

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-129

MICROBIOLOGY REVIEW(S)

REVIEW FOR HFD-120
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA

August 16, 1999

A. 1. NDA 21-129

SPONSOR Parke-Davis
P.O. Box 4119
Vega Baja
Puerto Rico, 00694-4119

2. PRODUCT NAMES: Neurontin® (Gabapentin) _____

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 250 mg/5 mL, _____, Oral

4. METHOD(S) OF STERILIZATION (_____)

5. PHARMACOLOGICAL CATEGORY: Anti-convulsant

6. DRUG PRIORITY CLASSIFICATION: 3/S

B. 1. DATE OF INITIAL SUBMISSION: April 30, 1999

2. DATE OF AMENDMENT: NA

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: July 6, 1999

C. REMARKS: The drug product must meet microbial limit specifications as well as satisfying the acceptance criteria for the Antimicrobial Effectiveness Test.

D. CONCLUSIONS: This submission is recommended for approval from the standpoint of product quality microbiology.

/S/

8-16-99

Bryan Riley, Ph.D.

cc: Original NDA 21-129
HFD 120/Consult File
HFD 120/Ware
HFD 120/Rzeszotarski
HFD 805/Consult File
HFD 805/B. Riley

APPEARS THIS WAY
ON ORIGINAL

Drafted by: B. Riley, 8/16/99
R/D initialed by: P. Cooney,

/S/ for

PHC

8-27-99

APPEARS THIS WAY
ON ORIGINAL

(B)

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RELEASABLE**

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