

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER: 20-152/S-026**

**ADMINISTRATIVE DOCUMENTS**

**REGULATORY PROJECT MANAGER  
LABELING REVIEW**

Review Date: March 16, 2001  
NDA: 20-152  
Sponsor: Bristol-Myers Squibb (BMS)  
DRUG: Serzone (nefazodone hydrochloride) 50 mg, 100 mg, 150 mg, 200 mg, and  
250 mg Tablets  
Supplements: SLR-026 dated 2-26-01

**Notes of interest:**

- The last approved labeling (Label Code 1092982A7) was submitted with SLR-025 which was approved in an Agency letter dated 1-23-01.

**REVIEW**

**20-152/SLR-026**

Dated: 2-26-01

CBE: Yes

Label Code:1092982A8

Reviewed by Medical Officer: Yes, acceptable.

The supplement provides for the addition of the terms "hyponatremia" and "thrombocytopenia" under the **ADVERSE REACTIONS-Postintroduction Clinical Experience** section of labeling.

The supplement also provides for several minor editorial revisions which are outlined in Attachment 1 of the sponsor's submission.

**CONCLUSIONS**

1. This supplement only provides for the labeling revisions listed above.
2. The medical officer concurs with the revisions provided for in the application
3. I recommend that an approval letter issue for SLR-026.

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Paul David, RPh  
Regulatory Project Manager

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John Purvis  
Supervisory Consumer Safety Officer

/s/

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Paul David  
3/20/01 01:47:12 PM  
CSO

Robbin Nighswander  
3/21/01 03:01:59 PM  
CSO  
Signed for Jack Purvis, SCSO.