four drug names thought to have some potential for confusion with the name Fanapta.

One of these names (Femara) was not identified in our Staff searches, the Expert Panel Discussion, or FDA prescription studies. The remaining three names (Fansidar, Fentora and Sonata) were identified by the Medication Error Staff as names that look and/or sound similar to Fanapta.

### **3.1.5 Safety Evaluator Risk Assessment**

Independent searches by the primary Safety Evaluator identified one additional name, Lipitor, thought to look similar to Fanapta and represent a potential source of drug name confusion. As such, a total of sixteen names were analyzed to determine if the drug names could be confused with Fanapta and if the drug name confusion would likely result in a medication error.

All of the identified names were determined to have some orthographic and /or phonetic similarity to Fanapta, and thus determined to present some risk of confusion. Failure mode and effect analysis was then applied to determine if the potential name, Fanapta, could potentially be confused with any of the sixteen names and lead to medication errors.

Two of the sixteen names (Femara and \_\_\_\_\_) were not considered further because they lack convincing orthographic and/or phonetic similarities with Fanapta (see Appendix C). Two products (Fynefta\*\*\*, \_\_\_\_\_\*) are proposed proprietary names for other products within the Agency which have not been approved or were approved under a different proprietary name, and thus were determined by FMEA to pose minimal risk of error in the usual practice settings (Appendix D). For eight of the names (Fansidar, Timoptic, Fentora, Tinactin, Taractan, Zarnestra\*\*\*, FemPatch and Tanafed) FMEA determined that medication errors were unlikely because the products do not overlap in strength or dosage with Fanapta and have minimal orthographic and/or phonetic similarity to Fanapta (Appendix E).

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Three names (Lipitor, Fareston, and Sonata) had some numerical overlap with Fanapta in either dosage or strength, however, the analysis of the failure mode did not determine the effect of this similarity to result in medication errors in the usual practice setting (see Appendix F). FMEA determined the remaining name, Lunesta, was vulnerable to confusion and medication error due to orthographic similarities in addition to overlapping product characteristics (See section 4 below for full discussion and Appendix G).

## **4 DISCUSSION**

### **4.1 PROPRIETARY NAME RISK ASSESSMENT**

The results of the Proprietary Name Risk Assessment found that the proposed name, Fanapta, is vulnerable to name confusion with the proprietary name Lunesta that could lead to medication errors. This finding was not consistent with the overall independent risk assessment of the proprietary name submitted by the Applicant. The independent analysis did not identify or consider Lunesta in their evaluation.

The orthographic similarity of this name pair stems from the scripted look-alike similarity of the first letter of each name in addition to the fact that they have the same number of letters (seven), and three of the seven letters are identical (see Appendix G for a complete comparison of orthographic similarities).

Additionally, these products share several overlapping product characteristics as noted in Appendix H. Therefore, the aforementioned overlapping product characteristics and the strong orthographic similarity

between Lunesta and Fanapta, increases the potential of risk of medication errors between the two drug products. This confusion will most likely occur if during ..... practitioners increase the dose by adding 1 mg or 2 mg, to a current dose. For example, a patient taking 12 mg per day is increased to 13 mg per day with a prescription for "Fanapta 1 mg, qd, #30". We envision such a prescription being misinterpreted as "Lunesta 1 mg, qd, #30". Furthermore, 21 CFR 201.10(c)(5) states "the labeling of a drug may be misleading by reason (among other reasons) of designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or established name of a different drug or ingredient."

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## **5 CONCLUSIONS AND RECOMMENDATIONS**

The Proprietary Name Risk Assessment findings indicate that the proposed name, Fanapta, appears to be vulnerable to name confusion that could lead to medication errors. This finding was not consistent with the overall findings of the independent risk assessment of the proprietary name submitted by the Applicant primary because Lunesta was not included in this evaluation. As such, the Division of Medication Error Prevention objects to the use of the proprietary name, Fanapta, for this product based upon the risk of confusion with Lunesta. The Applicant should submit two alternate proprietary names and identify their primary and secondary choice.

### **5.1 COMMENTS TO THE DIVISION**

Based upon our risk assessment of the proposed proprietary name the Division of Medication Error Prevention does not recommend approval of the proprietary name, Fanapta, for this product because it's potential confusion with Lunesta. We recommend that the comments in section 5.2 be forwarded to the Applicant. We note that the titration schedule and exact dose has not been determined. Therefore, if the titration schedule and the dose are determined to be something other than what was provided, the proprietary name will have to be re-reviewed taking into consideration all new pertinent factors which relate to the titration and the dose of the proposed drug product.

We would appreciate feedback on the final outcome of this review. We would be willing to meet with the Division for further discussion, if needed. Please copy the Division of Medication Error Prevention on any communication to the Applicant with regard to this review. If you have further questions or need clarifications, please contact Daniel Brounstein, OSE Project Manager, at 301-796-0674.

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**5.2 COMMENTS TO THE APPLICANT**

The findings of our Proprietary Name Risk Assessment indicate that the proposed name, Fanapta, is vulnerable to name confusion that could lead to medication errors with Lunesta. This determination was made based on the dosing information and other product characteristics at this time. These concerns are described in detail below.

The results of the Proprietary Name Risk Assessment found that the proposed name, Fanapta, is vulnerable to name confusion with the proprietary name Lunesta that could lead to medication errors. This finding was not consistent with the overall independent risk assessment of the proprietary name submitted by the Applicant. The independent analysis did not identify or consider Lunesta in their evaluation.

The orthographic similarity of this name pair stems from the scripted look-alike similarity of the first letter of each name in addition to the fact that they have the same number of letters (seven), and three of the seven letters are identical. Additionally, these products share several overlapping product characteristics see below.

Orthographic similarities and overlapping product characteristics:

 		
Product Characteristics	Lunesta	Fanapta
Indication of use	Sedative hypnotic	Schizophrenia
Dose	2 mg or 3 mg	The target dosage range should be achieved in daily dosage adjustments, for example:  1 mg, 2 mg, 4 mg and 6 mg twice daily on days 1, 2, 3 and 4, respectively, to reach 12 mg/day.  During the maintenance phase the target dose range is _____
Frequency	Once daily before retiring	Once or twice daily
Strength	1 mg, 2 mg and 3 mg	1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg
Route of Administration	Orally	Orally

b(4)

Therefore, the aforementioned overlapping product characteristics and the strong orthographic similarity between Lunesta and Fanapta, increases the potential of risk of medication errors between the two drug products. This confusion will most likely occur during the maintenance phase if practitioners increase the dose by adding 1 mg or 2 mg, to a current dose. For example, a patient taking 12 mg per day is increased to 13 mg per day with a prescription for "Fanapta 1 mg, qd, #30". We envision such a prescription being misinterpreted as "Lunesta 1 mg, qd, #30". Furthermore, 21 CFR 201.10(c)(5) states "the labeling of a drug may be misleading by reason (among other reasons) of designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or established name of a different drug or ingredient."

Therefore, due to the strong orthographic similarity and overlapping product characteristics, we believe there is a risk of confusion between Lunesta and Fanapta and do not recommend the name.

As such, the Division of Medication Error Prevention objects to the use of the proprietary name, Fanapta, for this product. We recommend the Applicant submit two alternate proprietary names and identify their primary and secondary choice.

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## 6 REFERENCES

### 1. *Adverse Events Reporting System (AERS)*

AERS is a database application in CDER FDA that contains adverse event reports for approved drugs and therapeutic biologics. These reports are submitted to the FDA mostly from the manufactures that have approved products in the U.S. The main utility of a spontaneous reporting system that captures reports from health care professionals and consumers, such as AERS, is to identify potential postmarketing safety issues. There are inherent limitations to the voluntary or spontaneous reporting system, such as underreporting and duplicate reporting; for any given report, there is no certainty that the reported suspect product(s) caused the reported adverse event(s); and raw counts from AERS cannot be used to calculate incidence rates or estimates of drug risk for a particular product or used for comparing risk between products.

### 2. *Micromedex Integrated Index (<http://weblern/>)*

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

### 3. *Phonetic and Orthographic Computer Analysis (POCA)*

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

### 4. *Drug Facts and Comparisons, online version, St. Louis, MO (<http://weblern/>)*

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

### 5. *AMF Decision Support System [DSS]*

DSS is a government database used to track individual submissions and assignments in review divisions.

### 6. *Division of Medication Error Prevention proprietary name consultation requests*

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

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

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

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

Provides a compilation of approved drug products with therapeutic equivalence evaluations.

**9. WWW location <http://www.uspto.gov>.**

Provides information regarding patent and trademarks.

**10. Clinical Pharmacology Online (<http://weblern/>)**

Contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. Provides a keyword search engine.

**11. Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at [www.thomson-thomson.com](http://www.thomson-thomson.com)**

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

**12. Natural Medicines Comprehensive Databases (<http://weblern/>)**

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

**13. Stat!Ref (<http://weblern/>)**

Contains full-text information from approximately 30 texts. Includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology and Dictionary of Medical Acronyms Abbreviations.

**14. USAN Stems (<http://www.ama-assn.org/ama/pub/category/4782.html>)**

List contains all the recognized USAN stems.

**15. Red Book Pharmacy's Fundamental Reference**

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

**16. Lexi-Comp ([www.pharmacist.com](http://www.pharmacist.com))**

A web-based searchable version of the Drug Information Handbook.

**17. Medical Abbreviations Book**

Contains commonly used medical abbreviations and their definitions.

## APPENDICES

### Appendix A:

The Medication Error Staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. We also compare the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. The Medication Error Staff also examine the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly *and* dissimilarly spelled drug name pairs to appear very similar to one another and the similar appearance of drug names when scripted has lead to medication errors. The Medication Error Staff apply their expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (i.e. "T" may look like "F," lower case 'a' looks like a lower case 'u,' etc), along with other orthographic attributes that determine the overall appearance of the drug name when scripted (see detail in Table 1 below). Additionally, since verbal communication of medication names is common in clinical settings, the Medication Error Staff compare the pronunciation of the proposed proprietary name with the pronunciation of other drug names. If provided, the Division of Medication Error Prevention will consider the Applicant's intended pronunciation of the proprietary name. However, because the Applicant has little control over how the name will be spoken in practice, we also considers a variety of pronunciations that could occur in the English language.

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

Type of similarity	Considerations when searching the databases		
	Potential causes of drug name similarity	Attributes examined to identify similar drug names	Potential Effects
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> <li>Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	Orthographic similarity	Similar spelling Length of the name Upstrokes Downstrokes Cross-strokes	<ul style="list-style-type: none"> <li>Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>

		<p>Dotted letters</p> <p>Ambiguity introduced by scripting letters</p> <p>Overlapping product characteristics</p>	
Sound-alike	Phonetic similarity	<p>Identical prefix</p> <p>Identical infix</p> <p>Identical suffix</p> <p>Number of syllables</p> <p>Stresses</p> <p>Placement of vowel sounds</p> <p>Placement of consonant sounds</p> <p>Overlapping product characteristics</p>	<ul style="list-style-type: none"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>

**Appendix B:**

**CDER Prescription Study Responses**

Outpatient Prescription	Voice Prescription	Inpatient Medication Order
Fanapta	Benacta	fanapta
Fanapata	FENACTA	Tanapta
Tanapta	FENAPTA	Tanapta
Tanapta	Fenacta	Fanapta
Fanapta	Fenacta	Tanapta
Ojanapta	Venacta	Fanapta
Tanapta	Phenapta	Fanapta
Inapta	Vanacta	Janapta
Fanopta	Venacta	Tanapta
Fanapta	Penapta	Tanapta
fanapta	Vinacta	Tanapta
	Phenacta	Fanapta
	Fenacta	Tanapta
	Fenapta	
	Vanacta	

**Appendix C:** Names lacking convincing look-alike and/or sound-alike similarities with Fanapta

Proprietary Name	Similarity to Fanapta
Femara	— did not specify
_____	Look/Sound

**Appendix D:** Withdrawn by applicant or marketed under a different proprietary name

Proprietary Name	Similarity to Fanapta	Status
Fynefta***	Look/Sound	_____
_____	Sound	Approved under the proprietary name. _____
***This review contains proprietary and confidential information that should not be released to the public.		

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**Appendix E:** Products with no numerical overlap in strength and dose.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
Fanapta (lloperidone)		1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg	12 mg to 24 mg once or twice daily
Fansidar (Sulfadoxine and pyrimethamine)	Look	500 mg sulfadoxine and 25 mg pyrimethamine	1 tablet 1 or 2 days before travel, daily while in endemic country and daily for 4 to 6 weeks after returning
Timoptic XE, Ocudose and Ocumeter (Timolol)	Look	0.25% and 0.5%	(Ocumeter and Ocudose) 1 drop into affected eye(s) twice daily. (XE) 1 drop into affected eye(s) once daily
Fentora (Fentanyl Citrate)	Look	100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 800 mcg	Initially 200 mcg buccally of mouth every 4 hours
Tinactin (Tolnaftate)	Sound	1%	Apply a thin layer twice daily
Taractan (discontinued)	Look and Sound	50 mg	No information available
Zarnestra *** (previously reviewed by Division of Medication Error Prevention review #01-0184 for IND and found acceptable)	Look	100 mg	
FemPatch (estradiol)	Look	0.025 mg/24 hour	1 patch on buttocks; replace every 7 days
Tanafed (Chlorpheniramine Maleate/Pseudoephedrine)	Look	4.5 mg/5 ml Chlorpheniramine Tannate and 75 mg/5 ml Pseudoephedrine Tannate	10 ml every
***This review contains proprietary and confidential information that should not be released to the public.			

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**Appendix F: Potential confusing name with numerical overlap in strength or dose**

Failure Mode: Name confusion	Causes (could be multiple)	Effects
Fanapta (Naloxone)	1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg	Usual dose: 12 mg to 24 mg once or twice daily
Lipitor (Atrovastatin)	<p>Orthographic similarity: Both names begin with letters which can look similar when scripted ('L' and 'F')</p> <p>Overlapping strengths (10 mg)</p>	<p>Orthographic differences in the names minimize the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i> The risk of medication errors is reduced by the orthographic differences in the names. Fanapta contains a 'p' at the fifth position compared to the third position in Lipitor. Additionally, the downstroke letter 'p' in Fanapta precedes the upstroke letter 't'. These two letters appearing together helps to differentiate this name pair. Fanapta ends with the letter 'a' compared to Lipitor which ends with the letter 'r'.</p>
Fareston (Toremifene)	<p>Orthographic similarity: Both names begin with same letter ('F') and contain the upstroke letter 't' in the same position (i.e., the sixth letter of the name).</p> <p>Numerical overlap in strength (60 mg versus 6 mg).</p>	<p>Orthographic differences in the names minimize the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i> The risk for medication error is minimized by the orthographic differences in the names. Fanapta has one downstroke 'p' in the fifth position.</p> <p>Usual practice would not typically involve the inclusion of trailing zeros, though medication errors have been linked to this dangerous habit. Numerous campaigns (Joint Commission, ISMP, FDA) to eliminate use of trailing zeros when communicating drug information should help to further reduce risk of medication error.</p>
Sonata (Zaleplon)	<p>Orthographic similarity: 'S' and 'F' and similar ending 'ta'.</p> <p>Phonetic similarity: Both names are three-syllable words and have similar sounding endings.</p> <p>Share a strength (10 mg).</p>	<p>Orthographic and phonetic differences in the names minimize the likelihood of medication error in the usual practice setting.</p> <p><i>Rationale:</i> The risk for medication error is minimized by the orthographic differences in the names. The downstroke 'p' in the fifth position in Fanapta provides differentiation between the names. Additionally, when scripted, the length of the names are different.</p> <p>Phonetic differences stem from the first syllable of each name ('Fa' versus 'So') which is distinct.</p>

Appendix G: Orthographic Similarities

Orthographic Similarities

unesta  
anapta

*Lunista*  
*Lanasta*  
*Janapta*  
*Lunista*  
*Lunista*  
*Janapta*

Both contain 7 letters. The names share 3 of the same letters in the same location ('n', 't,' and 'a'), scripted 'L' looks like scripted 'F', lower case 'u' looks like 'a'; lower case 'e' looks like 'a'.

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**Appendix H: Overlapping product characteristics**

Product Characteristics	Lunesta	Fanaxipita
Indication of use	Sedative hypnotic	Schizophrenia
Dose	2 mg or 3 mg	<p>The target dosage range should be achieved in daily dosage adjustments, for example:                      1 mg, 2 mg, 4 mg and 6 mg twice daily on days 1, 2, 3 and 4 respectively, to reach 12 mg/day.</p> <p>Alternately, the starting dose can begin at 2 mg twice daily.</p> <p>During the maintenance phase the target dose range</p> <hr/> <hr/>
Frequency	Once daily before retiring	Once or twice daily
Strength	1 mg, 2 mg and 3 mg	1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg
Route of Administration	Orally	Orally

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**Center for Drug Evaluation and Research**

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**TO:** Thomas Laughren, M.D., Director  
Division of Psychiatry Products

**THROUGH:** Todd Bridges, RPh, Team Leader  
Denise Toyer, PharmD, Deputy Director  
Carol Holquist, RPh, Director  
Division of Medication Error Prevention

**FROM:** Diane C. Smith, PharmD, Safety Evaluator  
Division of Medication Error Prevention

<b>PRODUCT NAME:</b> <b>Fiapta</b> (Iloperidone) Tablets 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg	<b>NDA APPLICANT:</b> Vanda Pharmaceuticals, Inc.
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**NDA #:** 22-192 (IND #36,827)

**RECOMMENDATIONS:**

1. The Division of Medication Error Prevention does not recommend the use of the proprietary name, Fiapta. We will proceed with an assessment of the alternate name, Fanapta, which will be forwarded in a separate review.
2. The Division of Medication Error Prevention's assessment of the container labels, carton and insert labeling will be forwarded in a separate review.
3. DMAC finds the proprietary name, Fiapta, acceptable from a promotional perspective.

We would be willing to meet with the Division for further discussion, if needed. We would appreciate feedback of the final outcome of this consult. Please copy the Division of Medication Error Prevention on any correspondence forwarded to the sponsor pertaining to this review. If you have further questions or need clarifications, please contact Daniel Brounstein, OSE Project Manager, at 301-796-0674.

**Division of Medication Error Prevention  
Office of Surveillance and Epidemiology  
HFD-420; WO 22; Mail Stop 4447  
Center for Drug Evaluation and Research**

**PROPRIETARY NAME REVIEW**

**DATE OF REVIEW:** April 14, 2008  
**NDA #:** 22-192 (IND #36,827)  
**NAME OF DRUG:** Fiapta  
(Iloperidone) Tablets  
1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg  
**NDA APPLICANT:** Vanda Pharmaceuticals, Inc.

**I. INTRODUCTION:**

This consult was written in response to a request from the Division of Psychiatry Products for assessment of the proprietary name, Fiapta, regarding potential name confusion with other proprietary or established drug names.

Additionally, \_\_\_\_\_ the marketing subsidiary of \_\_\_\_\_ completed a trademark evaluation study on behalf of Vanda Pharmaceuticals, Inc., in November 2006. The purpose of the research was to assess Fiapta as a potential proprietary name for Iloperidone tablets.

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**PRODUCT INFORMATION**

Fiapta (iloperidone) is indicated for the treatment of schizophrenia. The recommended maintenance dose is \_\_\_\_\_ daily. Patients should be titrated up over 7 days to the recommended daily dose. The titration may begin at 2 mg or 4 mg per day. The Applicant proposes the following schedule when starting at 2 mg per day.

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Day 1	Day 2	Day 3	Day 4
2 mg per day	4 mg per day	8 mg per day	12 mg per day

After reaching the 12 mg per day dose, titration to the maximum daily dose of 24 mg should occur over a 3-day period. During the titration phase the daily dose may be given once or twice a day. Fiapta will be supplied in strengths of 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg tablets.

## II. RISK ASSESSMENT:

The medication error staff of the Division of Medication Error Prevention conducted a search of the internet, several standard published drug product reference texts<sup>1,2</sup> as well as several FDA databases<sup>3,4</sup> for existing drug names which sound-alike or look-alike to Fiapta to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted<sup>5</sup>. The Saegis<sup>6</sup> Pharma- In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches.

In addition, our Division conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name. Following the completion of these initial components, an overall risk assessment is conducted that does not evaluate the name alone. The assessment considers the findings from above and more importantly integrates post-marketing experience in assessing the risk of name confusion, product label/labeling, and product packaging. Because it is the product that is inserted into the complex and unpredictable U.S. healthcare environment, all product characteristics of a product must be considered in the overall safety evaluator risk assessment.

### A. EXPERT PANEL DISCUSSION (EPD)

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

1. DDMAC finds the proprietary name, Fiapta, acceptable from a promotional perspective.
2. The Expert Panel identified ten proprietary names that were thought to have the potential for confusion with Fiapta. They are Tiazac, Taztia, Septra, Timoptic, Zemplar, Tiapride, Fiac, Viagra, Lipitor and Byetta.

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<sup>1</sup> MICROMEDEX Integrated Index, 2008, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

<sup>2</sup> Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.

<sup>3</sup> AMF Decision Support System [DSS], the Division of Medication Error Prevention database of Proprietary name consultation requests, New Drug Approvals 98-08, and the electronic online version of the FDA Orange Book.

<sup>4</sup> Phonetic and Orthographic Computer Analysis (POCA)

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

<sup>6</sup> Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at [www.thomson-thomson.com](http://www.thomson-thomson.com)

B. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

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

HANDWRITTEN ORDERS	VERBAL ORDER
<p>Outpatient RX:</p> <p><i>Fiapta 10mg</i> <i>#60</i> <i>T tab po daily</i></p>	<p>Verbal Prescription:</p> <p>Fiapta 10 mg 1 po qd</p>
<p>Inpatient RX:</p> <p><i>Fiapta 10mg 1 tab po daily</i></p>	

2. Results:

Three of the respondents from the inpatient written prescription study interpreted the proposed name as "Fioptor". Fioptor can look like Lipitor when scripted. Lipitor is a current approved product in the United States. See appendix A for the complete listing of interpretations from the verbal and written studies.

C. SAFETY EVALUATOR RISK ASSESSMENT

1. Division of Medication Error Prevention Name Analysis

In reviewing the proprietary name, Fiapta, ten names were identified as having a similar appearance or sound to Fiapta. These names include Tiazac, Taztia, Septra, Timoptic, Zemplar, Tiapride, Fiac, Viagra, Lipitor and Byetta.

Additionally, the Medication Error Prevention Staff conducted prescription studies to simulate the prescription ordering process. In this case, there was no confirmation that the proposed name could be confused with any of the aforementioned names. However, negative findings are not predicative as to what may occur once the drug is widely prescribed, as these studies have limitations primarily due to a small sample size. We note that three of the respondents from the inpatient written prescription study interpreted the proposed name as "Fioptor". Fioptor can look like Lipitor when scripted. Lipitor is a currently approved product in the United States. The majority of interpretations were misspelled/phonetic variations of the proposed name, Fiapta. See appendix A for the complete listing of interpretations from the verbal and written studies.

All ten names were determined to have some orthographic and/or phonetic similarity to Fiapta, and thus, determined to present some risk of confusion. Failure modes and effects analysis was then applied to determine if the proposed name, Fiapta, could potentially be confused with any of the ten names and lead to medication error. FMEA determined that these eight names Tiazac, Taztia, Septra, Timoptic, Zemplar, Tiapride, Fiac, and Byetta, were unlikely to result in medication errors in the usual practice setting because the products do not overlap in strength or dosage with Fiapta. Also, the name Viagra has minimal orthographic and/or phonetic similarity to Fiapta and thus determined would not result in medication errors in the usual practice setting.

FMEA determined the proprietary name Lipitor could cause confusion with Fiapta in the usual practice setting.

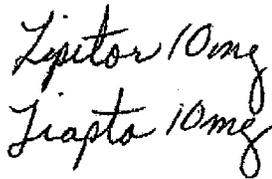
Table 1: Potential Look-Alike Names Identified by the Division of Medication Error Prevention Expert Panel

Product Name	Dosage form(s), Established name	Usual adult dose	Other
Fiapta	Allopurinol 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg Tablets	<ul style="list-style-type: none"> <li>Recommended range: dose 12 mg/day</li> <li>Titration schedule: 1 mg, 2 mg, 4 mg and 6 mg BID</li> <li>Maintenance daily dose: _____</li> <li>QD</li> </ul>	NA
Lipitor	Atorvastatin 10 mg, 20 mg, 40 mg and 80 mg Tablets	<ul style="list-style-type: none"> <li>10 to 20 mg QD. Dosage range is 10 to 80 mg QD</li> </ul>	LA

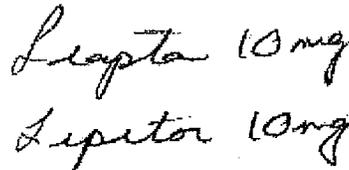
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Fiapta and Lipitor cannot safely co-exist in the market because of look alike similarity between these two names. Lipitor (atorvastatin) is a selective, competitive HMG-CoA reductase inhibitor used to lower cholesterol and triglycerides in patients with hypercholesterolemia and mixed dyslipidemia. The recommended dose is 10 to 80 mg once daily.

The beginning and ending of each name look similar. The first three letters of Lipitor ('Lip') may look similar to the first four letters of Fiapta ('Fiap'). This similarity is increased if the letter ('f') of Fiapta is not crossed (see below). Additionally, both names contain downstrokes of the letter 'p' and upstrokes of the letter 't'. Furthermore, the letter 't' in each name is followed by letters which may look similar when scripted (i.e., the letter 'o' of Lipitor and the letter 'a' of Fiapta). Moreover, Lipitor and Fiapta share several overlapping characteristics such as frequency of administration (once daily), usual dose (1 tablet), route of administration (orally) and strength (10 mg). These similarities can cause confusion and potentially lead to medication errors. We acknowledge that the target dose of Fiapta is 12 mg to 24 mg daily, but note that patients may be maintained on a Fiapta dose of 10 mg daily.



The image shows two lines of handwritten text in cursive. The first line reads "Lipitor 10mg" and the second line reads "Fiapta 10mg". The handwriting is fluid and somewhat slanted, with the 'L' in Lipitor and the 'F' in Fiapta being particularly prominent.



The image shows two lines of handwritten text in cursive. The first line reads "Fiapta 10mg" and the second line reads "Lipitor 10mg". The handwriting is fluid and somewhat slanted, with the 'F' in Fiapta and the 'L' in Lipitor being particularly prominent.

Additionally, three of the Fiapta strengths (2 mg, 4 mg, and 8 mg) overlap numerically with three of the Lipitor strengths (20 mg, 40 mg, and 80 mg). Thus there is the potential that prescriptions for Fiapta 2 mg, 4 mg or 8 mg may be interpreted as an order for Lipitor 20 mg, 40 mg or 80 mg, respectively, especially if a trailing zero is used in the Fiapta product strength and the decimal point is not apparent.

Thus, the Division of Medication Error and Prevention believes the potential for confusion between Lipitor and Fiapta is likely given the orthographic similarities and overlapping product characteristics such as product strength, usual dose, route of administration, and the frequency of administration. We believe this to be especially true when Fiapta first enters the marketplace and there is a knowledge deficit among practitioners regarding the existence of Fiapta. Therefore, the Division of Medication Error and Prevention does not recommend the use of the proprietary name Fiapta.

2 Independent Name Analysis

The sponsor commissioned \_\_\_\_\_ the marketing research subsidiary of \_\_\_\_\_  
\_\_\_\_\_ to conduct a name assessment for the proposed name, Fiapta \_\_\_\_\_ concluded  
that Fiapta is an acceptable proprietary name for the proposed drug product.

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The analysis conducted by \_\_\_\_\_ identified the names Viagra, Evista, Feiba VH and Kiacta  
as potential sound or look-alike products. Both \_\_\_\_\_ and the Medication Error Prevention  
Staff identified the name, Viagra. Following analysis of these names, we concur with \_\_\_\_\_  
that Viagra, Evista, Feiba VH and Kiacta do not pose a significant safety risk. However, we  
do not concur with \_\_\_\_\_'s overall conclusion that Fiapta is an acceptable proprietary name  
for this proposed drug product.

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In summary, as noted in Section II C the FMEA determined the proprietary name Lipitor could cause  
confusion with Fiapta in the usual practice setting. Therefore, based on our postmarketing experience  
and analysis of error we believe Lipitor and Fiapta would pose a potential safety risk.

**III. COMMENTS TO THE SPONSOR**

The Division of Medication Error Prevention does not recommend the use of the proprietary name  
Fiapta because it possesses strong orthographic similarities to Lipitor. The visual similarity makes it  
difficult to differentiate the two names when scripted, thereby increasing the risk for confusion between  
the two names which can lead to medication errors (see comments below for full discussion).

Fiapta and Lipitor cannot safely co-exist in the market because of look alike similarity between these  
two names. Lipitor (atorvastatin) is a selective, competitive HMG-CoA reductase inhibitor used to  
lower cholesterol and triglycerides in patients with hypercholesterolemia and mixed dyslipidemia. The  
recommended dose is 10 to 80 mg once daily.

The beginning and ending of each name look similar. The first three letters of Lipitor ('Lip') may look  
similar to the first four letters of Fiapta ('Fiap'). This similarity is increased if the letter ('f') of Fiapta is  
not crossed (see below). Additionally, both names contain downstrokes of the letter 'p' and upstrokes of  
the letter 't'. Furthermore, the letter 't' in each name is followed by letters which may look similar when  
scripted (i.e., the letter 'o' of Lipitor and the letter 'a' of Fiapta). Moreover, Lipitor and Fiapta share  
several overlapping characteristics such as frequency of administration (once daily), usual dose (1  
tablet), route of administration (orally) and strength (10 mg). These similarities can cause confusion and  
potentially lead to medication errors. We acknowledge that the target dose of Fiapta is 12 mg to 24 mg  
daily, but note that patients may be maintained on a Fiapta dose of 10 mg daily.

*Lipitor 10mg*  
*Fiapta 10mg*

*Fiapta 10mg*  
*Lipitor 10mg*

Additionally, three of the Fiapta strengths (2 mg, 4 mg, and 8 mg) overlap numerically with three of the Lipitor strengths (20 mg, 40 mg, and 80 mg). Thus there is the potential that prescriptions for Fiapta 2 mg, 4 mg or 8 mg may be interpreted as an order for Lipitor 20 mg, 40 mg or 80 mg, respectively, especially if a trailing zero is used in the Fiapta product strength and the decimal point is not apparent.

Thus, the Division of Medication Error and Prevention believes the potential for confusion between Lipitor and Fiapta is likely given the orthographic similarities and overlapping product characteristics such as product strength, usual dose, route of administration, and the frequency of administration. We believe this to be especially true when Fiapta first enters the marketplace and there is a knowledge deficit among practitioners regarding the existence of Fiapta. Therefore, the Division of Medication Error and Prevention does not recommend the use of the proprietary name Fiapta.

**APPEARS THIS WAY ON ORIGINAL**

**Appendix A: Prescription Study Results for Fiapta**

<b>Inpatient</b>	<b>Outpatient</b>	<b>Voice</b>
Fioptor	Fiapta	Fiapta
Fiaptin	Fiapta	Fiapta
FIAPTA	Fiapta	Fiacta
Fioptor	Fiapta	Fiacta
Fiopta	Fiapta	Fiapta
Hakta	Fiapta	Fiacta
Fiopton	Fiapta	Fiapta
Fropta	Fiapta	Fiapta
Fioptin	Fiapta	
Tiopta	Fiapta	
Frapta	Fiapta	
Fiafeta	Tiapta	
Fioptor	Fiapta	
Fioptin		

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