

April 26, 2001

American Pharmaceutical Partners, Inc.  
Attention: Michael Lisjak  
2045 North Cornell Avenue  
Melrose Park, IL 60160-1002

Dear Sir:

This is in reference to your abbreviated new drug application dated February 25, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Mesna Injection, 100 mg/mL (packaged in 10 mL multiple-dose vials).

Reference is also made to your amendments dated January 23, and March 8, 2001.

The listed drug referenced in your application, Mesnex Injection of Asta Pharma AG, is subject to a period of patent protection which expires on October 6, 2013 (U.S. Patent No. 5,696,172). We note that required information concerning this patent was not submitted to the agency in a timely manner as required under 21 CFR 314.94(a)(12)(vi). Therefore, American Pharmaceutical Partners, Inc. is not required to submit an amended patent certification to address this patent.

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 Mesna Injection, 100 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Mesnex<sup>®</sup> Injection, 100 mg/mL, of Asta Pharma AG).

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.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Validation of the regulatory methods has not been completed. It is the policy of the Office not to withhold approval until the validation is complete. We acknowledge your commitment to satisfactorily resolve any deficiencies, which may be identified.

Sincerely yours,

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