NDA 20-152/S-011

Bristol-Myers Squibb Company
Attention: Jay K. Gunther, Ph.D.
5 Research Parkway
P.O. Box 5100
Wallingford, Connecticut 06492-7660

MAR 31 1998

Dear Dr. Gunther:

Please refer to your March 31, 1997, supplemental new drug application (NDA) for Serzone (Nefazodone Hydrochloride) tablets.

We also acknowledge receipt of your additional communications dated June 4, 1997, March 18, March 27, and March 30, 1998.

Reference is also made to conference calls between representatives from Bristol-Myers Squibb (BMS) and the Agency dated March 25, and 31, 1998.

The User Fee goal date for this application is April 2, 1998.

Supplemental application S-011 provides clinical data supporting the use of Serzone for the maintenance treatment of depression and in the treatment of depressed inpatients.

We have completed our 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 enclosed marked-up draft labeling (see ATTACHMENT). Accordingly, this supplemental application is approved effective on the date of this letter.

Labeling

The labeling accompanying this letter should be used for marketing this drug product. This final labeling is based on an Agency telefacsimiles sent to each other dated March 30, 1998. We note your agreement to the Agency's proposed labeling, except for minor revisions, in a telephone conversation dated March 31, 1998, between representatives from BMS and the Agency. For convenience, all labeling changes made since the approval of your last labeling supplement (S-012, Label Code - 0039DIM-01/51-006377-00) appear as shaded text (redlined) in the attached labeling.

The final printed labeling (FPL) must be identical to the enclosed marked-up draft labeling. These revisions are terms of the supplemental NDA approval. Marketing the product before making the agreed upon revisions in the product's labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the printed labeling, ten of which are individually mounted on heavy-weight paper or similar material.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

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, please contact Mr. Paul David, Project Manager, at (301) 594-5530.

Sincerely yours,

3/31/98

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

ATTACHMENT