CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-266

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:	June 8, 2009
To:	Bob Rappaport , Director Division of Analgesics, Anesthetics, and Rheumatology Products
Through:	Carol Holquist, R.Ph. Director Division of Medication Error Prevention and Analysis
From:	Melina Griffis, R.Ph., Acting Team Leader Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s):	Onsolis [redacted] b(4)
Application Type/Number:	NDA 22-266
Applicant/sponsor:	Biodelivery Sciences International
OSE RCM #:	2009-1016

1 INTRODUCTION

This memorandum is in response to a request from the Division of Analgesics, Anesthetics, and Rheumatology Products for final review of the proposed proprietary name, Onsolis. This name was last reviewed on January 11, 2008 and found to be acceptable (see OSE review 2007-1849).

1.1 PRODUCT DESCRIPTION

Onsolis is the proposed name for [redacted] Onsolis is an opioid indicated for the management of breakthrough pain in cancer patients who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. b(4)

The dose will be titrated to an individually effective and tolerable dose. If patients need to treat more than four breakthrough pain episodes per day, their around-the-clock opioid maintenance may need to be adjusted.

Onsolis will be available as a bioerodible mucoadhesive system in strengths of 200 mcg, 400 mcg, 600 mcg, 800 mcg, and 1200 mcg. Onsolis will be packaged in outer cartons containing 4 inner cartons which will contain 28 systems.

2 DISCUSSION

During our final review of the proposed proprietary name, Onsolis, DMEPA identified 15 names not previously reviewed in OSE review 2007-1849 (listed Appendix A) and we determined that the 15 identified names were unlikely to result in medication errors with Onsolis. Therefore, we have concluded that the proposed proprietary name Onsolis is acceptable for this product.

3 CONCLUSIONS AND RECOMMENDATIONS

We have completed our review of the proposed proprietary name, Onsolis, and have concluded that it is acceptable. However, if the product approval is delayed beyond 90 day from the date of this memo, the proposed name must be resubmitted for evaluation.

We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Chris Wheeler, project manager, at 301-796-0151.

Appendix A: Additional names identified and reason to discard

Proprietary Name	Reason to Discard
Oncolym	Unapproved orphan designated drug product
Mobic (meloxicam) 7.5 mg and 15 mg tablets, 7.5 mg/5 mL [redacted] oral suspension	Different strength availability, dose and route of administration
Ansolysen (pentolinum) 10 mg/mL for injections	Discontinued drug product no generics available
Omnaris (ciclesonide) 50 mcg Intranasal spray	Different strength availability, dose and route of administration
Ansulina	International brand for Ampicillin
Ansal	International brand for Diflunisal
Anselol	International brand for Atenolol
Ansiloin	International brand for Diazepam
Ansilor	International brand for Lorazepam
Consolin	Marketed in Canada
[redacted]	Name found unacceptable by DDMAC, DMEPA and DMEP (OSE review 2006-0003)
Soliris (eculizumab) 300 mg/30 mL intravenous injection	Different strength availability, dose and route of administration
Ansaid (flurbiprofen) 50 mg and 100 mg tablets	Different strength availability, dose and route of administration
Duraclon (clonidine) 0.1 mg/mL and 0.5 mg/mL for epidural infusion	Different strength availability, dose and route of administration
Ancobon (flucytosine) 250 mg and 500 mg capsules	Different strength availability, dose and route of administration

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/s/

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6/8/2009 07:49:53 AM
DRUG SAFETY OFFICE REVIEWER

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6/8/2009 10:03:43 AM
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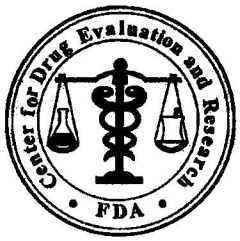

Department of Health and Human Services
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Center for Drug Evaluation and Research
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Date:	January 11, 2008
To:	Bob Rappaport , Director Division of Analgesics, Anesthetics, and Rheumatology Products
Thru:	Linda Kim-Jung, Team Leader, DMETS Denise Toyer, Deputy Director, DMETS Carol Holquist, Director, DMETS
From:	Kristina Arnwine, Acting Team Leader, DMETS
Subject:	Proprietary Name Review for Onsolis
Drug Name(s):	Onsolis [redacted] b(4
Application Type/Number:	IND 62,864/NDA 22-266
Applicant/sponsor:	Biodelivery Sciences International
OSE RCM #:	2007-1849

Contents

EXECUTIVE SUMMARY

DMETS has no objection to the use of the proprietary name, Onsolis for this product. The results of the Proprietary Name Risk Assessment found that the proposed name, Onsolis, has some similarity to other proprietary and established drug names, but the findings of the FMEA 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 Sponsor.

However; if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMETS rescinds 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 signature date of this review, the proposed name must be resubmitted for re-evaluation.

1 BACKGROUND

1.1 INTRODUCTION

This consult was written in response to a request from the Division of Anesthesia, Analgesia, and Rheumatology Products (DAARP) to evaluate the product for its potential to contribute to medication errors.

1.2 REGULATORY HISTORY

The sponsor initially submitted the proposed name ——— as an alternate to Onsolis, in the event that DMETS objected to the use of the name Onsolis. However, the Division of Drug Marketing, Advertising, and Communication (DDMAC) objected to the name ——— from a promotional perspective. DDMAC noted that the name ——— overstates the efficacy of the drug product". The Division concurred in an email sent September 14, 2007, and thus only one name, Onsolis will be evaluated further. b(4)

Additionally, the product design, carton and container label, and insert labeling is being evaluated under separate cover to identify areas that could lead to medication errors (OSE reviews 2007-1819 and 2007-2021).

1.3 PRODUCT INFORMATION

Onsolis is the proposed name for ——————————— Onsolis is an opioid indicated for the management of breakthrough pain in cancer patients who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. b(4)

The dose will be titrated to an individually effective and tolerable dose. If patients need to treat more than four breakthrough pain episodes per day, their around-the-clock opioid maintenance may need to be adjusted.

Onsolis will be available as a bioerodible mucoadhesive system in strengths of 200 mcg, 400 mcg, 600 mcg, 800 mcg, and 1200 mcg. Onsolis will be packaged in outer cartons containing 4 inner cartons which will contain 28 systems.

2 METHODS AND MATERIALS

This section consists of two sections which describe the methods and materials used by DMETS medication error staff conducting a proprietary name risk assessment (see 2.1 Proprietary Name Risk Assessment). The primary focus for both of the assessments is to identify and remedy potential sources of medication error prior to drug approval. DMETS 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, Onsolis, 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, Onsolis, the medication error staff of DMETS 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). DMETS also conducts 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. DMETS uses the clinical expertise of the medication error staff to anticipate the conditions of the clinical setting that the product is likely to be used in based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap, or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. As such, the Staff considers the product characteristics associated with the proposed drug throughout the risk assessment, since the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usua*l 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, DMETS 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.[3]

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[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.