DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-152/S-031

Bristol-Myers Squibb Company
Attention: Charles D. Wolleben, Ph.D.
Director Regulatory Science
Five Research Parkway, P.O. Box 5100
Wallingford, CT 06492-7660

Dear Dr. Wolleben:

Please refer to your supplemental new drug application dated January 29, 2002, and received on January 31, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Serzone (nefazodone hydrochloride) 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg Tablets.

Reference is also made to Agency action letters dated April 26, 2002, and August 29, 2002.

We acknowledge receipt of your submissions dated October 29, 2002, and December 30, 2002. Your submission of October 29, 2002 constituted a complete response to our August 29, 2002 action letter.

This "Prior Approval" supplemental new drug application provides for a response to Agency requests related to twenty-three medication error reports involving confusion between Serzone and Seroquel (quetiapine fumarate) tablets and your efforts to disseminate the message regarding name confusion between Serzone and Seroquel. Your efforts included revisions to the Patient Information section of the Serzone labeling, product container revisions, dissemination of a "Dear Healthcare Practitioner" letter, an ongoing evaluation of the name confusion, and additional efforts to rectify this problem.

We have completed the review of this supplemental application, S-031, 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 submitted final printed labeling (package insert submitted October 29, 2002/Label Code 1143332A2), which incorporates all of the labeling revisions listed above. Accordingly, this supplemental application is approved effective on the date of this letter.

However, please note that there are some issues that will need to be addressed in an ongoing fashion as well as some additional modifications which we believe would assist in this name confusion issue. They are as follows:

1. In the next printed labeling, in the Patient Information leaflet section where the appearance of the pill strengths is listed, the color of each tablet strength and the number on the tablet corresponding to the dose should be bolded or underlined. For example, **"50 mg** tablets are six-sided light pink tablets imprinted with "BMS" and "50" on one face of the tablet." This revision can be reported in your next annual report.

2. We note that you intend to provide the Agency with reports on newly occurring medication errors. Your proposal to submit these reports on a quarterly basis instead of a monthly basis, as requested by the Agency, is acceptable. Please submit these reports in a timely fashion to the Serzone NDA.

3. We note that you intend to conduct an evaluative survey of the educational plan. Please provide the Agency with the survey that you plan to use to measure prescriber awareness of the Serzone-Seroquel name confusion issue prior to implementing this program. The Agency will provide you with feedback on the survey in a timely fashion.

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 Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

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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