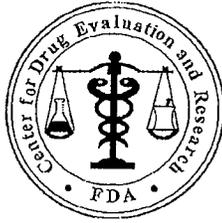


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-306

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: May 29, 2009

To: Norman Stockbridge, MD, Director
Division of Cardiovascular and Renal Products

Thru: Kristina C. Arnwine, PharmD, Team Leader
Denise P. Toyer, PharmD, Deputy Director
Carol A. Holquist, RPh, Director
Division of Medication Error Prevention and Analysis

From: Loretta Holmes, BSN, PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis

Subject: Proprietary Name Review

Drug Name: So-Aqueous (Sotalol Hydrochloride) Injection
15 mg/mL

Application Type/Number: NDA 22-306

Applicant: Academic Pharmaceuticals, Inc.

OSE RCM #: 2008-1406

1 INTRODUCTION

This memorandum is written in response to a request from the Division of Cardiovascular and Renal Products for a proprietary name review of So-Aqueous.

2 DISCUSSION

During the initial steps of this proprietary name review, DMEPA identified concerns that the proposed proprietary name "So-Aqueous" could be misleading for the following reasons:

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Thus, we object to the use of the proposed proprietary name, So-Aqueous, for this product for the aforementioned reasons. Our objection to the name was communicated to the Applicant via a telephone call on May 18, 2009.

3 CONCLUSIONS AND RECOMMENDATIONS

The Division of Medication Error Prevention and Analysis objects to the use of the proposed proprietary name, So-Aqueous, because it may be misleading and is error-prone. Therefore, we will not proceed with a full review of this name. The Applicant may submit an alternate proposed proprietary name for the drug product, Sotalol Hydrochloride Injection, for our review and comment.

If you have any questions or need clarifications, please contact Sean Bradley, OSE Project Manager, at 301-796-1332.

¹ Definition obtained from the MedlinePlus: Medical Dictionary at: <http://www2.merriamwebster.com/cgi-bin/mwmednlm?book=Medical&va=aqueous>. Accessed on February 3, 2009.

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/s/

Loretta Holmes
5/29/2009 04:02:44 PM
DRUG SAFETY OFFICE REVIEWER

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5/29/2009 05:00:01 PM
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