DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-058/S-019 **SUPPLEMENT APPROVAL**

Roxane Laboratories, Inc.
P.O. Box 16532
Columbus, OH 43216-6532

Attention: Elizabeth Ernst
Director, DRA and Medical Affairs

Dear Ms. Ernst:

Please refer to your supplemental new drug application dated July 23, 2007, received July 24, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for DISKETS Dispersible Tablets (methadone hydrochloride tablets for oral suspension, USP) 40 mg.

We acknowledge receipt of your submission dated December 20, 2007, received January 3, 2008.

This "Changes Being Effected" supplemental new drug application provides for changes to the package insert and container label to comply with USP naming standards, as well as modifications to the PRECAUTIONS section of the package insert to include information for breastfeeding women.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text for the package insert. For administrative purposes, designate this submission **"Content of Labeling for approved NDA 17-058/S-019."** Upon receipt and verification that the content of labeling in SPL format is identical to the approved labeling text, we will transmit that version to the National Library of Medicine for public dissemination.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your July 23, 2007 submission containing final printed container labels.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Matt Sullivan, Regulatory Project Manager, at 301-796-1245.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

/s/

Bob Rappaport

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