Application Number 21-129

PHARMACOLOGY REVIEW(S)

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: March 1, 2000

FROM: Glenna G. Fitzgerald, Ph.D. 3/1/00
Pharmacology Team Leader
Division of Neuropharmacological Drug Products, HFD-120

TO: NDA 21-129
Neurontin (gabapentin) oral solution
Sponsor: Parke Davis Pharmaceutical Research

SUBJECT: Approvability

There were no preclinical studies submitted to this NDA for a new formulation for Neurontin and there are no unusual excipients in the new formulation. The pharmacology and toxicology studies submitted to NDA 20-235 for Neurontin capsules support approval of the oral solution dosage form and no additional studies are needed.

APPEARS THIS WAY
ON ORIGINAL

cc:
NDA 21-129
HFD-120 Division File
HFD-120/Fitzgerald/Fisher/Ware

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