CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-152/S-026

MEDICAL REVIEW

Review and Evaluation of Clinical Data

NDA:	20-152
DRUG:	SERZONE (Nefazodone HCI) Tablets
SPONSOR:	Bristol-Myers Squibb
COOERSPONDANCE DATE:	2-26-2001
DATE RECEIVED:	2-27-2001
SUBMISSION NO.	205, Changes Being Effected

I. REVIEW:

Pursuant to 21 CFR 314.70 the sponsor submits a supplement application that revises the labeling for SERZONE Tablets to provide prescribers with new information regarding nefazodone. They have also incorporated into this supplement additional postmarketing reports of adverse experiences including hyponatremia and thrombocytopenia as "changes being affected". In addition, minor formatting changes were made to the label.

As part of their ongoing review of the Bristol-Myers Squibb worldwide safety database for nefazodone, they have identified the following as adverse events that should be listed in the Postintroduction Clinical Experience subsection of the ADVERSE REACTIONS section of labeling: hyponatremia and thrombocytopenia. See below and in attachment to this review.

Postintroduction Clinical Experience

Anaphylatic reactions; angioedema; convulsions (including grand mal seizures); galactorrhea; gynecomastia (male); hyponatremia; liver necrosis and liver failure, in some case leading to liver transplantation and or death; priapism (see **PRECAUTIONS**); prolactin increased; rhabdomyolisis involving patients receiving the combination of SERZONE and lovastatin or simvastain (see **PRECAUTIONS**); serotonin syndrome; Stevens-Johnson syndrome; and thrombocytopenia.

II. RECOMMEDATION:

I recommend that these changes be accepted.

Earl D. Hearst, M.D.
Medical Reviewer
HFD-120
cc:file\tlaughren\ehearst\pdavid

/s/

Earl Hearst
3/13/01 01:20:51 PM
MEDICAL OFFICER

Thomas Laughren
3/13/01 03:02:27 PM
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I agree that these changes can be approved.--TPL