DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-977/S-004, S-007

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

Attention: Ann M. Maloney
Director, Drug Regulatory Affairs - Approved Products

Dear Ms. Maloney:

Please refer to your supplemental new drug applications S-004 dated July 1, 1993, received July 2, 1993, and S-007 dated December 22, 1994, received December 27, 1994, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Oramorph (morphine sulfate) Sustained Release Tablets.

We acknowledge receipt of your submissions dated February 8, 2001 and June 11, 2001. Your June 11, 2001, submission constituted a complete response to our January 29, 2001, action letter.

Supplement S-004 proposes changes in the DOSAGE AND ADMINISTRATION, and PHARMACOKINETICS sections. Supplement S-007 proposes changes in the PHARMACOKINETICS section.

We have completed the review of these supplemental applications, as amended, and they are approved for use as recommended in the submitted final printed labeling (package insert submitted June 11, 2001), effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Victoria Kao, Project Manager, at (301) 827-7416.

Sincerely,

{See appended electronic signature page}

Cynthia G. McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research