DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-152/S-034

Bristol-Myers Squibb Company
Attention: Charles Wolleben, Ph.D.
Director, Global Regulatory Strategy
Five Research Parkway
Wallingford, CT 06492

Dear Dr. Wolleben:

We acknowledge receipt of your supplemental new drug application dated May 14, 2004, 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.

Supplemental application S-034, submitted under "Changes Being Effected", provides for the following changes to product labeling as requested in our Agency letter dated March 19, 2004, and revised in an electronic communication to you from Paul David, of this office, on April 19, 2004:

1. The addition of a new subsection under **WARNINGS** entitled **Clinical Worsening and Suicide Risk**.
2. Revisions to the **PRECAUTIONS-Information for Patients** section.
3. Delete the section in **PRECAUTIONS-General** entitled “Suicide”.
4. Add a reference to the **WARNINGS** section at the end of the **PRECAUTIONS- Pediatric Use** section, i.e., (see **WARNINGS-Clinical Worsening and Suicide Risk**).

This supplemental application also provides for revisions to the **INDICATIONS AND USAGE** and **DOSAGE AND ADMINISTRATION** sections to discourage use of Serzone as a first line drug. These revisions were requested by the Agency in a conference call with you held on April 15, 2004.

We have completed the review of this supplemental application, S-034, 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 dated May 14, 2004, which incorporates all of the revisions listed above. Accordingly, this supplemental application is approved effective on the date of this letter.

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 Mr. 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
5/27/04 08:06:14 AM