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RESEARCH**

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PROPRIETARY NAME REVIEW(S)



Department of Health and Human Services
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Subject: Proprietary Name, Label, and Labeling Review for Vimpat

Drug Name(s): Vimpat (Lacosamide) Tablets, Oral Syrup, and Injection

Application Type/Number: NDA 22-253, NDA 22-254, NDA 22-255, (b) (4)

Applicant: Schwarz Biosciences, Inc.

OSE RCM #: 2007-1610

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EXECUTIVE SUMMARY

The Proprietary Name Risk Assessment found that the proposed name, Vimpat, has some similarity to other proprietary and established drug names, but the Failure Modes and Effects Analysis (FMEA) findings indicate that the proposed name does not appear to be vulnerable to 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. Thus, the Division of Medication Error Prevention does not object to the use of the proprietary name, Vimpat, for this product.

The results of the Label and Labeling Risk Assessment found that the presentation of information and design of the proposed insert labeling and measuring devices appear to be vulnerable to confusion that could lead to medication errors. We believe the risks we have identified can be addressed and mitigated prior to drug approval, and provides recommendations in Section 5.2 that aim at reducing the risk of medication errors.

However; if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, we rescind this Risk Assessment finding, and recommends that the name be resubmitted for review. Additionally, if the product approval is delayed beyond 90 day from the date of this review, the proposed name must be resubmitted for evaluation.

1 BACKGROUND

1.1 INTRODUCTION

This consult was written in response to a request from the Division of Neurology to evaluate the proprietary name, insert labeling, and measuring device of Vimpat for its potential to contribute to medication errors. The proposed proprietary name, Vimpat, was evaluated to determine if the name could be potentially confused with other proprietary or established drug names. A forthcoming review (OSE Review #2008-633) will assess the container labels and carton labeling.

1.2 PRODUCT INFORMATION

Vimpat (Lacosamide) is a new molecular entity indicated for partial-onset seizures as adjunctive therapy in patients aged (b) (4) years and older. (b) (4)

The recommended dose for partial onset seizures is 100 mg per day twice daily initially, then increased to 200 mg per day to 400 mg per day. (b) (4)

The dose can be increased at weekly intervals by increments of 100 mg per day based on clinical response and tolerability. The maximum daily dosage of Vimpat is (b) (4) per day. When switching from oral to intravenous dose, the initial total daily intravenous dosage should equal the oral total daily dosage and frequency. The parenteral formulation of Vimpat can be administered without further dilution or may be mixed in a compatible diluent and should be administered intravenously over (b) (4). Vimpat will be available in 50 mg, 100 mg, 150 mg, 200 mg, (b) (4) oral syrup, and 10 mg/mL solution for injection.

(b) (4). For partial seizure indication, tablets, oral syrup and injectables are indicated.

2 METHODS AND MATERIALS

This section consists of two sections which describe 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) and labeling, and/or packaging risk assessment (see 2.2 Insert Label Risk Assessment). The primary focus for both of the assessments 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.¹

2.1 PROPRIETARY NAME RISK ASSESSMENT

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name, Vimpat, 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, Vimpat, the Division of 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.² 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. We use the clinical expertise of the Medication Error Prevention 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 entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.³

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

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

³ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

2.1.1 Search Criteria

The Medication Error Prevention 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 ‘V’ 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.⁴⁵

To identify drug names that may look similar to Vimpat, 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 (2, capital letter ‘V’ and lower case letter ‘t’), downstroke (lower case letter ‘p’), cross-strokes (lower case letter ‘t’), and dotted letters (one, lower case letter ‘i’). Additionally, several letters in Vimpat may be vulnerable to ambiguity when scripted, including the letter ‘V’ may appear as ‘Y,’ ‘U,’ or ‘L’; and a lower case ‘v’ appear as a lower case ‘r,’ ‘u,’ or ‘x’. As such, the Staff also consider these alternate appearances when identifying drug names that may look similar to Vimpat.

When searching to identify potential names that may look or sound similar to Vimpat, the Medication Error Prevention Staff search for names with similar number of syllables (2), and placement of vowel and consonant sounds. The Applicant’s intended pronunciation of the proprietary name (VIM-pat) was also taken into consideration.

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 Prevention Staff were provided with the following information about the proposed product: the proposed proprietary name (Vimpat), the established name (Lacosamide), proposed indications (partial onset seizures (b) (4)), strength (50 mg, 100 mg, 150 mg, 200 mg, (b) (4)), oral syrup; 10 mg/mL solution for injection), dose (200 mg/day to 400 mg/day for partial onset seizures, (b) (4)), frequency of administration (twice a day), route (oral and intravenous) and dosage form of the product (tablet, oral syrup, and injection). Appendix A provides a more detailed listing of the product characteristics the Medication Error Prevention Staff general take into consideration.

Lastly, the Medication Error Prevention 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 Prevention Staff provide 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, Vimpat, was provided to the Division of Medication Error Prevention staff to conduct a search of the internet, several standard published drug product reference texts, and FDA

⁴ Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

⁵ Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

databases to identify existing and proposed drug names that may sound-alike or look-alike to Vimpat, using the criteria outlined in 2.1.1. A standard description of the databases used in the searches is provided in Section 7. To complement the process, the Medication Error Prevention 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 Prevention Staff review 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 the Division of Medication Error Prevention to gather CDER professional opinions on the safety of the product and the proprietary name, Vimpat. Potential concerns regarding drug marketing and promotion related to the proposed names are also discussed. This group is composed of The Division of Medication Error Prevention Staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC).

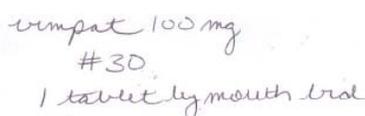
The pooled results of the Medication Error Prevention staff were presented to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of names, additional searches by the Safety Evaluator to supplement the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

2.1.2 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 Vimpat 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 Vimpat 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 Division of Medication Error Prevention staff.

Figure 1. Vimpat Study (conducted on August 10, 2007)

HANDWRITTEN PRESCRIPITON AND MEDICATION ORDER	VERBAL PRESCRIPTION
<p><u>Outpatient Prescription:</u></p> 	<p>Vimpat 100mg #30 Take one tablet by mouth twice a day</p>

Inpatient Medication Order :	
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<u>Vimpat 1190mg T tablet by mouth BID</u>	
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2.1.3 External Proprietary Name Risk Assessment

For this product, the Applicant submitted two independent risk assessments of the proposed proprietary name conducted by (b) (4) and Drug Safety Institute. We conduct 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 Prevention 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.

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, we provide a detailed explanation of these differences.

2.1.4 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.⁶ When applying FMEA to assess the risk of a proposed proprietary name, we seek 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 Vimpat, 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 Vimpat 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.

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

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.

We 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. The Division of Medication Error Prevention 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. The Division of Medication Error Prevention 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 IOM, WHO, JCAHO, and ISMP, 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, we contend 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 section 4: "Discussion" for 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. We are likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for us 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 we may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error would render the proposed name acceptable.

2.2 LABEL AND LABELING RISK ASSESSMENT

The label and labeling of a drug product are the primary means by which practitioners and patients (depending on configuration) interact with the pharmaceutical product. The container labels and carton labeling communicate critical information including proprietary and established name, strength, form, container quantity, expiration, and so on. The insert labeling is intended to communicate to practitioners all information relevant to the approved uses of the drug, including the correct dosing and administration.

Given the critical role that the label and labeling has in the safe use of drug products, it is not surprising that 33 percent of medication errors reported to the USP-ISMP Medication Error Reporting Program may be attributed to the packaging and labeling of drug products, including 30 percent of fatal errors.⁷

Because our staff analyze reported misuse of drugs, our staff are able to use this experience to identify potential errors with all medication similarly packaged, labeled or prescribed. We use FMEA and the principles of human factors to identify potential sources of error with the proposed product labels and insert labeling, and provided recommendations that aim at reducing the risk of medication errors.

For this product the Applicant submitted on September 28, 2007 the following labeling and measuring device for our review (see Appendix E for images):

- Measuring devices:  (b) (4)
- Prescribing Information (no image)
- Patient Information (no image)
- Sample measuring devices (no image)

A forthcoming review (OSE Review #2008-633) will assess the container labels and carton labeling for Vimpat tablets, oral syrup and injectable.

⁷ Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006. p275.

3 RESULTS

3.1 PROPRIETARY NAME RISK ASSESSMENT

3.1.1 Data base and information sources

We conducted a search of the internet, several standard published databases and information sources (see Section 7 References) for existing drug names which sound-alike or look-alike to Vimpat to a degree where potential confusion between drug names could occur and result in medication errors in the usual clinical practice settings. In total, seven names were identified as having some similarity to the name Vimpat.

Four of the seven names were thought to look like Vimpat, which include: Vimar, Campath, Simplet, and Semprex-D. Fempatch was thought to sound like Vimpat and two names, (b) (4) and Impact, were thought to look and sound similar to Vimpat. No USAN stems are present within the proposed name.

3.1.2 Expert panel discussion

The Expert Panel also noted that despite orthographic similarity of the letter 'V' with the letters 'Z', 'N', 'L', and 'R' in some handwriting samples, no names beginning with those letters were included in the pool. The Expert Panel recommended that independent searches consider the potential for confusion with drug names beginning with these letters.

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 30 practitioners responded, but none of the responses overlapped with any existing or proposed drug names. About 60% of the participants (n=18) interpreted the name correctly as "Vimpat," with correct interpretation occurring more frequently in the written studies. The remainder of the responses misinterpreted the drug name. Four respondents in the verbal prescription study each misinterpreted Vimpat as Zymtec, Zimpack, Zynpak, and Zin Pac. In the written prescription studies, the letter 'a' was misinterpreted as an 'i' by another respondent. The ending '-at' was misinterpreted as '-art' by five respondents and '-ert' by one respondent. See Appendix B for the complete listing of interpretations from the verbal and written prescription studies.

3.1.4 External Name studies

In the two proposed name risk assessments submitted by the Applicant, the (b) (4) study identified and evaluated a total of 8 drug names thought to have some potential for confusion with the name Vimpat, and the Drug Safety Institute identified and evaluated a total of 28 names thought to have some potential for confusion with the name Vimpat. However, both studies identified the names Viracept and Viroptic in their results, therefore the total number of names from both studies excluding duplications is 34.

Thirty of the total 34 names were not previously identified in our searches, the Expert Panel Discussion, or FDA prescription studies. Five names (vinblastine, Z-pack, enalapril, Actiq, and Symbyax) were thought by practitioners to sound similar to Vimpat. Three names (Viroptic, Zovirax, and ramipril) were thought by practitioners to look similar to Vimpat. Two names (Viracept and vincristine) were thought by practitioners to look and sound similar to Vimpat. The remaining 20 names were identified by the

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

DSI's Expert Panel or their Computerized Orthographic and Phonetic Analyiss (COPA) as having some similarity (phonetic or orthographic) to Vimpat: Viread, Zymar, Compat, Vamate, Viaspan, Vi-atro, Vibal, Vicam, Vinate 90, Vinate-M, Vioday, Virac, Viscoat, (b) (4) Vitapap, Vitaped, Vitara, Vitrax and Vi-zac.

3.1.5 Safety evaluator risk assessment

In the independent searches by the primary Safety Evaluator, careful evaluation was afforded to drug names beginning with the letters 'Z', 'N', 'L', and 'R' in accordance with the Expert Panel's recommendations, but no additional drug names beginning with these letters were thought to have the potential for confusion with Vimpat. As such, a total of 37 names were analyzed to determine if the drug names could be confused with Vimpat 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 Vimpat, and thus determined to present some risk for confusion. Failure modes and effects analysis (FMEA) was then applied to determine if the proposed name, Vimpat, could potentially be confused with any of the 37 names and lead to medication error.

This analysis determined that the name similarity between Vimpat and the identified names was unlikely to result in medication errors. (b) (4)

For 31 of the names identified, FMEA determined that medication errors were unlikely because the products do not overlap in strength or dosage with Vimpat and have minimal orthographic and/or visual similarity to Vimpat (Appendix C). Five names (Viracept, Z-Pak, Zovirax, Viread, and Vamate) had some overlap with Vimpat in either dosage or strength, but 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 D).

3.2 LABELING AND MEASURING DEVICE RISK ASSESSMENT

A review of the insert labeling and measuring device identified several potential sources of medication error, specifically with respect to the number of different dosage forms available, presentation of oral syrup concentration, and measuring device issues.

The injectable concentration is not consistently presented as total drug content (200 mg/20 mL) followed by the concentration (10 mg/mL) throughout the labeling.

The precautionary statement for Phenylketonurics in the labeling states (b) (4)

There will be three dosage forms of Vimpat available, but not all can be used for all the proposed indications of use. Also, it is unclear if the dosing conversion from one dosage form to another is equivalent. The dosing instructions in the insert labeling for switching from oral dosing to intravenous administration and vice versa is unclear and confusing (i.e. unclear frequency of administration).

(b) (4) Additionally, there are no instructions for dosing the oral syrup (e.g. converting mg dosing to mL) in the insert labeling. The clear embossed demarcations on the measuring devices are

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

also difficult to read. Furthermore, the devices are not attached to the container bottle and do not have any product identifiers on it.

4 DISCUSSION

4.1 PROPRIETARY NAME

The results of the Proprietary Name Risk Assessment found that the proposed name, Vimpat, has some similarity to other proprietary and established drug names, but the findings of the FMEA indicates that the proposed name does not appear to be vulnerable to 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. Thus, the Division of Medication Error Prevention has no objections to the use of the proprietary name, Vimpat for this product.

4.2 LABELING AND MEASURING DEVICE RISK ASSESSMENT

The results of the Label and Labeling Risk Assessment found that the presentation of information and design of the proposed insert labeling and (b) (4) appears to be vulnerable to confusion that could lead to medication errors.

4.2.1 *Insert Labeling*

We noted the presentation of injectable strength does not follow the USP standard of total drug content (200 mg/20 mL) followed by the concentration (10 mg/mL) throughout the labels and labeling.

We also noted the precautionary statement for Phenylketonurics (b) (4) is misleading (b) (4)

4.2.2 *Multiple Dosage Forms*

We are also concerned with the availability of three dosage forms that do not have the same indications of use. This may lead to errors if prescribers do not indicate the dosage form on orders for Vimpat.

Typically, products are used for the same indications of use regardless of dosage form. (b) (4) there is a risk of the wrong dosage form (oral syrup and injectable) being prescribed for this indication, or being substituted if a patient can't swallow a tablet. It will be difficult to convey that the indication of use is tied to the route of administration.

In review of the dosing instructions in the insert labeling, we noted there is no clear explanation of how to switch from oral dosing to intravenous administration and vice versa. It is unclear if the frequency of administration should be once daily or twice daily and which frequency of administration should be used when switching back to oral dosing.

4.2.3 *Oral Syrup Measuring Device*

The proposed presentation of oral syrup concentration is designated in mg/mL (b) (4) but we noted the measuring device is demarcated in terms of 'mg.' Most oral liquids are prescribed in terms of 'mL' not 'mg'. Postmarketing experience has shown numerous errors that occur when the measuring device is demarcated in 'mg' instead of the usual 'mL.' Typically, oral liquids are ordered in teaspoonful or milliliter unit. The (b) (4) 'mg' increases risk for confusion due to the conflict in units of measure. Additionally, prescribers do not order the oral liquid products in a consistent measuring unit (e.g. cubic centimeters, mg, mL, or teaspoonful). This can lead to errors during prescribing, dispensing and administration of the product due to misinterpretation or miscalculation of the dose. Even if the

prescriber orders the product in ‘mg,’ an error can occur if the measuring device is not dispensed with the product and the pharmacist, the nurses or the patient tries to achieve the dose by converting to ‘mL’ or teaspoonful. Conversely, if a patient is prescribed in ‘mL,’ patients would have to calculate that this volume equals the correct mg dose. Additionally, the lack of dosing conversion in the insert labeling further increases the risk of dosing errors that may arise as a result of miscalculation.

(b) (4)

(b) (4) we are concerned that the higher doses (greater than 150 mg) cannot be accurately measured in one dose (b) (4) and the smaller doses (less or equal to 50 mg) cannot be measured accurately (b) (4) for each container since this increases the risk of confusion.

(b) (4)

. The measuring device should also have a product specific identifier and be attached to the container bottle since these devices should not be used with any other products. When unattached to the product, the device can get lost or confused with other measuring devices owned by patients.

The oral syrup will be available in the bottle sizes of (b) (4) 465 mL and we question if the sizes are appropriate to the dosing and whether these bottles will be dispensed as unit-of-use. If the measuring device is attached to the bottle but the whole bottle is not dispensed to patients, there is a risk of inaccurate dosing since patients will not receive the product specific measuring device.

Finally, we note that the oral syrup concentration (b) (4) does not convert to whole milliliter units for usual recommended doses which increases the risk of over- or under-dosing (see table below). We recognize that in order for it to be dosed in whole number milliliter units, it would require reformulating the concentration of the product. We believe reformulation warrants consideration since the current proposed concentration will likely result in dosing errors due to difficulty in converting to ‘mL’ and measuring the dosage accurately. Another option is to consider an alternate measuring device (b) (4) (b) (4) (e.g. oral syringe) that will measure the doses more accurately. However, since this device will have measurements specific to Vimpat dosing, the Applicant must ensure that all patients have access to the dosing device and that it cannot be lost or destroyed.

Dose in mg	Dose in mL
50 mg	3.33 mL
100 mg	6.66 mL
200 mg	13.33 mL

(b) (4)

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Vimpat, does not appear to be vulnerable to name confusion that could lead to medication errors. This finding was consistent with and supported by an independent risk assessments of the proprietary name submitted by the Applicant. As such, the Division of Medication Error Prevention does not object to the use of the proprietary name, Vimpat, for this product.

The Labeling and Measuring Device Risk Assessment findings indicate that the presentation of information and design of the proposed carton and container labels introduces vulnerability to confusion that could lead to medication errors. We believe the risks we have identified can be addressed and

mitigated prior to drug approval, and provides recommendations in Section 5.2 that aim at reducing the risk of medication errors.

5.1 COMMENTS TO THE DIVISION

The Division of Medication Error Prevention does not object to the use of the proprietary name, Vimpat, for this product. However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, we rescind this Risk Assessment finding, and recommend that the name be resubmitted for review. Additionally, if the product approval is delayed beyond 90 days from the date of this review, the proposed name must be resubmitted for evaluation.

Based upon our assessment of the proprietary name, labeling and measuring device, we have identified areas needed of improvement. We have provided recommendations in Section 5.2 and request this information be forwarded to the Applicant.

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

5.2 COMMENTS TO THE APPLICANT

The Division of Medication Error Prevention does not object to the use of the proprietary name, Vimpat, for this product.

Overall, our Risk Assessment is limited by our current understanding of medication errors and causality. The successful application of Failure Modes and Effect Analysis depends upon the learning gained from a spontaneous reporting program. It is quite possible that our understanding of medication error causality would benefit from unreported medication errors; and, that this understanding could have enabled the Staff to identify vulnerability in the proposed name, packaging, and labeling that was not identified in this assessment. To help minimize this limitation in future assessments, we encourage the Applicant to provide the Agency with medication error reports involving their marketed drug products regardless of adverse event severity.

5.2.1 *Proprietary Name*

1. If any of the proposed product characteristics as stated in this review are altered prior to approval of the product, the Division of Medication Error Prevention rescinds this Risk Assessment finding, and recommends that the name be resubmitted for review.

5.2.2 *Oral Syrup Measuring Device*

Consider an alternate measuring device that is able to measure the recommended doses safely and accurately. Areas to consider in device design include:

- Calibrations using mL rather than mg since most oral syrups are prescribed in volume ('mL' or teaspoonful) and this type of calibration is most familiar to patients and practitioners. Postmarketing experience has shown numerous errors that occur when the oral liquid measuring device is demarcated in 'mg' instead of the usual 'mL.' Additionally, we suggest that the doses be cross referenced with a corresponding mL volume in the Prescribing Information.
- One device to measure all recommended doses
- Improve the readability of the demarcations on the measuring device by using black or dark-colored ink for demarcation

- The measuring device should be attached to the drug product and there should be a product identifier so that it is not used with any products other than Vimpat.

5.2.3 *Insert Labeling*

1. Revise the presentation of the injectable strength to follow the USP standard of total drug content (200 mg/20 mL) followed by the concentration (10 mg/mL) throughout the labels and labeling. Total drug content should have greater prominence than strength.
2. Clarify whether the dosing for the three dosage forms are equivalent when switching from one to another. Additionally, clarify the dosing instructions in the insert labeling for switching from oral dosing to intravenous administration and vice versa. It is unclear if the frequency of administration should be once daily or twice daily and which frequency of administration should be used when switching to oral dosing.
3. Under the *Warnings and Precautions – Phenylketonurics* section, revise the statement (b) (4)
4. Include a dosing conversion table or instructions in the insert labeling (from ‘mg’ to ‘mL’).

5.2.4 *Oral Syrup*

1. Consider reformulating the oral syrup concentration as the current concentration does not calculate the recommended doses in whole milliliter units. We believe reformulation warrants consideration since the current proposed concentration will likely result in dosing errors due to difficulty in converting to ‘mL’ and measuring the dosage accurately.
2. Clarify whether the supply bottle sizes are appropriate for the recommended dosing and if the bottles will be dispensed as unit-of-use. If not dispensed as unit-of-use but the measuring device is attached to the bottle, there is a risk of dosing error since the patients will not receive the product specific measuring device with the drug.

6 REFERENCES

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

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, FDA.

3. ***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.

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 and Technical Support 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.

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](#) and [generic drugs](#) and [therapeutic biological products](#); [prescription](#) and [over-the-counter](#) human drugs and [therapeutic biologicals](#), [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*** (<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.

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

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

11. 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.

12. 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.

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.pharmacist.com)

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

16. Medical Abbreviations Book

Contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A:

The Division of Medication Error Prevention 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 Prevention 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 Prevention 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 Prevention Staff compare the pronunciation of the proposed proprietary name with the pronunciation of other drug names. If provided, we 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 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"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name Upstrokes Downstrokes Cross-strokes	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication

		<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"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Appendix C: Products with no overlap in strength and dose.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
Vimpat (Lacosamide)		Tablets: 50 mg, 100 mg, 150 mg, 200 mg, (b) (4) Oral syrup: (b) (4) mg/mL Injection: 10 mg/mL	Partial onset seizure: 200 mg/day to 400 mg/day (twice daily dosing); Maximum dose (b) (4) mg/day (b) (4)
Vimar (Over-the-Counter)	Look	Multivitamin combination	Information not available
Campath	Look	30 mg/mL	30 mg/day
Simplet (Acetaminophen/ Chlorpheniramine/ Pseudoephedrine) (Over-the-Counter)	Look	650 mg/4 mg/60 mg	1 tablet every 4-6 hours
Semprex-D	Look	8 mg/60 mg	1 capsule every 4-6 hours
Viroptic	Look	1%	1 drop every 2 hours
Ramipril	Look	1.25 mg, 2.5 mg, 5 mg, 10 mg	2.5 mg/day to 20 mg/day administered as a single dose or in two equally divided doses
Fempatch (Estradiol) (Discontinued)	Sound	0.025 mg/24 hours	1 patch weekly
Vinblastine	Sound	10 mg/vial; 1 mg/mL	3.7 to 7.4 mg/m ²
Enalapril	Sound	Tablets: 2.5 mg, 5 mg, 10 mg, 20 mg Injectable: 1.25 mg/mL	10 mg/day to 40 mg/day administered in a single dose or 2 divided doses
Symbyax (Fluoxetine/Olanzapine)	Sound	25 mg/3 mg; 25 mg/6 mg; 25 mg/12 mg; 50 mg/6 mg; 50 mg/12 mg	6 mg/25 mg once daily in the evening
Actiq (Fentanyl Citrate)	Sound	0.2 mg, 0.4 mg, 0.6 mg, 0.8 mg, 1.2 mg, 1.6 mg	Individualized to patient
Vincristine	Look/Sound	1 mg/mL	1.4 mg/m ²

Zymar	Look/Sound	0.3%	Days 1 and 2: Instill 1 drop in affected eye(s) every 2 hours while awake, up to 8 times/day. Days 3 through 7: Instill 1 drop up to 4 times/day while awake.
Compat	Look/Sound	Gastrostomy tube; Top fill feeding containers: 28 fr	Information not available
Viaspan	Look/Sound	Cold storage solution for organs	Detailed preparation instructions
Vi-atro (Diphenoxylate/Atropine)	Look/Sound	2.5 mg/0.025 mg	2 tablets three to four times a day
Vibal (Vitamin B12) (Discontinued)	Look/Sound	Information not found	Information not available
Vicam (Vitamin B and C)	Look/Sound	Multivitamin combination	Information not available
Vinate 90	Look/Sound	Multivitamin combination	Information not available
Vinate-M	Look/Sound	Multivitamin combination	Information not available
Vioday (Discontinued)	Look/Sound	Nutritional vitamin supplement	Information not available
Virac (Discontinued)	Look/Sound	0.5 %; 1.8%	Information not available
Viscoat (Chondroitin/Sodium Hyaluronate) (Discontinued)	Look/Sound	40 mg/30 mg per mL	Intraocular injection
(b) (4)			
Vitapap (Acetaminophen) (Over-the-Counter)	Look/Sound	500 mg	500 mg every 4-6 hours
Vitaped (Discontinued)	Look/Sound	Multivitamin combination	Information not available
Vitara (Over-the-Counter)	Look/Sound	Female sexual aid/enhancer topical gel	Information not available
Vitrax (Hyaluronate Sodium) (Discontinued)	Look/Sound	3%	Information not available

Vi-Zac (Over-the-Counter)	Look/Sound	Multivitamin combination	Information not available
Impact (Sodium and calcium caseinate, L-arginine)	Look/Sound	Nutritional supplement	Based on individual need
*** This review contains proprietary and confidential information that should not be released to the public.			

Appendix D: Potential confusing name with overlap in strength or dose

Failure Mode: Name confusion	Causes (could be multiple)	Effects
Vimpat (Lacosamide)	<p>Tablets: 50 mg, 100 mg, 150 mg, 200 mg, (b) (4)</p> <p>Oral syrup: (b) (4) mg/mL</p> <p>Injection: 10 mg/mL</p>	<p>Usual dose: Partial onset seizure: 200 mg/day to 400 mg/day (twice daily dosing); Maximum dose (b) (4) mg/day</p>
Viracept (Nelfinavir Mesylate)	<p>Orthographic similarity (starts with ‘Vi-’ and ends in ‘t’; share -p-)</p> <p>Overlap in strength (b) (4) and frequency of administration (twice daily)</p>	<p>Orthographic differences in the names minimize 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. Viracept is longer in length than Vimpat (8 letters vs. 6 letters). The downstroke in Viracept is not in the same location as Vimpat.</p> <p>Although they overlap in strength, the recommended dose for Viracept is 1,250 mg (five 250 mg tablets or two 625 mg tablets) twice daily or 750 mg (three 250 mg tablets) 3 times daily. The difference in dosing may help in distinguishing the name pair.</p>
Z-Pak (Azithromycin)	<p>Orthographic similarity (‘Z’ and ‘V’ look similar; endings ‘-pak’ and ‘-pat’ look similar)</p> <p>Overlap in strength (b) (4)</p>	<p>Orthographic differences in the names minimize 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. Z-pak is shorter in length than Vimpat (4 letters vs. 6 letters). Z-pak may be written with a hyphen after ‘Z’ which further distinguishes the name.</p> <p>Although they overlap in strength, Z-pak is generally prescribed without the strength since it is available in a single strength and is more likely prescribed as a unit (e.g. #1 UD). Z-pak is also only supplied for 5 days.</p>

<p>Zovirax (Acyclovir)</p>	<p>Orthographic similarity ('Z' and 'V' look similar; 'x' and 't' look similar)</p> <p>Overlap in strength (200 mg)</p>	<p>Orthographic differences in the names minimize 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 including the downstroke 'p' and upstroke 't' in Vimpat and the lack of overlapping letters except for 'i' in the name pair. Additionally, the difference in frequency of administration (four or five times daily vs. twice daily) minimizes the risk.</p>
<p>Viread (Tenofovir Disoproxil Fumarate)</p>	<p>Orthographic similarity ('Vi-'; upstroke at the end 'd' vs. 't')</p> <p>Overlap in strength ((b) (4))</p>	<p>Orthographic differences in the names minimize 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 including downstroke 'p' in Vimpat and different middle letters. Also the difference in frequency of administration (once daily vs. twice daily) minimizes the risk.</p>
<p>Vamate (Hydroxizine Pamoate)</p>	<p>Orthographic similarity ('V-'; overlapping 'm' and 'at')</p> <p>Overlap in strength (50 mg)</p>	<p>Medication errors unlikely to occur in usual practice setting.</p> <p><i>Rationale:</i></p> <p>Limited information was available for Vamate. It was not found in common online drug references such as Drugs@FDA, Facts and Comparison or Micromedex. However, the active ingredient (hydroxyzine pamoate) is still available in the U.S. But since Vamate is not a well-known tradename for hydroxyzine, the likelihood of being prescribed as Vamate is low. Additionally, the orthographic differences minimize the risk of confusion. Vamate has no downstroke in the name and has an extra 'e' at the end.</p>

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