

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**20-782**

**PHARMACOLOGY REVIEW**

April 24, 1998

REVIEW AND EVALUATION OF PHARMACOLOGY AND TOXICOLOGY DATA  
Original Summary

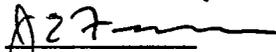
NDA: 20-782  
REC'D: 6/16/97  
SPONSOR: Abbott Laboratories  
DRUG: Divalproex Sodium (Depakote) tablets  
CATEGORY: Antiepileptic

EVALUATION and RECOMMENDATION:

No preclinical pharmacology/toxicology studies were submitted to this NDA for a new formulation of Depakote, and there are no unusual excipients in the new formulation. The pharmacology/toxicology data submitted by Abbott to previous NDAs for sodium valproate (NDA 18-081, Depakene) support approval of the dosage form and no additional studies are needed.

cc: NDA 20-782  
HFD-120  
HFD-120/GFitzgerald/EFisher/JWare

*Rec'd 5/11/98  
ggf*

  
E. Fisher, Ph.D.

APPEARS THIS WAY  
ON ORIGINAL