

O.P.R. Development, L.P.  
c/o Roxane Laboratories, Inc.  
P.O. Box 16532  
Columbus, Ohio 43216

Attention: Sean Alan F.X. Reade  
Director of Regulatory Affairs

Dear Mr. Reade:

Please refer to your supplemental new drug application dated October 11, 1999, received October 12, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cafcit (caffeine citrate) Oral Solution.

We acknowledge receipt of your submissions dated February 23, March 22, and April 7, 2000.

This supplemental new drug application provides for the use of Cafcit (caffeine citrate) Oral Solution for the short term treatment of apnea of prematurity in infants between 28 and <33 weeks gestational age.

We have completed the review of this supplemental 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 agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert, patient package insert, and immediate container and carton labels submitted April 10, 2000).

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 supplement NDA 20-793/S-001." Approval of this submission by FDA is not required before the labeling is used.

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

We remind you of the following agreements.

1. Communicate the labeling changes that effect your current promotional materials for Cafcit Injection.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" 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

2. Revise the embossed instructions on the Medi-Lock container to be consistent with the instructions provided in the Patient Package Insert by the next date of production or 6 months, whichever is earlier.

We also 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 LCDR James Lindsay Cobbs, Regulatory Project Manager, at (301) 827-5922.

Sincerely,

Robert J. Meyer, M.D.  
Director  
Division of Pulmonary and Allergy Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research