ANDA 74-253/S-001, S-002 March 13, 2002

Watson Laboratories, Inc.
Attention: Ernest E. Lengle
311 Bonnie Circle
Corona, CA 92880

Dear Sir:

This is in reference to your supplemental new drug applications dated July 11, 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, 10 mg, and 15 mg.

Reference is also made to our letter issued on March 28, 2001 for the tentative approval of the 15 mg strength and approval of the 5 mg and 10 mg strengths and to your amendment dated February __, 2002.

These supplemental applications provide for the final approval of the 15 mg strengths and the following changes:

S-001: Control Revision

S-002: Labeling

The listed drug product (RLD) referenced in your application, BuSpar Tablets of Bristol Myers Squibb Company Pharmaceutical Research Institute, 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 Watson Laboratories, Inc. (Watson) 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 Watson within the statutory forty-five day period.

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 Mylan Pharmaceuticals, Inc. for the 15 mg strength of the drug product expired on September 24, 2001.

We have completed the review of these supplemental abbreviated applications and have concluded that the 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 BMS). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

We remind you that you must comply with the requirements for an approved abbreviated application described 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. 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 material submitted is being retained in our files.

Sincerely yours,

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