



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville, MD 20857

ANDA 90-747

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

Dear Madam:

This letter corrects our approval letter of July 31, 2009, in which your drug product was not named according to the current USP nomenclature. This letter replaces the previous letter and is backdated to the date of the original approval letter, July, 31, 2009.

This is in reference to your abbreviated new drug application (ANDA) dated July 18, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension USP, 6 mg/mL [3 mg (base)/mL and 3 mg/mL], 5 mL multiple-dose vials.

Reference is also made to your amendments dated September 8, October 18, and November 25, 2008; January 21, March 18, March 19, May 2 (2 submissions), June 12, June 22 (2 submissions), June 28, and July 13 (2 submissions), 2009.

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 Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension USP, 6 mg/mL [3 mg (base)/mL and 3 mg/mL], 5 mL multiple-dose vials to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Celestone Soluspan Injectable Suspension, 6 mg/mL, of Schering-Plough Corporation. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS, See 505-1(i).

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(s) 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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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/s/  
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SIMON S ENG  
07/30/2009

ROBERT L WEST  
07/31/2009  
Deputy Director, for Gary Buehler