DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-731/S-043

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

Dear Dr. Eison:

Please refer to your supplemental new drug application dated March 20, 2000, received March 21, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BuSpar® (buspirone hydrochloride) Tablets.

We acknowledge receipt of your submission dated April 3, 2001, which constituted a complete response to our January 18, 2001 action letter.

Further reference is made to the March 1, 2001, teleconference between FDA and Bristol-Myers Squibb regarding the proposed pediatric labeling for BuSpar® Tablets.

This supplemental new drug application provides for new language for pediatric use.

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 enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) which was approved on May 3, 2001, for S-045 and S-039 including the newly approved pediatric use language provided for in this supplement (S-043). Also included are the minor changes listed in your May 11, 2001, facsimile.

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-043." 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 have any questions, call Ms. Anna Marie Homonnay, R.Ph., Regulatory Health 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

Enclosure