DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-793/S-003

O.P.R. Development, L.P.
c/o 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 application dated July 20, 2001, received July 23, 2001, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Cafcit (caffeine citrate) Injection and Oral Solution.

This "Changes Being Effected" supplemental new drug application provides for revised labeling (package insert, vial and Medi-Lock multi-vial container) for Cafcit Oral Solution.

We have completed the review of this supplemental application 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 submitted final printed labeling (package insert, vial and Medi-Lock container labels submitted July 20, 2001). Accordingly, the supplemental application is approved 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 Christine Yu, R.Ph., Regulatory Project Manager, at (301) 827-1051.

Sincerely,

{See appended electronic signature page}

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products, HFD-570
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

Marianne Mann
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