CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022450Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Date:	January 8, 2010
To:	Bob Rappaport, MD, Director Division of Analgesia, Anesthesia, and Rheumatology Products
Through:	Melina Griffis RPh, Team Leader Denise Toyer, PharmD, Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Richard Abate, RPh, MS, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Ofirmev (Acetaminophen) Injection 1000 mg/100 mL
Application Type/Number:	NDA # 22450
Applicant:	Cadence Pharmaceuticals
OSE RCM #:	2009-2054

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EXECUTIVE SUMMARY

Ofirmev is the proposed proprietary name for Acetaminophen Injection. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name Ofirmev conditionally acceptable for this product. We note the NDA PDUFA date has been extended to February 11, 2009. The proposed proprietary name must be re-reviewed if approval of the NDA is more than 90 days after the date of this review.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from Cadence Pharmaceuticals October 23, 2009, for an assessment of the proposed proprietary name, Ofirmev, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. Cadence Pharmaceuticals also submitted revised container labels and carton labeling for review on October 30, 2009, which are reviewed under separate cover (OSE Review #2009-2204).

1.2 PRODUCT INFORMATION

Ofirmev (Acetaminophen) Injection (NDA 22-450) is indicated for the treatment of acute pain and fever. Ofirmev is provided as a 10 mg/mL solution packaged in glass single-use vials containing 1000 mg/100 mL requiring no further dilution prior to administration. The dose for adult and adolescent patients weighing 50 kg or more is 650 to 1000 mg intravenously every four to six hours up to maximum of 4000 mg in 24 hours. The dose for children older than 2 years of age and adult or adolescent patients weighing less than 50 kg is 12.5 to 15 mg/kg intravenously every four to six hours up to a maximum of 75 mg/kg in 24 hours (b) (4) [redacted] The dose of Ofirmev is administered as an infusion over 15 minutes. The vials of Ofirmev are stored at room temperature (20ºC).

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Ofirmev.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'O' 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.[1,2]

To identify drug names that may look similar to Ofirmev, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (seven letters), upstrokes (one, capital letter 'O'), down strokes (one, lower case 'f,' if scripted), cross strokes (one, lower case 'f,' if printed), and dotted (one, lower case 'i'). Additionally, several letters in Ofirmev may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Ofirmev.

When searching to identify potential names that may sound similar to Ofirmev, the DMEPA staff search for names with similar number of syllables (three), stresses (OH-fur-mev or oh-FUR-mev), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary such as 'Ofir-' may sound like 'Over-' or 'Ofeer-.' (See Appendix B.) The Sponsor's intended pronunciation (oh-FUR-mev) was also taken into consideration, as it was included in the Proprietary Name Review Request. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

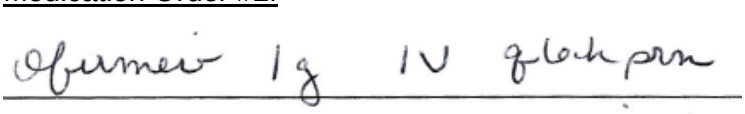
2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following two inpatient medication orders and a verbal medication order was communicated during the FDA prescription studies.

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

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

Figure 1. Ofirmev Study (conducted on November 9, and November 16, 2009)

HANDWRITTEN MEDICATION ORDER	VERBAL PRESCRIPTION
Medication Order #1 : 	Ofirmev 1 gram every six hours as needed
Medication Order #2: 	

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of nine names as having some similarity to the name Ofirmev.

Eight of the names were thought to look like Ofirmev. These include: Afinitor, Aflaxen, Afluria, Effient, Ofloxacin, Oticair, Otimar and Oti-Med. The ninth name, Firmagon, was thought to sound like Ofirmev.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of November 16, 2009.

3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to insert Ofirmev.

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

3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of twenty practitioners responded with none of the responses overlapping with an existing name. Two of the participants interpreted the name correctly as "Ofirmev," with correct interpretation occurring in the written studies. It is noted that the name Ofirmev was misspelled as "Ofiremev" in the writing sample for Medication Order #1. Six of the participants interpreted the name as spelled in this study. The remainder of the written responses misinterpreted the drug name. In the verbal studies, the single response was a misspelled phonetic variation of the proposed name, Ofirmev. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 COMMENTS FROM THE DIVISION OF ANALGESICS, ANESTHETICS, AND RHEUMATOLOGY PRODUCTS (DAARP)

3.4.1 Initial Phase of Review

In response to the OSE November 5, 2009 e-mail, DAARP did not forward any comments and/or concerns on the proposed name at the initial phase of the name review.

3.4.2 Midpiont of Review

DMEPA notified the Division of Analgesics, Anesthetics, and Rheumatology Products via e-mail that we had no objections to the proposed proprietary name, Ofirmev, on November 23, 2009. Per email correspondence from the Division of of Analgesics, Anesthetics, and Rheumatology Products on December 14, 2009, they indicated that they concur with our assessment of the proposed proprietary name.

3.5 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator identified seven additional names which were thought to look or sound similar to Ofirmev and represent a potential source of drug name confusion.

The names identified to have look-alike similarities are Obenix-30, Atromid-S, Afrin, Atrovent, Ativan and Oticaine. The name, Ovidrel, was identified to have sound-alike similarities.

Thus, we evaluated a total of 16 names for their similarity to the proposed name: seven identified by the primary safety evaluator and nine identified in section 3.1 above.

4 DISCUSSION

This proposed name, Ofirmev, was evaluated from a safety and promotional perspective. Furthermore, input from pertinent disciplines involved with the review of this application was considered accordingly.

4.1 PROMOTIONAL ASSESSMENT

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

4.2 SAFETY ASSESSMENT

Other than the identification of potentially similar names to Ofirmev, no issues were identified that rendered the name unacceptable.

Sixteen names were evaluated for their potential similarity to the proposed name, Ofirmev. Failure mode and effects analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the 16 names and lead to medication errors. This analysis determined that the name similarity between Ofirmev was unlikely to result in medication errors with any of the 16 products for the reasons presented in Appendices D through F.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Ofirmev, is not promotional or vulnerable to name confusion that could lead to medication errors. The Division of Analgesics, Anesthetics, and Rheumatology Products concurs with this assessment. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Ofirmev, for this product at this time.

If you have further questions or need clarifications, please contact Abolade Adeola, project manager, at 301-796-4264.

5.1 COMMENTS TO THE APPLICANT

5.1.1 Proprietary Name

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

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

6 REFERENCES

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

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

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. 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.

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

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

4. FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

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

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

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

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

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

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

USPTO provides information regarding patent and trademarks.

9. Clinical Pharmacology Online (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also 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 trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

11. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)

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

12. Stat!Ref (www.statref.com)

Stat!Ref contains full-text information from approximately 30 texts; it 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)

USAN Stems List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

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

15. Lexi-Comp (www.lexi.com)

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

16. Medical Abbreviations Book

Medical Abbreviations Book contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. 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. [3]

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases

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

the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail. [4] DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used 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. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug throughout the risk assessment because 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 proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, 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, DMEPA staff considers 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.[5] DMEPA provides the product characteristics considered for this review in section one.

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

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

[5] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

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	• 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 Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, the DMEPA staff also considers the potential for the proposed proprietary 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. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA staff conducts searches of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA staff review the USAN stem list to determine if any USAN stems are present within the

proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the DMEPA staff 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 primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Analysis Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of 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 the 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 DMEPA.

4. Comments from the OND review Division or Generic drugs

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and 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 DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or 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 concur/not concur with DMEPA's final decision.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment 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, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, 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 orthographically or phonetically similar 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 primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section one. 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 Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

> ***"Is the proposed proprietary name 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 the proposed proprietary name 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 posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes 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 not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name 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 the use of an alternate proprietary name.

DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Risk Assessment:

a. 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

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

suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

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

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative 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 a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and a preventable source of medication error that, in many instances, the Agency and/or Applicant can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Applicants have undertaken higher-leverage strategies, such as drug name changes, 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 approving the error-prone proprietary name. Moreover, even after Applicants' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. . (See Section 4 for limitations of the process).

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

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

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in Name, Ofirmev	Scripted may appear as	Spoken may be interpreted as
capital 'O'	A, or Q	any vowel
lower case 'o'	a, c, e, u, or v	any vowel
lower case 'f'	b or t	'ph' or 'v'
lower case 'i' in combination 'ir'	c, e, or l u or v	any vowel
lower case 'r'	n, t, or v	
lower case 'm'	n, 'on,' 'rn,' or 'ss'	'n'
lower case 'e'	c, i, or l	any vowel
lower case 'v'	n, o, r, or u	'b' or 'f'

Appendix C: FDA Prescription Study Responses.

Medication Order #1	Medication Order #2	Voice Prescription
Ofiremev	Ofirmev	Ofirmab
Ofiremer	Ofumeri	
Ofiremev	Ofumev	
Ofiremiv	Ofumeir	
Ofiremiv	Ofumev	
Ofiremiv	Ofirmev	
Ofiremev		
Ofirenev		
Ofiremev		
Ofiremiv		
Ofiremev		
Ofirimiv		
Ofiremev		

Appendix D: Discontinued product with no available generics

Proprietary Name	Active Ingredient	Similarity to Ofirmev
Atromid-S (with the modifier omitted)	Clofibrate	Look

Appendix E: Risk of name confusion minimized by preventions listed. (Potential contributing causes highlighted by *italics*)

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Ofirmev **(Acetaminophen) Injection**		**1000 mg/ 100 mL vial** **(Strength may be omitted during procurement step of medication use process for single strength products.)**	**Adults and adolescents ≥ 50 kg: 650 mg intravenously every four hour or 1000 mg intravenously every six hours as needed.** **Weight based dosing** **Adults and adolescents < 50 mg: 12.5 mg/kg every four hours or 15 mg/kg every six hours.** **Children >2 to 12 years of age: 12.5 mg/kg every four hours or 15 mg/kg every six hours.** (b) (4)	
Afinitor (Everolimus)	Look	5 mg and 10 mg tablets	One tablet (5 or 10 mg) daily	**Orthographic differentiation:** contains the letter 't' in the sixth position which provides for an upstroke and cross stroke in the name. **Dose:** 5 or 10 mg vs. 650 mg, 1000 mg, 12.5 mg/kg or 15 mg/kg in adult populations. **Dosage form:** tablet vs. injection in a vial. **Route of administration:** oral vs. intravenously **Frequency of use:** Once daily vs. every four to six hours in adult populations
Aflaxen (Naproxen Sodium)	Look	550 mg tablets *(Single Strength)*	One tablet (550 mg) twice daily	**Dosage form:** tablet vs. injection in a vial. **Route of administration:** oral vs. intravenously **Frequency of use:** twice daily vs. every four to six hours.
Afluria (Influenza Virus Type A and B Vaccine)	Look	15 mcg/0.5 ml prefilled syringe 5 mL multidose	Adults and children 36 months or older: One dose (0.5 mL) intramuscularly one time.	**Dose:** no dose or in mL vs. dose in milligrams. **Frequency of use:** once or repeated

		vial *(Single strength)*	Unvaccinated children repeat dose in 28 days, Children 6 months to 35 months: One dose (0.25 mL) intramuscularly one time. Unvaccinated children repeat dose in 28 days,	in 28 days vs. every four, six, or eight hours depending on patient age. **Afluria has more than one packaging configuration and is ordered annually prior to the influenza season.**
Afrin (Oxymetazoline HCl) or Afrin PureSea (sodium chloride)	Look	Oxymetazoline products Afrin All Night 0.05% Afrin Extra Moisturizing 0.05 % Afrin Original 0.05 % Afrin Severe Congestion 0.05 % Afrin Sinus 0.05 % Sodium Chloride Products: Afrin PureSea Medium Stream 0.9 % Afrin PureSea Gentle Mist 0.9 % Afrin PureSea Ultra Gentle Mist 0.9%	Two to three sprays in each nostril twice daily. Rinse each nostril as directed on package.	**Orthographic difference:** Afrin is five letter and thus shorter than Ofirmev which contains seven letters. **Dose:** number of spray vs. number of milligrams (650 mg, 1000 mg, 7.5 mg/kg, 10 mg/kg, 12.5 mg/kg, or 15 mg/kg. **Dosage form:** nasal spray or nasal rinse vs. Injection in a vial. **Route of administration:** Intranasal vs. intravenously **Frequency of use:** Twice daily (spray), daily, or as directed (for rinse) vs. every four to six hours
Atrovent (Ipratropium Bromide)	Look	Inhaler: 17 mcg/ actuation Solution for nebulization: 0.02% (500 mcg/ 2.5 mL) *vials* Nasal spray: 0.03 % or 0.06 %	Two inhalations by mouth *four times daily.* One vial (500 mcg) via nebulization *four times daily.* Two sprays in each nostril two to three times daily.	**Orthographic difference:** Last letter, 't,' provides for an upstroke and cross stroke when scripted. **Dosage form:** Inhaler, Solution for nebulization, or nasal spray vs. Injection in a vial **Route of administration:** oral inhalation or intranasal vs. intravenous.
Effient (Prasugrel)	Look	5 mg or 10 mg tablets	60 mg (six tablets) by mouth one time, then one tablet (5 mg or 10 mg) by mouth.	**Orthographic differentiation:** Contains two 'f's' and the letter 't' at the end of the name provides for an upstroke and cross stroke. **Dose:** 5 mg, 10 mg or 60 mg vs. 650 mg, 1000 mg, 12.5 mg/kg or 15 mg/kg in adult populations. **Dosage form:** tablet vs. injection in a vial.

				Route of administration: oral vs. intravenously **Frequency of use:** Daily vs. every four to six hours in adult populations
Firmagon (Degralex Acetate)	Sound	80 mg and 120 mg *vials*	Loading dose: 240 mg (2 vials) subcutaneously one time Maintenance dose: 80 mg (one vial) subcutaneously every 28 days.	**Dose:** 80 mg or 240 mg vs. 650 mg, 1000 mg, 12.5 mg/kg or 15 mg/kg in adult populations. **Frequency of use:** every 28 days vs. every four to six hours. **Firmagon is used specifically in patients with prostate cancer, usually on an outpatient basis.**
Obenix – 30 (without then modifier) (Phentermine HCl) Discontinued unapproved product with similar products available.	Look	37.5 mg capsules *(single strength)*	One capsule (37.5 mg) by mouth daily before breakfast or two hours after.	**Dose:** One capsule (37.5 mg) vs. 650 mg, 1000 mg, 12.5 mg/kg or 15 mg/kg in adult populations. **Dosage form:** Capsule vs. Injection in a vial. **Route of Administration:** Oral vs. intravenous. **Frequency of use:** daily vs. every four to six hours.
Ofloxacin (Available under the proprietary names Floxin, Floxin Otic and Ocuflox)	Look	Floxin: 200 mg, 300 mg and 400 mg tablets Floxin Otic: 0.3 % otic solution Ocuflox: 0.3 % ophthalmic solution	Oral dose depends on type of infection: One tablet (200 mg. 300 mg, or 400 mg) by mouth twice daily. Floxin Otic: five to ten drops into affected ear once or twice daily. frequency dependent upon indication (otitis externa or otitis media) Ocuflox: Instill 1-2 drops in affected eye(s) every 2-*4 hours* for the first 2 days, then use 4 times/day for an additional 5 days.	**Orthographic differentiation:** contains an additional two letters providing added length. In addition contains the letter 'x' which provides a cross stroke in the name. **Dose:** The numeric doses may overlap however, these overlapping doses for Ofirmev would be pediatric and ofloxacin as an oral quinolone is not indicated for use in pediatric patients. **Dosage form:** multiple (tablets, otic solution, and ophthalmic solution) vs. single (injection) and none are similar. **Route of administration:** oral, otic, or ophthalmic vs. intravenous in a vial.
Oticaine (Benzocaine)	Look	20% otic solution *(single strength)*	Four to five drops in affected ear every one to two hours as needed	**Dose:** Four to five drops vs. number of milligrams (650 mg, 1000 mg, 7.5 mg/kg, 10 mg/kg, 12.5 mg/kg, or 15 mg/kg. **Dosage form:** Otic solution vs. injection in a vial. **Route of administration:** Otic vs. intravenous. **Frequency of use:** every one to two hours vs. every for to six hours.

Oticair (Hydrocortisone, neomycin Sulfate, and Polymyxin B Sulfate) Discontinued unapproved product with similar products available.	Look	1 %/3.5 mg/ 10,000 units per mL otic suspension *(single strength)*	Three drops into affected ear three or *four times daily.*	**Dose:** three drops vs. number of milligrams (650 mg, 1000 mg, 7.5 mg/kg, 10 mg/kg, 12.5 mg/kg or 15 mg/kg **Dosage form:** otic solution vs. injection **Route of Administration:** otic vs. intravenously
Otimar (Hydrocortisone, neomycin Sulfate, and Polymyxin B Sulfate)		1 %/3.5 mg/ 10,000 units per mL otic solution *(single strength)*	Three drops into affected ear three or *four times daily.*	**Dose:** three drops vs. number of milligrams (650 mg, 1000 mg, 7.5 mg/kg, 10 mg/kg, 12.5 mg/kg or 15 mg/kg **Dosage form:** otic solution vs. injection **Route of Administration:** otic vs. intravenously
Oti-med (Hydrocortisone, pramoxine and chloroxylenol) Discontinued unapproved product with similar products available.	Look	1 %/1 %/0.1 % Otic Solution *(single strength)*	Adults: Four to five drops in affected ear three to *four times daily.* Infants and small children: three drops to affected ear three to *four times daily.*	**Dose:** three, four, or five drops vs. number of milligrams (650 mg, 1000 mg, 7.5 mg/kg, 10 mg/kg, 12.5 mg/kg, or 15 mg/kg **Dosage form:** otic solution vs. injection **Route of Administration:** otic vs. intravenously.
Ovidrel (Choriogonadotropin alfa)	Sound	250 mcg prefilled syringe. *(single strength)*	<u>As a part of Assisted Reproductive technology:</u> Inject one prefilled syringe (250 mcg) subcutaneously the day following the last dose of the follicle stimulating agent.	**Ovidrel is limited to use in the specialty practice of Assisted Reproduction Technology (ART) and limited to outpatient use only.**

Appendix F: Products with similar doses where the risk of medication errors due to product confusion is minimized by dissimilarity of the names and other product characteristics

Proposed name:	**Strength:**	**Usual dose:**
Ofirmev (Acetaminophen) Injection	**1000 mg/100 mL vial**	**Adults and adolescents ≥ 50 kg: 650 mg intravenously every four hour or 1000 mg intravenously every six hours as needed.** **Weight based dosing** **Adults and adolescents < 50 mg: 12.5 mg/kg every four hours or 15 mg/kg every six hours.** **Children >2 to 12 years of age: 12.5 mg/kg every four hours or 15 mg/kg every six hours.** (b) (4)
Failure Mode: Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode;(name confusion)**
Ativan (Lorazepam) 0.5 mg, 1 mg, and 2 mg tablets 2 mg/mL, 4 mg/ml, 20 mg/ 10 mL, and 40 mg/10 mL injection in vials 2 mg/mL oral solution (generic lorazepam)	Orthographic similarities: The first two letters in each name may appear similar when scripted (A vs. O and t vs. f) the third letter 'i' is the same, the fourth letter may appear similar when scripted (v vs. r) and the final two letters of each name may appear similar when scripted ('an' vs. 'ev'). Share numeric dose: 1 mg vs. 1 gram Share dosage form (injection), route of administration (intravenously), frequency of administration (every six hours) and practice setting (intensive care units)	Orthographic differentiation as well as the use of medications in the usual practice settings minimize the potential for medication errors: Rationale: The orthographic differences stem from how these names are written. The letter 'A' and 'O' appear similar when these letters are scripted. Scripting these names provides differentiation from the down stroke in the second letter, f. However, we noted the second letters (t vs. f) appear similar when printed. When these names are printed, the capitalized first letter in each name (O vs. A) appears significantly different. Finally, the extra letter 'm' in Ofirmev provides added length. The dose of Ativan in an ICU setting is usually written as a dose higher than 1 mg (e.g. 2 mg), as a range dose (1-2 mg), more frequently than every six hours or as a continuous infusion when administered intravenously for sedation while on a ventilator, an unapproved use for Ativan.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22450	ORIG-1	CADENCE PHARMACEUTICALS INC	ACETAMINOPHEN FOR INJECTION FOR IV USE

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/s/

RICHARD A ABATE
01/08/2010

MELINA N GRIFFIS
01/08/2010

DENISE P TOYER
01/08/2010

CAROL A HOLQUIST
01/08/2010

Department of Health and Human Services

Public Health Service

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Surveillance and Epidemiology

Date:	October 25, 2010
Application Type/Number:	NDA 022450
Through:	Melina Griffis, RPh, Team Leader Denise P. Toyer, PharmD, Deputy Director Division of Medication Error Prevention and Analysis
From:	Richard A. Abate, RPh, MS Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s):	Ofirmev (Acetaminophen) Injection 1000 mg/100 mL vial
Applicant:	Cadence Pharmaceuticals
OSE RCM #:	2010-1091

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Ofirmev, is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Ofirmev, acceptable in OSE Review # 2009-2054 dated January 8, 2010. DDMAC reviewed the proposed name on August 6, 2010 and had no concerns regarding the proposed name from a promotional perspective.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA safety evaluator searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria used in OSE Review 2009-2054 for the proposed proprietary name, Ofirmev.

Since the previous proprietary name review, the Division of Analgesia and Anesthesia Products reconsidered the ages to be approved for use to 2 years and older. This change in patient population did not affect the evaluation of the previous names of concern identified in OSE review # 2009-2054.

Additionally, the DMEPA safety evaluator searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases yielded three additional names thought to look or sound similar to Ofirmev and represent a potential source of drug name confusion. These names include: Alsuma, (b) (4)

Two of the three names were eliminated for reasons described in Appendix A.

Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with the remaining name and lead to medication errors. This analysis determined that the name similarity between Ofirmev and the remaining name was unlikely to result in medication error for the reasons presented in Appendix B.

Additionally, the DMEPA Safety evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of October 5, 2010.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Ofirmev, did not identify any vulnerabilities that would result in medication errors with the additional names noted in this review. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Ofirmev, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Analgesia and Anesthesia Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

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

4 REFERENCES

1. OSE review # 2009-2054, Proprietary Name Review for Ofirmev; January 8, 2010, Abate, R.

2. Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)

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

3. USAN Stems (http://www.ama-assn.org/ama/pub/category/4782.html)

USAN Stems List contains all the recognized USAN stems.

4. Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

APPENDICES

Appendix A: Names of products not used in usual clinical practice for the reasons described.

Proprietary Name	Similarity to Ofirmev	Reason/Comments
(b) (4)	Look-Alike	Proposed proprietary name for NDA 200603; found unacceptable in OSE review 2010-1230 dated August 11, 2010 due to likely confusion with two marketed products.
	Look-Alike	Proposed proprietary name for NDA 022573; found unacceptable in OSE Review #2010-117 dated April 5, 2010 due to likely confusion with three marketed products.

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

Appendix B: Risk of name confusion minimized by preventions listed. (Potential contributing causes highlighted by *italics*)

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Ofirmev **(Acetaminophen) Injection**		**1000 mg/100 mL vial (10 mg/mL)** **(Strength may be omitted during procurement step of medication use process for single strength products.)**	**Adults and adolescents ≥ 50 kg: 650 mg intravenously every four hour or 1000 mg intravenously every six hours as needed.** **Weight based dosing** **Adults and adolescents < 50 mg: 12.5 mg/kg every four hours or 15 mg/kg every six hours.** **Children >2 to 12 years of age: 12.5 mg/kg every four hours or 15 mg/kg every six hours.**	
Alsuma (Sumatriptan Succinate)	Look	6 mg/0.5 mL *injection* in an prefilled ready to administer auto-injector *single strength*	The contents of one injector (6 mg) subcutaneously one time, may repeat after one hour if no effect. (maximum dose in 4 hours is 12 mg, or two injectors)	**Orthographic difference:** Ofirmev includes the letter 'f' which may provide a down stroke or a cross stroke when scripted. **Dose:** 6 mg (always) vs., 650 mg or 1000 mg for adults 50 kg or more. Calculated doses for adults are likely to be in the range of 500 mg to 750 mg. **Route of administration:** Auto injector device to be administered subcutaneously for outpatient use vs. vial from which the drug may be infused intravenously in an inpatient or clinic setting.

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/s/

RICHARD A ABATE
10/25/2010

MELINA N GRIFFIS
10/25/2010

DENISE P TOYER
10/25/2010

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

Date:	June 5, 2009
To:	Bob Rappaport, MD, Director Division of Anesthesia, Analgesia, and Rheumatology Products
Through:	Melina Griffis, RPh, Acting Team Leader Division of Medication Error Prevention and Analysis (DMEPA)
From:	Richard Abate, RPh, MS, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Acetavance (Acetaminophen) Injection
Application Type/Number:	NDA 22-450
Applicant:	Cadence Pharmaceuticals, Inc
OSE RCM #:	2009-1008

1 INTRODUCTION

This memorandum is in response to a request from Cadance Pharmaceuticals for a review of the proposed proprietary name Acetavance.

1.1 PRODUCT DESCRIPTION

Acetavance is the proposed proprietary name for acetaminophen injection (NDA 22-450) indicated for the treatment of acute pain and fever. Acetavance will be available in a 10 mg/mL solution packaged in ready-to-use single-use glass vials containing 1000 mg/100 mL. The dose for adult and adolescent patients weighing 50 kg or more is 650 to 1000 mg intravenously every four to six hours up to a maximum of 4000 mg in 24 hours. The dose for children older than 2 years of age and adult or adolescent patients weighing less than 50 kg is 12.5 to 15 mg/kg intravenously every four to six hours up to a maximum of 75 mg/kg in 24 hours. (b) (4) The dose must be administered over 15 minutes. The vials of Acetavance are stored at room temperature (20ºC).

2 DISCUSSION

(b) (4)


(b) (4)

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/s/

Richard Abate
6/5/2009 01:41:38 PM
DRUG SAFETY OFFICE REVIEWER

Melina Griffis
6/5/2009 01:45:55 PM
DRUG SAFETY OFFICE REVIEWER