DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-731/S-046

Bristol-Myers Squibb Company
Attention: Michael Eison, Ph.D.
Director, Regulatory Science
5 Research Parkway
Wallingford, CT 06492

Dear Dr. Eison:

Please refer to your supplemental new drug application dated November 15, 2000, received June 15, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BuSpar® (buspirone HCl) Tablets.

We refer to our December 17, 2001, communication, your January 15, 2002, correspondence, and to our January 30, 2002, communication.

This supplemental new drug application provides for the following addition to the labeling about concomitant dosing with nefazodone tablets under PRECAUTIONS 'Drug Interactions''Nefazodone':

> *'Subjects receiving buspirone 5 mg b.i.d. and nefazodone 250 mg b.i.d. experienced lightheadedness, asthenia, dizziness, and somnolence, adverse events also observed with either drug alone. If the two drugs are to be used in combination, a low dose of buspirone (eg, 2.5 mg q.d.) is recommended. Subsequent dose adjustment of either drug should be based on clinical assessment.'*

We also refer to your February 4, 2002, communication indicating agreement with the language proposed in our January 30, 2002, communication.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon attached labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

We also refer to our July 19, 2001, approval letter for S-043 which incorporated all of the recent labeling changes for BuSpar® Tablets. These recent approved changes are also reflected in the attached labeling.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-731/S-046." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you should have any questions, please call Ms. Anna Marie Homonnay, R.Ph., Regulatory Project Manager, at (301) 594-5535.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz

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