DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 74-736

JAN 2 1 1997

Royce Laboratories, Inc.
Attention: Loren Gelber, Ph.D.
16600 N.W. 54 Avenue
Miami, FL 33014

Dear Madam:

This refers to your abbreviated new drug application dated August 30, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Pentazocine and Naloxone Hydrochlorides Tablets, USP, 50 mg (base)/0.5 mg (base).

Reference is also made to your amendments dated December 7, 1995, April 9, and July 31, 1996.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined that your Pentazocine and Naloxone Hydrochlorides Tablets, USP, 50 mg (base)/0.5 mg (base), are bioequivalent and, therefore therapeutically equivalent to the listed drug (Talwin NX Tablets, 50 mg (base)/0.5 mg (base), of Sanofi Winthrop Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FDA-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FDA-2253 at the time of their initial use.

Sincerely yours,

Roger L. Williams, M.D.
Deputy Center Director for Pharmaceutical Science
Office of Generic Drugs
Center for Drug Evaluation and Research