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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-710

Pharmacology Review(s)

November 29, 2004

Review and Evaluation of Pharmacology and Toxicology
NDA Labeling Review

NDA: NDA 21-710

Sponsor: Shire
Rockville, MD

Submission
Date: February 13, 2004

Drug: SPD417 (carbamazepine extended-release capsules)

Indication: Bipolar disorder

Evaluation and Recommendations:

The sponsor has proposed new language for the clinical pharmacology section of the label based on a review of the open literature, since the current carbamazepine labeling is inappropriate for the new indication. The following changes are recommended:

Mechanism of Action

The [mechanism(s) of action of carbamazepine in the treatment of bipolar disorder has not been elucidated.

Numerous pharmacological effects of carbamazepine have been described in the published literature.

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[

] The contribution of these effects to the efficacy of carbamazepine in bipolar disorder is unknown.

cc:
NDA (21-710)
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J.E. Fisher, Ph.D.

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/s/

Edward Fisher
12/2/04 02:31:18 PM
PHARMACOLOGIST