

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number NDA 50-777

MICROBIOLOGY REVIEW(S)

REVIEW FOR HFD-540

OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review # 1 of NDA 50-777

May 2, 2000

MAY 5 2000

- A. 1. APPLICATION NUMBER: NDA 50-777
- APPLICANT: Fujisawa Healthcare, Inc.
3 Parkway North Center
Deerfield, IL 60015-2548
(tel) 847-317-8872
2. PRODUCT NAME: PROTOPIC®
3. DOSAGE FORM: Tacrolimus ointment (0.03% and 0.1%) in 30g and 60g laminate tubes. For topical administration.
4. METHOD OF STERILIZATION: None (non-sterile product).
5. PHARMACOLOGICAL CATAGORY and/or PRINCIPLE INDICATION:
Macrolide immunosuppressant indicated for short and long-term treatment of the signs and symptoms of atopic dermatitis.
- B. 1. DATE OF INITIAL SUBMISSION: 9/8/99
2. DATE OF CONSULT: 10/13/99
3. ASSIGNED FOR REVIEW: 10/28/99
- C. REMARKS: Phase I and II studies were conducted using drug product manufactured in _____ The new Grand Island, NY manufacturing facility was constructed to produce drug product for Phase II and commercial batches.

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ON ORIGINAL

D. CONCLUSIONS:

The application is recommended for approval for issues concerning product quality microbiology. Specific comments are provided in section "E. REVIEW NOTES".

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ON ORIGINAL

/S/ 5/2/00
Neal Sweeney, Ph.D.
/S/ 5/5/00

cc:

Original NDA 50-777
HFD-540/Division File
HFD-540/M Wright
HFD-805/Consult File/N. Sweeney

Drafted by: Neal Sweeney, May 2, 2000
R/D initialed by P. Cooney, May 2, 2000

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