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**

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.
D. CONCLUSIONS: The submission is recommended for approval from the standpoint of microbial product quality.

Stephen E. Langille, Ph. D.

cc: Original NDA 21-302-BI
    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
10/31/01 10:04:48 AM
MICROBIOLOGIST

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

APPEARS THIS WAY
ON ORIGINAL
REVIEW TO HFD 540
OFFICE OF NEW DRUG CHEMISTRY
Microbiology Staff, HFD-805
Microbiologist's Review #1 of NDA
May 30, 2001

A. 1. **NDA**

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: Pimecrolimus
   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:**

5. **ASSIGNED FOR REVIEW:**
   February 9, 2001

6. **SUPPORTING/RELATED DOCUMENTS:**
   DMF —

C. **REMARKS:**
   DMF — was submitted —
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".

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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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