



ANDA 40-583

Food and Drug Administration
Rockville MD 20857

JUL 30 2004

American Pharmaceutical Partners, Inc.
Attention: Kathleen Dungan
2045 North Cornell Avenue
Melrose Park, IL 60160

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated February 25, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Methylprednisolone Sodium Succinate for Injection USP, 40 mg (base)/vial and 125 mg (base)/vial.

Reference is also made to your amendments dated April 30, May 18, June 30, and July 30, 2004.

We note that Center Director has determined that your ANDA is for a medically necessary drug product for which a market shortage currently exists. As a result, your ANDA has been granted expedited review status.

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 your Methylprednisolone Sodium Succinate for Injection USP, 40 mg (base)/vial and 125 mg (base)/vial, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Solu-Medrol[®] for Injection, 40 mg (base)/vial and 125 mg (base)/vial, of Pharmacia and Upjohn Co.).

Under Section 506A of the Act, 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 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
Division of Drug Marketing, Advertising, and Communications,
HFD-42
5600 Fishers Lane
Rockville, MD 20857

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 (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours, 

(b)(6)

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