DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22036/S-001

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Somaxon Pharmaceuticals, Inc.
Attention: Brian Dorsey
Senior Vice President, Technical Operations
10935 Vista Sorrento Parkway, Suite 250
San Diego, CA 92130

Dear Mr. Dorsey,

Please refer to your Supplemental New Drug Application (sNDA) dated August 5, 2011, received August 5, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Silenor (doxepin HCl) tablets.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated August 5, 2011 and amended August 17, 2011. After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be adequate.

This supplemental new drug application proposes to eliminate the requirement for the approved Silenor (doxepin HCl) REMS.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Silenor (doxepin HCl) was originally approved on March 17, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Silenor (doxepin HCl).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Silenor (doxepin HCl) outweigh its risks.

Therefore, we agree with your proposal and a REMS for Silenor (doxepin HCl) is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Cathleen Michaloski, Regulatory Project Manager, at (301) 796-1123.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RUSSELL G KATZ
10/30/2011