DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-304

SEP 21 2006

PharmaForce, Inc.
Attention: Marilyn A. Friedly
Director of Regulatory Affairs
960 Crupper Avenue
Columbus, OH 43229

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated September 30, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Caffeine Citrate Oral Solution USP, 20 mg/mL, packaged in 60 mg/3 mL vials.

Reference is also made to the tentative approval letter issued by this office on June 20, 2005, and to your amendments dated January 4, February 25, February 26, and June 10, 2005; and August 1, 2006.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Caffeine Citrate Oral Solution, 20 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Cafcit Oral Solution, 20mg/mL, of Mead Johnson and Company.

As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", the Orphan Drug Exclusivity provided for the listed drug product (RLD) expired on September 21, 2006.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

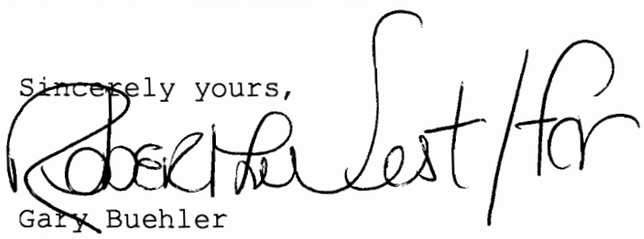
Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,



Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research