

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**205410Orig1s000**

**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  
Office of Medication Error Prevention and Risk Management**

**Proprietary Name Memorandum**

Date: February 12, 2014

Reviewer: Jacqueline Sheppard, PharmD  
Division of Medication Error Prevention and Analysis

Acting Team Leader Lisa Khosla, PharmD, MBA  
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Hemangeol (Propranolol Hydrochloride) Oral Solution  
4.28 mg/mL

Application Type/Number: NDA 205410

Applicant/sponsor: Pierre-Fabre Pharmaceuticals

OSE RCM #: 2014-16886

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

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## 1 INTRODUCTION

This memorandum is to re-assess the proposed proprietary name, Hemangeol, in response to the Applicant's re-submission of the proposed proprietary name under NDA 205410.

Due to changes in product characteristics, the proposed name (b) (4) had to be resubmitted for review. (b) (4)

A teleconference was held with the Applicant on February 3, 2013 to communicate the unacceptability of the name (b) (4) and provide recommendations on revising the spelling of the proposed proprietary name in order to avoid (b) (4). Pursuant to the teleconference, the Applicant submitted the name Hemangeol.

## 2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA 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. For this review we used the same search criteria described in OSE Reviews #2012-1054 and #2013-1269. We note that the concentration of Hemangeol has changed from 3.75 mg/ml to 4.28 mg/ml. Therefore, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience and also evaluated the (b) (4), in order to assess if our previous conclusion regarding the acceptability of the proposed proprietary name would be altered. The searches of the databases did not yield any new names thought to look or sound similar to Hemangeol and represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The January 27, 2014 search of USAN stems did not find any USAN stems in the proposed proprietary name.

## 3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Cheryle Milburn, OSE project manager, at 301-796-2084.

#### 4 REFERENCES

1. *OSE Review 2012-1054 dated October 25, 2012*

2. *OSE Review 2013-1269 dated August 7, 2013*

3. *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.

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

USAN Stems List contains all the recognized USAN stems.

5. *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.

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/s/  
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JACQUELINE E SHEPPARD  
02/12/2014

LISA V KHOSLA  
02/14/2014

**Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Surveillance and Epidemiology  
Office of Medication Error Prevention and Risk Management**

**Proprietary Name Review**

Date: August 7, 2013

Reviewer: Kimberly DeFronzo, RPh, MS, MBA  
Division of Medication Error Prevention and Analysis

Team Leader: Irene Z. Chan, PharmD, BCPS  
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh  
Division of Medication Error Prevention and Analysis

Drug Name and Strength: (b) (4) (Propranolol Hydrochloride) Oral Solution  
3.75 mg/mL

Application Type/Number: NDA 205410

Applicant/Sponsor: Pierre Fabre Dermatologie

OSE RCM #: 2013-1269

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/s/  
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IRENE Z CHAN on behalf of KIMBERLY A DE FRONZO  
08/07/2013

IRENE Z CHAN  
08/07/2013

CAROL A HOLQUIST  
08/07/2013

**Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Surveillance and Epidemiology  
Office of Medication Error Prevention and Risk Management**

Date: October 5, 2012

Reviewers: Ray Ford, RPh, Safety Evaluator  
Division of Medication Error Prevention and Analysis

Irene Z. Chan, PharmD, BCPS, Team Leader  
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh  
Division of Medication Error Prevention and Analysis

Drug Name and Strength: (b) (4) (Propranolol Hydrochloride) Oral Solution  
3.75 mg/mL

Application Type/Number: IND 104390

Applicant/Sponsor: Pierre Fabre Dermatologie

OSE RCM #: 2012-1054

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/s/  
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IRENE Z CHAN  
10/05/2012

CAROL A HOLQUIST  
10/05/2012