ANDA 75-467/S-004, S-005 February 28, 2002

Par Pharmaceutical, Inc.
Attention: Janis A. Picurro
One Ram Ridge Road
Spring Valley, NY 10977

Dear Madam:

This is in reference to your supplemental abbreviated new drug applications (SANDAs) dated August 27, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), regarding your abbreviated new drug application for Buspirone Hydrochloride Tablets USP, 5 mg, 7.5 mg, 10 mg, and 15 mg.

Reference is also made to our Tentative Approval letters dated December 28, 1999,May 23, 2000, and to our approval letter dated March 28, 2001, for the 7.5 mg strength only. We also refer to your amendment dated February 15, 2002.

These supplemental applications dated August 27, 201, provide for the following:

S-004 Revised final-printed labeling incorporating additional drug product strengths of 5 mg, 10 mg, and 15 mg, and appropriate pediatric use statement; and

S-005 Additional drug product strengths of 5 mg, 10 mg, And 15 mg.

The listed drug product (RLD) referenced in your application, BuSpar Tablets of Bristol Myers Squibb Company Pharmaceutical Research Institute (Bristol Myers Squibb), is subject to a period of patent protection which will expire on November 14, 2008 (U.S. Patent No. 5,015,646 (the ‘646 patent). Your application contains a patent certification to this patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on the ‘646 patent. Section 505(j)(5)(B)(iii) of the Act

provides that approval of an ANDA shall be made effective immediately unless an action is brought for infringement of the '646 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 FDA that Par Pharmaceutical, Inc. (Par) has complied with the requirements of Section 505(j)(2)(B) of the Act, and that no action for patent infringement against the '646 patent was brought against Par within the statutory forty-five day period.

We also note that Bristol Myers Squibb, holder of the NDA for BuSpar Tablets, has informed the agency that it will not enforce any exclusivity rights to pediatric use information against ANDA applicants that seek to include such information in their labeling for this drug product.

Furthermore, the agency's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations", (the "Orange Book"), reveals that 180-day generic drug exclusivity previously granted to Danbury Pharmacal, Inc. for the 5 mg and 10 mg strengths of the drug product and to Mylan Pharmaceuticals, Inc. for the 15 mg strength of the drug product expired on September 26, and September 24, 2001, respectively.

We have completed the review of theie supplemental abbreviated applications and have concluded that the additional 5 mg, 10 mg, and 15 mg strengths of the drug product are safe and effective for use as recommended in the submitted labeling. Accordingly, the supplemental applications are approved. The Division of Bioequivalence has determined your Buspirone Hydrochloride Tablets USP, 5 mg, 10 mg, and 15 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug BuSpar® Tablets, 5 mg, 10 mg, and 15 mg, respectively, of Bristol Myers Squibb Company Pharmaceutical Research Institute). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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 that you intend to use in your initial advertising or promotional campaigns for the newly approved strengths. 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.

The materials submitted are being retained in our files.

Sincerely yours,

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