DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022195/S-009

**SUPPLEMENT APPROVAL**

Roxane Laboratories
1809 Wilson Road,
Columbus, OH 43228

Attention: Anton Amann, PhD
Executive Director, Drug Regulatory and Medical Affairs

Dear Dr. Amann:

Please refer to your Supplemental New Drug Application (sNDA) dated December 3, 2013, received December 3, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Morphine Sulfate Oral Solution, 10 mg/5 mL, 20 mg/5 mL, and 100 mg/5 mL (20 mg/mL).

This Changes Being Effected supplemental new drug application provides for revisions to the Morphine Sulfate Oral Solution 10 mg/5 mL and 20 mg/ 5 mL Carton and Immediate Container Labels consistent with our November 25, 2013, Supplement Request letter.

## APPROVAL & LABELING

We have completed our review of this supplemental application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

## CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your December 3, 2013, submission containing final printed carton and container labels.

## 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 Christopher Hilfiger, Regulatory Project Manager, at (301) 796-4131.

Sincerely,

*{See appended electronic signature page}*

Bob A. Rappaport, MD,
Division Director
Division of Anesthesia, Analgesia, and
Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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/s/

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BOB A RAPPAPORT
01/09/2014