

ANDA 75-467

December 28, 1999

Par Pharmaceutical, Inc.
Attention: Michelle Bonomi-Huvala
One Ram Ridge Road
Spring Valley, NY 10977

Dear Madam:

This is in reference to your abbreviated new drug application dated September 29, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Bupirone Hydrochloride Tablets USP, 5 mg, 7.5 mg, 10 mg, and 15 mg.

Reference is also made to your amendments dated November 9 (2 amendments), December 9, and December 18, 1998; and February 11, April 9, October 8, October 26, November 19, and December 20, 1999.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacturing and testing of the drug product), and is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product (RLD) referenced in your application, BuSpar Tablets of Bristol Myers Squibb Co. Pharmaceutical Research Institute, is subject to periods of patent protection which expire on May 22, 2000, (patent 4,182,763, the '763 patent) and May 14, 2008, (patent 5,015,646, the '646 patent). Your application contains a Paragraph IV Certification to the

'646 patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your commercial manufacture, use, or sale of this drug product will not infringe on this patent. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified the agency that Par Pharmaceutical, Inc. (Par) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for infringement against the '646 patent was brought against Par within the statutory forty-five day period. In addition, your application contains a Paragraph III Certification to the '763 patent under Section 505(j)(2)(A)(vii)(III) of the Act. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the '763 patent has expired, i.e., currently May 22, 2000.

Because the agency is granting a tentative approval for this application, please submit an amendment to this application at least 60 days (but not more than 90 days) prior to the expiration of the '763 patent. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved and should include updated information such as final-printed labeling (to include appropriate changes made to the labeling of the RLD), as well as updated chemistry, manufacturing, and controls data as appropriate. The amendment serves to reactivate this application prior to final approval, and should be submitted even if none of these changes were made. This submission should be clearly designated as a MINOR AMENDMENT in your cover letter. In addition to, or instead of, the amendment requested above, the Agency may request that you submit a similar amendment at any time prior to the final date of approval.

Failure to submit such an amendment requested by the Agency will prompt a review of the application which may result in rescission of this tentative approval letter.

Any significant change in the conditions outlined in this abbreviated application requires Agency approval before the change may be made effective.

Prior to the issuance of a final approval letter by the

Agency, your product will not be deemed approved for marketing under

21 U.S.C. 355 and not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to the expiration of the '763 patent on May 22, 2000, you should amend your application accordingly.

Prior to submitting an amendment, please contact Ms. Elaine Hu, R.Ph., Project Manager, at (301)827-5848, for further instructions.

The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under 21 U.S.C. 311(d).

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and

Research

