

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-285

MICROBIOLOGY REVIEW(S)

Review for Division of Neuropharmacological Drug Products, HFD-120
Office of New Drug Chemistry, Microbiology Staff, HFD-805
Microbiologists's Review No. 1

May 15, 2001

Review Microbiologist: Carol K. Vincent

A. 1. NDA No.: 21-285

PRODUCT NAME: Trilipal® [oxcarbazepine] Oral Suspension

APPLICANT: Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, NJ 07936-1080

2. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Preserved liquid, oral.

3. METHOD(s) OF STERILIZATION: Non-sterile product for oral administration.

4. PHARMACOLOGICAL CATEGORY AND / OR PRINCIPAL INDICATION:

Trilipal® [oxcarbazepine] Oral Suspension is "indicated for use as monotherapy or adjunctive therapy in the treatment of partial seizures in adults with epilepsy and as adjunctive therapy in the treatment of partial seizures in children ages 4 - 16 with epilepsy [p 2-10].

5. DRUG PRIORITY CLASSIFICATION: Standard

B. 1. DOCUMENT DATE: July 28, 2000

2. CONSULT REQUEST DATE: March 8, 2001

3. DOCUMENT RECEIVED FOR CONSULT REVIEW: March 27, 2001

4. AMENDMENT DATE: April 18, 2001

C. REMARKS: This is a consultative Microbiology review for the Microbial Limits and Preservative Effectiveness data only.

D. CONCLUSION and RECOMMENDATION: We recommend approval for microbiological quality, *provided the applicant commits to continue on a post-approval basis microbiological limits testing at each lot's release and throughout the stability protocol.*

E. See "E. REVIEW NOTES:" and Draft of Letter to Applicant, below.

Orig. NDA 21-285
HFD-120/Christodoulo/Fanari
HFD-160/Consult file/CK Vincent
Drafted by: CK Vincent/03-29-2001
Revised by: CK Vincent/05-15-01
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Carol K. Vincent
Reviewing Microbiologist, HFD-805

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/s/

Carol Vincent
5/16/01 02:02:49 PM
MICROBIOLOGIST

Peter Cooney
5/16/01 02:26:29 PM
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**APPEARS THIS WAY
ON ORIGINAL**

**THIS SECTION
WAS
DETERMINED
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3 pages