NDA 20-152/S-026

Bristol-Myers Squibb Company
Attention: Ronald Marcus, M.D.
Group Director, Regulatory Science
Five Research Parkway
Wallingford, CT 06492

21 MAR 2001

Dear Dr. Marcus:

Please refer to your supplemental new drug application dated February 26, 2001, 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-026, submitted under "Changes Being Effected", provides for the addition of the terms “hyponatremia” and “thrombocytopenia” under the **ADVERSE REACTIONS-Postintroduction Clinical Experience** section of labeling.

We have completed the review of this supplemental application, S-026, 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 February 26, 2001/Label Code1092982A8), which incorporates all of the revisions listed. Accordingly, this supplemental application is approved effective on the date of this letter.

Labeling changes of the kind which you have proposed under the above supplemental application are permitted by section 314.70(c) of the regulations to be instituted prior to approval of the supplement. It is understood that the changes, described in the above NDA supplement, have been made.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" 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 Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

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