



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

ANDA 40-612

Food and Drug Administration  
Rockville MD 20857

AUG 12 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 June 16, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Methylprednisolone Sodium Succinate for Injection USP, 1 gram (base)/vial.

Reference is also made to your amendments dated August 2, and August 5, 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, 1 gram (base)/vial, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Solu-Medrol<sup>®</sup> for Injection, 1 gram (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