CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-278

APPROVAL LETTER

ANDA 75-278

JUL 23 2001

Mylan Pharmaceuticals, Inc.
Attention: Frank R. Sisto
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your abbreviated new drug application dated December 19, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Paclitaxel Injection, 6 mg/mL, (packaged in 30 mg/5 mL, 100 mg/16.7 mL, and 300 mg/50 mL multiple-dose vials).

Reference is also made to the Tentative Approval letter issued by this office September 19, 2000, and to your amendments dated May 11, May 14, May 22, May 23, May 30, June 12, and June 14, 2001.

The listed drug product referenced in your application, Taxol Injection of Bristol Myers Squibb Co. Pharmaceutical Research Institute, is subject to a period of patent protection which expires on August 3, 2012, (U.S. Patent No. 5,641,803 [the '803 patent] and U.S. Patent No. 5,670,537 [the '537 patent]). Your application contains a patent certification under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of Paclitaxel Injection will not infringe on the '803 or '537 patents. Your application also contains a patent statement under Section 505(j)(2)(A)(viii) of the Act indicating that U.S. Patent No. 5,496,804 [the '804 patent] and U.S. Patent No. 6,150,398 [the '398 patent] are method of use patents, and these patents do not claim any of the proposed indications for which you are seeking approval. You have informed the Agency that Mylan Pharmaceuticals, Inc. has complied with the requirements of Section 505(j)(2)(B) of the Act and that Bristol Myers Squibb Co. Pharmaceutical Research Institute initiated a patent infringement suit against you in the United States District Court for the District of New Jersey with respect to

the '803 and '537 patents (Bristol Myers Squibb Company v. Mylan Pharmaceuticals, Inc., Civil Action No. 98-1488).

With regard to the litigation, the Agency recognizes that the 30-month period identified in Section 505(j)(5)(B)(iii) of the Act during which time FDA is precluded from approving your application, has expired.

Please see the accompanying letter for a description of FDA's resolution of issues related to U.S. Patent Number 6,096,331.

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 Paclitaxel Injection, 6 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Taxol® Injection, 6 mg/mL, of Bristol Myers Squibb Co. Pharmaceutical Research Institute).

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.

Sincerely yours,

/S/

Gary Buehler 7/23/01
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL