NDA 20-152/S-029

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

Dear Dr. Marcus:

We acknowledge receipt of your supplemental new drug application dated December 6, 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-029, submitted under "Changes Being Effected", provides for revisions to the prescriber labeling regarding Serzone and hepatic failure to incorporate a patient package insert and a "Dear Healthcare Practitioner" letter as agreed upon between you and the Agency on November 27, 2001.

We have completed the review of this supplemental application, S-029, 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 December 6, 2001/Label Code 1143332), 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

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