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RESEARCH**

APPLICATION NUMBER: 20-152/S-009/S-010

APPROVAL LETTER

MAY 5 1997

NDA 20-152/S-009/S-010

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

Dear Dr. Gunther:

Please refer to your supplemental New Drug Applications dated November 20, 1996 (S-009) and November 21, 1996 (S-010) for Serzone (Nefazodone Hydrochloride) tablets.

Reference is also made to an Agency unacceptable letter for S-010 dated January 31, 1997, and to a conference call between the Agency and yourself dated February 13, 1997, discussing the issues submitted in S-009.

We acknowledge receipt of your two amendments both dated April 10, 1997, submitted to supplements S-009 and S-010, providing for alternative labeling.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in your draft labeling. Accordingly, these supplemental applications are approved effective on the date of this letter.

The supplemental applications referenced above provide for labeling revisions as listed below:

S-009

The revision of the **CONTRAINDICATIONS** and the **WARNINGS** sections to include and/or modify the safety concerns associated with the concomitant use of triazolam and nefazodone.

S-010

The revision to the Seizures and Priapism subsections under the **PRECAUTIONS** section, and the addition of a new subsection entitled Postintroduction Clinical Experience under the **ADVERSE REACTIONS** section to list the terms seizures and priapism.

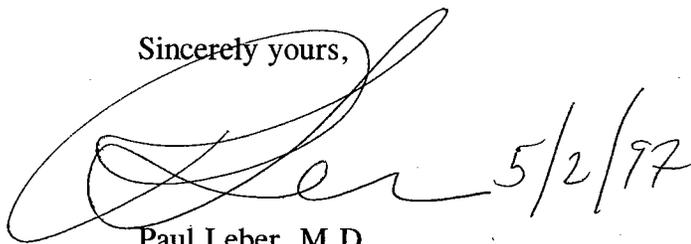
Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED

LABELING" for approved supplemental NDAs 20-152/S-009/S-010. Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Should you have any questions concerning this NDA, please contact Mr. Paul A. David, Project Manager, at (301) 594-5530.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Paul Leber", followed by the date "5/2/97". The signature is written in a cursive style.

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

cc:

NDA ORIG 20-152

HFD-120/DIV File

HFD-120/PLeber/TLaughren/EHearst

HFD-120/PDavid

DISTRICT OFFICE

HF-2/Medwatch (with labeling)

HFD-92/DDM-DIAB (with labeling)

HFD-40/DDMAC (with labeling)

HFD-613/OGD (with labeling)

HFD-735/DPE (with labeling)

HFI-20/Press Office (with labeling)

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APPROVAL (AP)

5-2-97

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