DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 20-932

OCT 26 1998

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

Attention: Sean Alan Reade, M.A.
Director, Regulatory Affairs

Dear Mr. Reade:

Please refer to your new drug application (NDA) dated December 22, 1997, received December 29, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Roxicodone (oxycodone hydrochloride) Sustained Release Tablets, 10 mg and 30 mg.

We acknowledge receipt of your submissions dated January 12, January 13, February 3, February 10, March 6, March 13, April 24, May 4, June 30, October 8, October 20, and October 23, 1998. The user fee goal date for this application is October 29, 1998.

This new drug application provides for the use of Roxicodone (oxycodone hydrochloride) Sustained Release Tablets, 10 mg and 30 mg for the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

We have reviewed your dissolution method and find it acceptable. However, your proposed dissolution specifications need to be modified. The final approved dissolution specifications and dissolution method are provided below, as agreed upon in our teleconference of October 26, 1998:

Apparatus, USP: Type 1 (basket)
Rotation Speed: 100 rpm
Dissolution Volume : 900 mL
Dissolution Media: Simulated Gastric Fluid TS (w/o enzymes) –hour 1 pH=about 1.2
Simulated Intestinal Fluid TS (w/o pancreatin)-hours 2-24
pH=7.5±0.1
Temperature: 37±0.5° C
Sampling Times: 1, 2, 6, 12, and 24 hours

Specifications: 1 hr:
2 hr:
6 hr:
12 hr
24 hr

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-932". Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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, contact Bonnie McNeal, Project Manager, at (301) 443-3741.

Sincerely,

MD

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and Addiction
Drug Products, HFD-170
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure