CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-285

PHARMACOLOGY REVIEW(S)

May 18, 2001

Review and Evaluation of Pharmacology and Toxicology
Original NDA Review

NDA: 21-285

Sponsor: Novartis Pharmaceuticals
East Hanover, NJ

Rec'd: 7/28/00

Drug: Trileptal (oxcarbazepine) Oral Suspension

Indication: Epilepsy

Related NDA: NDA 21-014 (Trileptal tablets)

Summary and Evaluation:

This NDA for an oral suspension of oxcarbazepine relies on preclinical data previously submitted for the tablet. There appear to be no additional safety concerns associated with the new dosage form. The excipients are acceptable and there are no new degradation products in the suspension formulation. The specification limits are very similar and the maximum dose is the same for both formulations. Therefore, the pharmacology/toxicology data submitted by Novartis to the previous NDA for oxcarbazepine tablets support approval of the oral suspension for the same indication.

NDA (21-285)
Div File
HFD-120/BRosloff/EFisher/MFanari

/S/
E. Fisher, Ph.D.

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