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RESEARCH**

APPLICATION NUMBER:

20-152/ S-031

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

**REGULATORY PROJECT MANAGER
LABELING REVIEW**

Review Date: April 4, 2003
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-031 dated 1-29-02, and amended on 6-21-02, 10-29-02, and 12-30-02

Notes of interest:

- The last approved prescriber labeling (Label Code 1143332) was submitted as SLR-033 which was approved in an Agency letter dated 6-20-02.
- The Agency took 2 AE actions on SLR-031 in letters dated 4-26-02 and 8-29-02

REVIEW

20-152/SLR-031

Dated: 10-29-02 and amended on 12-30-02
CBE: No, Prior Approval
Label Code: 1143332A2
Reviewed by Medical Officer: Yes, acceptable.

The supplement provides for a response to Agency related requests in regard to twenty-three medication error reports involving confusion between Serzone and Seroquel (quetiapine fumarate) tablets and BMS's efforts to disseminate the message regarding name confusion between Serzone and Seroquel. These items included revisions to the Patient Information section of the Serzone labeling, product container revisions, dissemination of a "Dear Healthcare Practitioner" letter, an ongoing evaluation of the name confusion, and additional efforts to rectify this problem.

CONCLUSIONS

1. This supplement only provides for the labeling revisions listed above. The medical officer concurs with the revisions provided for in the application.
2. I recommend that an approval letter issue for SLR-031.

{See appended electronic signature page}

Paul David, R.Ph
Senior Regulatory Project Manager

{See appended electronic signature page}

Robbin Nighswander, R.Ph
Supervisory Regulatory Health Officer

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/s/

Paul David
4/10/03 01:06:29 PM
CSO

Robbin Nighswander
4/10/03 01:11:10 PM
CSO