

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-302

MICROBIOLOGY REVIEW(S)

REVIEW TO HFD 540
OFFICE OF NEW DRUG CHEMISTRY
Microbiology Staff, HFD-805
Microbiologist's Review #2 of NDA
October 31, 2001

- A. 1. NDA 21-302-BI
2. APPLICANT/SPONSOR: Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, NJ 07936-1080
- Contact: James L. DeMartino
(973) 781-2645
3. MANUFACTURING SITE: Novartis Pharma AG
Lichtstrasse 35
CH-4056 Basel
Switzerland
4. DRUG PRODUCT NAME:
Proprietary: Elidel™
Established: Pimercrolimus
Drug Priority Classification: Standard
5. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:
• 1% Topical Cream
6. METHOD(S) OF STERILIZATION: N/A
7. PHARMACOLOGICAL CATEGORY AND/OR PRINCIPLE INDICATION:
Atopic Dermatitis
- B. 1. DOCUMENT/LETTER DATE: December 15, 2000
2. RECEIPT DATE: December 19, 2000
3. CONSULT DATE: January 30, 2001
4. DATE OF AMMENDMENT: July 6, 2001
5. ASSIGNED FOR REVIEW: July 30, 2001
6. SUPPORTING/RELATED DOCUMENTS: DMF →
- C. REMARKS: DMF — was submitted _____ . The first review of NDA 21-302 was completed on 6/15/01.

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/s/

Stephen Langille
10/31/01 10:04:48 AM
MICROBIOLOGIST

Peter Cooney
10/31/01 04:16:01 PM
MICROBIOLOGIST

**APPEARS THIS WAY
ON ORIGINAL**

D. CONCLUSIONS: **The submission is approvable pending resolution of microbiological deficiencies. Specific comments regarding the _____ process are provided in "E. Review Notes" and "List of Microbiology Deficiencies and Comments".**

Stephen E. Langille, Ph. D.

cc: Original **NDA 21-302**
HFM-540/Division File
HFM-540/Wright
HFM-540/Decamp
HFD 805/Consult File/Langille
Drafted by S. Langille _____
Initialed by P. Cooney

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/s/

Stephen Langille
6/15/01 12:58:03 PM
MICROBIOLOGIST

Peter Cooney
6/15/01 01:39:56 PM
MICROBIOLOGIST

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ON ORIGINAL**