CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-285

PHARMACOLOGY REVIEW(S)

September 14, 2008

Review and Evaluation of Pharmacology and Toxicology
Original NDA Review

NDA: 22-285

Sponsor: UCB
Smyrna, GA

Rec'd: 11/13/07

Drug: Keppra XR (levetiracetam) extended release tablet

Indication: Epilepsy

Related NDA: NDA 21-035 (Keppra Tablet)

Summary and Evaluation:

No pharmacology or toxicology studies were submitted to this NDA for an extended release form of levetiracetam, which relies on preclinical data previously submitted for the IR tablet (NDA 21-035), oral solution (21-505), and injection (21-872). The basis for approval are a safety and efficacy study (N01235) of the extended release tablet (500 mg) as adjunctive therapy in the treatment of partial onset seizures in patients [redacted] years of age and older with epilepsy, and two PK studies (N01260 and N01160) intended to show dose proportionality and bioequivalence of the XR and IR tablets. There are no unusual excipients or new degradation products in the XR formulation and no additional safety concerns associated with the dosage form. Therefore, the pharmacology/toxicology data submitted by UCB to the previous NDAs support approval of the XR tablet for the same indication.

b(4)

NDA (22-285)
Div File
HFD-120/LFreed/EFisher/SDaugherty

J. E. Fisher, Ph.D.

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