CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-822/S-019
21-046/S-003

ADMINISTRATIVE DOCUMENTS

REGULATORY PROJECT MANAGER
LABELING REVIEW

Celexa (citalopram Hydrobromide) Tablets (NDA 20-822)
Celexa (citalopram Hydrobromide) Oral Solution (NDA 21-046)

Date:	October 25, 2002	
DRUG:	**Celexa Tablets (NDA 20-822)**	**Celexa Solution (NDA 21-046)**
Supplements:		
(last approved)	SLR-011 (AP letter dated 6-27-01)	Original NDA AP date 12-22-99
(pending action)	SLR-019 (dated 9-30-02)	SLR-003 (dated 9-30-02)

Notes of interest:

- Since Celexa Tablets and Celexa Solution share the same product labeling, this labeling review will incorporate both of these products.
- The last approved FPL was for Label Code 13940-13. An acknowledge and retain letter issued on 4-17-02.
- Lexapro (escitalopram oxalate) tablets (NDA 21-323), which is the enantiomer of citalopram HBr, was issued an approvable letter on 1-23-02 and was subsequently approved on 8-14-02.
- The AE labeling for Lexapro incorporated the **Other Events Observed During the Non-US Postmarketing Evaluation of Celexa (citalopram HBr)** section of the Celexa labeling, and we requested that the sponsor update this section to include more recently reported adverse events, both US and Non-US, for Celexa.
- The sponsor updated this section in their complete response to the Lexapro AE letter, and we found it acceptable. Therefore, an AP letter issued for the Lexapro NDA on 8-14-02.

REVIEW

20-822/SLR-019
21-046/SLR-003
Dated: 9-30-02
CBE: Yes
Label Code: 13940-14
Reviewed by Medical Officer: No

The supplement provides for revisions to the **ADVERSE REACTIONS-Other Events Observed During the Postmarketing Evaluation of Celexa (citalopram HBr)** section of labeling in order to make it more consistent with the Lexapro (escitalopram oxalate) labeling, NDA 21-323.

Additional Notes Of Interest

- The revisions of the adverse event terms in this section are identical to the adverse event terms approved in the Lexapro application, NDA 21-323, except that the sponsor has now added the terms "chest pain".
- The sponsor has deleted the reference that "approximately 8 million people have been treated with Celexa" and changed it to "over 30 million people have been treated with Celexa".

- The sponsor has added the following caveat, at the end of the second sentence "… and have not been described elsewhere in labeling.".

CONCLUSIONS

1. The supplements only provide for the labeling revisions as listed above when compared to the last approved FPL.
2. Although the sponsor has slightly revised the title of this subsection by deleting the terms "Non-US", this is acceptable since this section is applicable to reports obtained from both US and Non-US reported events.
3. The other minor modifications to this section of labeling should be reviewed by the medical officer.
4. If the medical officer concurs with these changes, I recommend that an approval letter issue.

Paul David. RPh
Senior Regulatory Project Manager

Robbin Nighswander, R.Ph
Supervisory Regulatory Health Officer

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Paul David
10/29/02 07:54:55 AM
CSO

Robbin Nighswander
10/29/02 11:53:19 AM
CSO