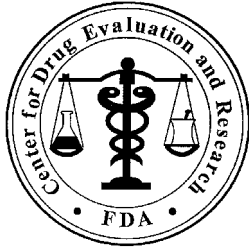


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
022036Orig1s000

OTHER 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: March 8, 2010

To: Russell Katz, MD, Director
Division of Neurology Products

Thru: Melina Griffis, R.Ph, Team Leader
Denise Toyer, PharmD, Deputy Director
Division of Medication Error Prevention and Analysis

From: Lubna Najam, M.S., PharmD, Safety Evaluator
Division of Medication Error Prevention and Analysis

Subject: Label and Labeling Review

Drug Name: Silenor (Doxepin Tablets)
3 mg, and 6 mg

Application Type/Number: NDA 022036

Applicant: Somaxon Pharmaceuticals, Inc.

OSE RCM #: 2008-1836

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INTRODUCTION

The Division of Medication Error Prevention and Analysis (DMEPA) completed a labeling review for Silenor (OSE RCM #2008-96) on October 23, 2008 in which we made recommendations regarding the proposed container labels and carton labeling. The Applicant submitted their revisions dated December 15, 2008 addressing DMEPA's requested changes which were found to be acceptable (OSE RCM #2008-1836) on January 13, 2009. Subsequently, the applicant has submitted revised carton labeling, container and blister pack labels in addition to new physician sample pack.

1 METHODS AND MATERIAL REVIEWED

In a submission dated February 25, 2010, the applicant has submitted revised container labels and carton labeling to incorporate the required medication guide statement. In addition this submission contained new physician sample pack labels, which were not previously reviewed by DMEPA. Our review of the container labels and trade blister pack labels and carton labeling was limited to the evaluation of the medication guide statement since these labels and labeling were previously found to be acceptable (OSE RCM #2008-1836) on January 13, 2009. However the physician sample blister pack label and labeling was fully evaluated since they were not previously reviewed by DMEPA. Using Failure Mode and Effects Analysis (FMEA),¹ we evaluated the blister physician sample pack label and labeling. See Appendices A through C for pictures of the labels and labeling.

- Commercial Bottle Labels (3 mg, 6 mg)
- Trade Pack Blister Card Label and Carton Labeling
- Physician Sample Blister Card Label and Carton Labeling (4 and 7 count samples)

2 CONCLUSIONS AND RECOMMENDATIONS

We provide recommendations in Section 2.1 and request they be communicated to the Applicant prior to approval.

Please copy the Division of Medication Error Prevention and Analysis on any communication to the Applicant with regard to this review. If you have further questions or need clarifications on this review, please contact the OSE Regulatory Project Manager, Laurie Kelley at 301-796-5068.

2.1 COMMENTS TO THE APPLICANT

A. General Comment (all labels)

In accordance with 21 CFR 201.10 (g)(2), ensure that the established name is printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

¹ Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

B. Bottle Container Label (3 mg and 6 mg)- 30, 100 and 500 tablet containers

1. The medication guide statement is currently displayed (b) (4) and is difficult to identify and read. In accordance with 21 CFR 208.24 (2)(d) the medication guide statement should appear in a prominent and conspicuous manner on the label. Relocate the medication guide statement to the principal display panel on the label. This statement should not intervene with other pertinent information, e.g. strength, established name and proprietary name and should also not decrease the prominence of this information.
2. Please ensure that sufficient numbers of Medication Guides are provided with the product such that a dispenser can provide one Medication Guide with each new or refilled prescription.

C. Physician Sample Blister Carton Labeling (3 mg and 6 mg) 4 and 7 count samples

In several instances the proprietary and established names are displayed without the strength presentation or vice versa. Revise these labels to ensure that the product strength appears in conjunction with the proprietary and established names.

D. Physician Sample Blister Pack Label (3 mg and 6 mg) 4 and 7 count samples

Increase the font size of the statement “Each tablet contains the equivalent of 3 mg doxepin” present on both the 3 mg and 6 mg blister card label to increase its prominence.

13 pp of Draft Labeling have been withheld in full as b4 (CCI/TS) immediately following this page.

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