DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022195/S-005

SUPPLEMENT APPROVAL
REMS ASSESSMENT ACKNOWLEDGMENT
RELEASE REMS REQUIREMENT

Roxane Laboratories, Inc.
1809 Wilson Road
Columbus, OH 43228

Attention: Elizabeth Ernst
Executive Director, Drug Regulatory Affairs and Medical Affairs

Dear Ms. Ernst:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 19, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Morphine Sulfate Oral Solution.

We acknowledge receipt of your amendment dated October 13, 2011, and your risk evaluation and mitigation strategy (REMS) assessment dated July 19, 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 Prior Approval Supplement, as amended, proposes to eliminate the requirement for the approved Morphine Sulfate Oral Solution REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Morphine Sulfate Oral Solution was originally approved on January 25, 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 Morphine Sulfate Oral Solution.

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 Morphine Sulfate Oral Solution outweigh its risks.

Therefore, we agree with your proposal, and a REMS for Morphine Sulfate Oral Solution 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 Lisa Basham, Senior Regulatory Health Project Manager, at (301) 796-1175.

Sincerely,

{See appended electronic signature page}

Judith A. Racoosin, MD, MPH
Division of Anesthesia, Analgesia,
and Addiction Products
Office of Drug Evaluation II
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/

JUDITH A RACOOSIN
10/18/2011