

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

207793Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW MEMORANDUM

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

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

Date of This Review:	October 20, 2015
Application Type and Number:	NDA 207793
Product Name and Strength:	Onivyde (irinotecan liposome injection), 4.3 mg/mL
Total Product Strength:	43 mg/10 mL
Applicant/Sponsor Name:	Merrimack Pharmaceuticals, Inc.
Submission Date:	October 19, 2015
Panorama #:	2015-329269
DMEPA Primary Reviewer:	Otto L. Townsend, Pharm. D.
DMEPA Deputy Division Director:	Lubna Merchant, M.S., Pharm. D.

1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Onivyde, which was previously found acceptable in OSE Review #2013-1883, dated August 8, 2013 under IND 102799¹; and in OSE Review #2015-329269, dated July 17, 2015 under NDA 207793.² We note that there is a change in the strength (from 50 mg/10 mL [5 mg/mL] to 43 mg/10 mL [4.3 mg/mL]) and usual dosage (from 80 mg/m² to 70 mg/m²) since our last review. The change in strength and dose were made to comply with the USP salt policy (i.e., presentation of established name as active moiety). All other product characteristics remain the same.

2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, DMEPA conducted a gap analysis and searched the POCA database to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review #2015-329269. Additionally, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. We also evaluated previously identified names taking into account the change in strength and dose. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, our POCA search did not identify any new names that represent a potential source of drug name confusion. As a result, we maintain that the name is acceptable.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The October 20, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

DMEPA maintains the proposed proprietary name, Onivyde, is acceptable from both a promotional and safety perspective under NDA 207793.

If you have further questions or need clarifications, please contact Latonia Ford, OSE Project Manager, at 301-796-4901.

¹ Abdus-Samad, J. Proprietary Name Review for Onivyde (irinotecan sucrosfate liposome) IND 102799. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2014 JAN 16. RCM No.: 2013-1883.

² Townsend, O. Proprietary Name Review Memo for Onivyde (NDA 207793). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 JUL 17. 24 p. OSE RCM No.: 2015-329269.

4 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your October 19, 2015 submission are altered, the name must be resubmitted for review.

REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

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

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

/s/

OTTO L TOWNSEND
10/20/2015

LUBNA A MERCHANT
10/20/2015

PROPRIETARY NAME REVIEW

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

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Date of This Review:	July 17, 2015
Application Type and Number:	NDA 207793
Product Name and Strength:	Onivyde (irinotecan liposome injection), 50 mg/10 mL (5 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Merrimack Pharmaceuticals, Inc.
Panorama #:	2015-329269
DMEPA Primary Reviewer:	Otto L. Townsend, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Onivyde under IND 102799 on August 8, 2013¹. Additionally, on August 19, 2013, Merrimack Pharmaceuticals, Inc. submitted a request for feedback on the appropriate established name for Irinotecan [REDACTED]^{(b) (4)} Liposome Injection under United States Pharmacopeia (USP) Salt Policy as described in MAPP 5021.1.² DMEPA did not identify any safety reasons that would allow for an exception to the USP Salt Policy (OSE Review 2013-2017, dated September 18, 2013). At that time, the established name of the proposed product was irinotecan [REDACTED]^{(b) (4)} liposome.

The Applicant submitted the name, Onivyde, for review as part of the NDA for review on May 4, 2015. The established name of the proposed product is irinotecan liposome injection.

¹ Abdus-Samad, J. Proprietary Name Review for Onivyde (irinotecan sucrosfate liposome) IND 102799. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2014 JAN 16. RCM No.: 2013-1883.

² Townsend, O. USP Salt Policy Exception Policy Memorandum for MM-398 (irinotecan liposome) IND 102799. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2013 SEP 18. RCM No.: 2013-2017.

1.2 PRODUCT INFORMATION

The following product information is provided in the May 4, 2015 proprietary name submission and the May 14, 2015 amended proprietary name submission.

<i>Intended Pronunciation</i>	ON-ih-vide
<i>Active Ingredient</i>	irinotecan liposome injection
<i>Indication of Use</i>	Treatment of metastatic adenocarcinoma of the pancreas, in combination with 5- fluorouracil and leucovorin, in patients who have been previously treated with gemcitabine.
<i>Route of Administration</i>	intravenous infusion
<i>Dosage Form</i>	Injection
<i>Strength</i>	50 mg/10 mL (5 mg/mL)
<i>Dose and Frequency</i>	The usual dosage for this product is 80 mg/m ² . The frequency of administration is every 2 weeks in combination with 5-fluorouracil and leucovorin (5-FU/LV). The maximum daily dose is administered over 90 minutes.
<i>How Supplied</i>	10 mL single use vial
<i>Storage</i>	Refrigerated at 2°C to 8°C in the original package to protect from light; do not freeze.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Oncology Products 2 (DOP2) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name³.

³USAN stem search conducted on May 18, 2015.

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Onivyde in their submission. This proprietary name is comprised of a single word that does not contain any component, such as a modifier, route of administration, or dosage form, that is misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Due to technical difficulties, we had to perform a second round of name simulation studies. Prior to disregarding the first set of results, we reviewed the results for any names of concern. Upon review, we noted one respondent interpreted the name, Onivyde, as Omnizole. Since Omnizole is the name of a currently marketed product, we further evaluated this name. Omnizole is a veterinary product. It is an anthelmintic given as a drench or paste to cattle, goats, and sheep for the treatment of intestinal worms and other parasites. These differences in product characteristics are sufficient to address the risk of name confusion between Onivyde and Omnizole.

Seventy-seven practitioners participated in the second round of name simulation studies. Two of the responses had the potential for name confusion with the proposed proprietary name, Onivyde. One respondent from the inpatient medication simulation study interpreted the name, Onivyde, as Amivyd and one respondent in the outpatient simulation study interpreted it as Amivyde. Neither name is a proprietary name of a currently marketed product; however, a similar name, Amyvid, is the proprietary name of a currently marketed product. POCA Scores for the name pair (Onivyde and Amyvid) are as follows: Phonetic 69%, Combined 50%, and Orthographic 30%. However, the orthographic similarity between the name pair increases when the letters ‘y’ and ‘i’ are transposed in writing or typing (Onivyde vs. Onyvide and Amyvid vs. Amivyd).

Amyvid is a radioactive diagnostic agent for PET imaging of the brain. Amyvid has the following restrictions:

- Storage in the original container or an equivalent radiation shielding.
- Preparation by properly licensed nuclear pharmacies.
- Use only by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radioactive materials.
- Prescribed in terms of 370 MBq (10 mCi) (vs. mg/m² with Onivyde).

In addition, Amyvid is restricted to diagnosis of cognitive impairment compared to Onivyde that is indicated in the treatment of pancreatic cancer in combination with 5-fluorouracil and leucovorin.

The restrictions and special conditions associated with both products are sufficient to address the risk of name confusion between Onivyde and Amyvid.

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

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 15, 2015 e-mail, DOP2 did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 50\%$ retrieved from our POCA search⁴ organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation Studies and by (b) (4)

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	80
Low similarity name pair: combined match percentage score $\leq 49\%$	10

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

Our analysis of the 91 names contained in Table 1 determined none of the names would pose a risk for confusion as described in Appendices C through H.

2.2.6 *Communication of DMEPA's Analysis at Midpoint of Review*

DMEPA communicated our findings to DOP2 via e-mail on June 24, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DOP1 on June 29, 2015, they stated no additional concerns with the proposed proprietary name, Onivyde.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your May 4, 2015 and May 14, 2015 submissions are altered prior to approval of the marketing application, the name must be resubmitted for review.

⁴ POCA search conducted on May 20, 2015.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present.

Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.⁵

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

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

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

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

- Highly similar pair: combined match percentage score $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 49\%$.

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

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

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

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

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

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

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

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

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

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

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

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

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

<p>Step 1</p>	<p>Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> ○ Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. ○ Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. ○ Similar sounding doses: 15 mg is similar in sound to 50 mg
<p>Step 2</p>	<p>Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</p>

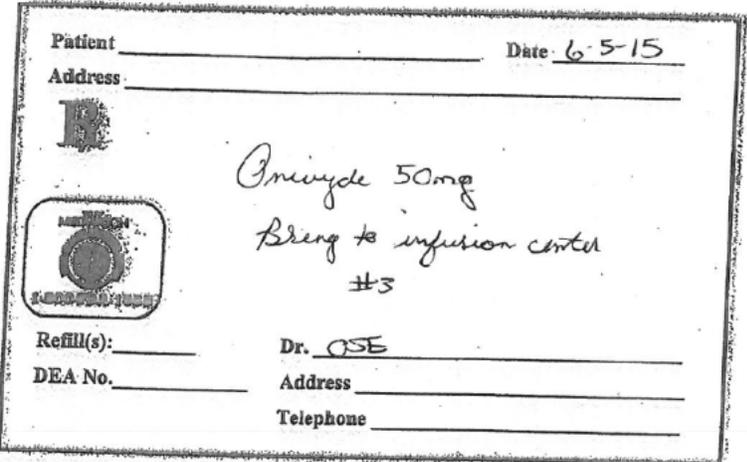
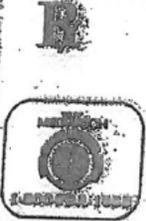
<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none">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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Onivyde Study (Conducted on June 5, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Onivyde 80mg/m² IV today</i></p>	<p>Onivyde 50 mg. Bring to infusion center. Dispense 3 vials.</p>
<p><u>Outpatient Prescription:</u></p>  <p>Patient _____ Date <u>6-5-15</u> Address _____  <i>Onivyde 50mg</i> <i>Bring to infusion center</i> <i>#3</i> Refill(s): _____ Dr. <u>OSE</u> DEA No. _____ Address _____ Telephone _____</p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Onivyde

As of Date 6/19/2015

245 People Received Study
77 People Responded

Study Name: Onivyde

Total	25	28	24	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
AMIEYDI	0	0	1	1
AMIVYD	0	0	1	1
AMIVYDE	1	0	0	1
AMIVYDI	0	0	2	2
ANEBIDE	0	1	0	1
ANIUYDE	0	0	1	1
ANIVYDE	0	0	2	2
ANIVYDO	0	0	1	1
OMICYD	0	0	1	1
OMICYDE	0	0	1	1
OMIVYDE	0	0	2	2
OMIVYDI	0	0	1	1
OMNIVYDE	0	0	1	1
ONAVEID	0	1	0	1
ONAVIDE	0	9	0	9
ONERIYDE	0	0	1	1
ONEVID	0	1	0	1
ONICYCLE	0	0	1	1
ONIUYDI	0	0	1	1
ONIVDA	1	0	0	1
ONIVIDE	0	10	0	10
ONIVIDE 50 MG	0	1	0	1
ONIVITE	0	1	0	1
ONIVYDA	0	0	1	1
ONIVYDE	19	0	1	20
ONIVYDI	0	0	4	4
ONIVYDO	0	0	1	1

ONNIVIDE	0	1	0	1
ONOVIDE	0	1	0	1
ONYVIDE	1	0	0	1
ORNAVITE	0	1	0	1
PNIVYDE	1	0	0	1
PRIVYDE	2	0	0	2
VONIVIDE	0	1	0	1

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

No.	<p>Proposed name: Onivyde (irinotecan liposome injection) Strength: 50 mg/10 mL (5 mg/mL) Usual Dose: The usual dosage for this product is 80 mg/m². The frequency of administration is every 2 weeks in combination with 5-fluorouracil and leucovorin (5-FU/LV). The maximum daily dose is administered over 90 minutes.</p>	POCA Score (%)	<p>Orthographic and/or phonetic differences in the names sufficient to prevent confusion</p> <p>Other prevention of failure mode expected to minimize the risk of confusion between these two names.</p>
1.	ONIVYDE***	100	Name is subject of this review.

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

No.	Name	POCA Score (%)
1.	BONIVA	50
2.	ENOVID	59
3.	ENOVID-E	62
4.	ENOVID-E 21	62
5.	FORMALYDE-10	52
6.	LONITEN	53
7.	MINIVELLE	54
8.	NONIVAMIDE	54
9.	OBEZINE	53
10.	OMNI GEL	50
11.	OMNICIDE	60
12.	OMNI-MED	57
13.	OMNIPEN	54
14.	OMNIPRED	50
15.	ONGLYZA	50
16.	ONZETRA***	53
17.	OPTIMYD	54
18.	ORBIVAN	51

No.	Name	POCA Score (%)
19.	OTIC EDGE	53
20.	OTI-MED	51
21.	OTI-SONE	51
22.	OVIDE	50
23.	UNIVASC	50

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

No.	<p>Proposed name: Onivyde (irinotecan liposome injection)</p> <p>Strength: 50 mg/10 mL (5 mg/mL)</p> <p>Usual Dose: The usual dosage for this product is 80 mg/m². The frequency of administration is every 2 weeks in combination with 5-fluorouracil and leucovorin (5-FU/LV). The maximum daily dose is administered over 90 minutes.</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
1.	AMYVID	50	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>It is unlikely Onivyde, an intravenous oncology drug, or Amyvid, a radiopharmaceutical drug, will be prescribed verbally.</p> <p>We also considered the potential transposition of the letters “i” and “y” in the proposed name: Onyvide (instead of Onivyde) as compared to Amyvid, which increases the orthographic similarity between the name pair. However, Amyvid, a radiopharmaceutical, has a restrictive distribution channel and special preparation system compared to Onivyde. The restrictions and special conditions associated with both products are sufficient to address the risk of name confusion between Onivyde and Amyvid.</p>
2.	OMNICEF	52	<p>The suffixes of this name pair have sufficient orthographic differences.</p> <p>The third syllables of this name pair sound different.</p>
3.	OMNIPEN-N	52	<p>The suffixes of this name pair have sufficient orthographic differences.</p> <p>The third syllables of this name pair sound different.</p>
4.	ONCOVIN	54	<p>The suffixes of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different.</p>

No.	<p>Proposed name: Onivyde (irinotecan liposome injection)</p> <p>Strength: 50 mg/10 mL (5 mg/mL)</p> <p>Usual Dose: The usual dosage for this product is 80 mg/m². The frequency of administration is every 2 weeks in combination with 5-fluorouracil and leucovorin (5-FU/LV). The maximum daily dose is administered over 90 minutes.</p>	POCA Score (%)	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
5.	(b) (4) ***	51	The suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
6.	ORNIDYL	52	The suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.

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

No.	Name	POCA Score (%)
1.	Dyazide	39
2.	Glipizide	32
3.	Glyburide	24
4.	Octreotide	32
5.	Ocuvite	49
6.	Omeprazole	34
7.	Omnaris	38
8.	Onfi	40
9.	Ovidrel	44
10.	Pomalidomide	33

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4)***	64	Proposed proprietary name found conditionally acceptable by DMEPA (OSE# 2007-240 and 2008-1817). The Applicant withdrew the application (NDA (b) (4)) effective, 01/26/2010.
2.	(b) (4)***	60	Proposed proprietary name found unacceptable by DMEPA (OSE# 2011-1379). Product approved under new proprietary name Pomalyst.
3.	(b) (4)***	52	This is a secondary proposed proprietary name and the product was approved under proprietary name Pomalyst.
4.	OLIVINE	52	Product is not a drug. Product is a mineral and a mineral group.
5.	OMNIZOLE	51	Veterinary Product
6.	ORNACYN	50	Veterinary Product
7.	ORNADE	58	Brand discontinued with no generic available. NDA 012152 withdrawn FR Effective 02/20/2014. Product was formulated with chlorpheniramine maleate and phenylpropanolamine hydrochloride. Phenylpropanolamine is not generally recognized as safe and effective and all products were to be withdrawn from the market.
8.	ORINDYL	52	Name identified by (b) (4) but unable to find product characteristics in commonly used drug databases. POCA score is the same as Ornidyl. It's possible the name was misspelled in their report.
9.	OTRIVIN	51	Brand discontinued with no generic available. NDA 011919 withdrawn. FR Effective 09/25/1997.
10.	OTRIVINE	50	International proprietary name marketed in several countries.
11.	UNIVER	54	International product marketed in the United Kingdom.
12.	UNIVERT	57	Name identified in RxNorm database. Product characteristics found in Redbook, but product is no longer marketed and no generic alternatives are available.

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

No.	Name	POCA Score (%)
1.	ANISATE	54
2.	BANADYNE	54
3.	BILYTE	52
4.	BREFYTE	50
5.	DIALYTE	51
6.	DIVITAZ	50
7.	DONNAZYME	60
8.	ENSKYCE	50
9.	ERIVEDGE	50
10.	EUMOVATE	52
11.	EVADYNE	50
12.	FONAZINE	50
13.	INFALYTE	50
14.	INNOVACE	51
15.	INOVEN	51
16.	JOLIVETTE	50
17.	LUMIZYME	58
18.	MEDI-LYTE	50
19.	MINIDYNE	60
20.	MINIZIDE	52
21.	MONOCID	50
22.	MYOZYME	52
23.	NAVANE	53
24.	NAVSTEL	50
25.	NIRDEX	50
26.	RON ACID	52
27.	SONAZINE	50
28.	UNI SALVE	52
29.	UNI-CENNA	57
30.	UNIDAB	52
31.	UNIFED	58
32.	UNI-FED	58
33.	UNIFIBER	54
34.	UNI-LEV 5.0	50
35.	UNIPEN	51
36.	UNIPHYL	50
37.	UNI-SED	56
38.	ZENAVOD	52
39.	ZONTIVITY	51

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/s/

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