CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-302

CHEMISTRY REVIEW(S)
DIVISION OF DERMATOLOGIC AND DENTAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

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NAME & ADDRESS OF APPLICANT: Novartis Pharmaceutical Corporation
59 Route 10
East Hanover, New Jersey 07936-1080

DRUG PRODUCT NAME
- Proprietary: Elidel
- Nonproprietary/USAN: pimecrolimus
- Code Names/#'s: ASM-981
- Chem.Type/Ther.Class: 1 S

ANDA Suitability Petition/DESI/Patent Status: N/A [if applicable]

PHARMACOL.CATEGORY/INDICATION: Atopic Dermatitis

DOSAGE FORM: Cream

STRENGTHS: 1%
ROUTE OF ADMINISTRATION: Topical
DISPENSED:  x  Rx  __ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA,
Molecular formula: C_{43}H_{68}ClNO_{11}
Mol. Wt.: 810.47
Systematic Chemical Names:
IUPAC
CAS
(3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-3-\{(1E)-2-\{(1R,3R,4S)-4-chloro-3-methoxycyclohexyl\}-1-methylethenyl\}-8-ethyl-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-3H-pyrido[2,1-c][1,4]oxazaclyctricosine-1,7,20,21(4H,23H)-tetron (9CI)

2.1.2. Other names
[3S-3R\{E(1S*,3S*,4R*)\},4S*,5R*,8S*,9E,12R*,14R*,15S*,16R*,18S*,19S*,26aR*\}]-3-\{2-\{(4-chloro-3-methoxycyclohexyl\}-1-methylethenyl\}-8-ethyl-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-3H-pyrido[2,1-c][1,4]oxazaclyctricosine-1,7,20,21(4H,23H)-tetron
33-epi-chloro-33-desoxyascomycin

Table 3

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NDA 21-302
Novartis Pharmaceuticals Corp.
Elidel Cream 1%

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Polypropylene cap

RELATED DOCUMENTS (if applicable):
IND — (ASM 981 Cream 1% for Atopic Dermatitis), Novartis Pharmaceutical Corporation

CONSULTS:

(1) The project manager requested a microbiology consult on 1/30/01 to review microbial limit test (see Vol. 1.4; pg. 4-193). This issue was addressed in the 5/30/01 microbiology review.

(2) Chemist requested additional microbiology consult on 2/26/01 to review the manufactured in the subject NDA (Vol. 1.3; pg. 4-122)] Microbiology review was completed on 5/30/01.

REMARKS/COMMENTS:

The applicant submitted a New Drug Application for Elidel Cream 1% for the treatment of Atopic Dermatitis. This NDA has 1S classification. A comprehensive description of the CMC information was submitted for this drug product in support of this NDA.
NDA 21-302  
Novartis Pharmaceuticals Corp.  
Elidel Cream 1%

Even though the CMC information was comprehensive, deficiencies were observed for both drug substance and drug product. These deficiencies were in the areas of manufacturing, packaging, specifications, and stability (see chemist review notes below). Having said this, the drug substance deficiencies have been corrected; see amendment dated 5/21/01 below. The drug product deficiencies remained open.

Furthermore, the applicant submitted additional amendments to update the NDA. These amendments were reviewed and are summarized as follows:

- Amendment/BC dated 3/8/01- Provided additional information requested by the FDA on 1/23/01 regarding the ---- forms of pimecrolimus drug substance; see review notes below

- Amendment/BC dated 5/21/01- provided additional information requested by FDA’s IR letter dated 5/3/01 regarding CMC deficiencies found in the drug substance; see review notes below

- Amendment/BC dated 5/29/01- provided replacement documentation for inclusion to more accurately represent the manufacturing process that is presently being used to manufacture pimecrolimus drug substance; see review notes below

- Amendment/BL dated 06/19/01- provided revised draft labeling for the package insert and the latest color representation of carton and container labeling; see review notes

- Amendment/BI dated 07/06/01- provided information as requested by the microbiologist (see Microbiologist Review dated 5/30/01).

- Amendment/BC dated 07/12/01- provided additional stability data to support the proposed 24-month expiration date.

- Amendment/BC dated 08/07/01- provided batch analysis documentation as the result of a GMP inspection that took place on July 2-4, 2001, whereby the inspector requested this information.

Methods Validation is pending; to be initiated as soon as possible.

EER was found acceptable on 9/14/01 for the facilities as listed below.
NDA 21-302
Novartis Pharmaceuticals Corp.
Elidel Cream 1%

CONCLUSIONS & RECOMMENDATIONS:

The NDA is found approvable from a manufacturing and controls standpoint. However, minor deficiencies in the CMCs have been observed in the drug product. These CMC deficiencies were communicated to the applicant by fax on 10/24/01.

Ernest G. Pappas

__________
Review Chemist

cc: Orig. NDA 21-302
HFD-540/Division File
HFD-540/Pappas
HFD-540/MO/Cook
HFD-540/Pharm/Hill
HFD-540/Micro
HFD-540/PM/Wright
R/D Init by: Team Leader

APPEARS THIS WAY
ON ORIGINAL
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Ernest G. Pappas
11/1/01 11:59:48 AM
CHEMIST
I have completed my chemistry review and I am recommending approval.

Wilson H. DeCamp
11/1/01 12:05:36 PM
CHEMIST
concur with review

APPEARS THIS WAY
ON ORIGINAL
NDA 21-302

Elidel (pimecrolimus) Cream 1%

Novartis Pharmaceutical Corporation

Ernest G. Pappas
Division of Dermatological and Dental Drug Products
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APPEARS THIS WAY ON ORIGINAL
Chemistry Review Data Sheet

1. NDA 21-302

2. Review #: 2

3. REVIEW DATE: 11/28/01

4. REVIEWER:
   Ernest G. Pappas

5. PREVIOUS DOCUMENTS:

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7. NAME & ADDRESS OF APPLICANT:

   Name: Novartis Pharmaceutical Corporation
   Address: 59 Route 10
             East Hanover, New Jersey 07936-1080
   Representative: Ms Sheryl LeRoy
8. DRUG PRODUCT NAME/CODE/TYPE:
   a) Proprietary Name: Elidel
   b) Non-Proprietary Name (USAN): pimecrolimus
   c) Code Name/# (ONDC only): ASM-981
   d) Chem. Type/Submission Priority (ONDC only):
      • Chem. Type: 1
      • Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 505(b)(1)

10. PHARMACOL. CATEGORY: Atopic Dermatitis

11. DOSAGE FORM: CREAM

12. STRENGTH/POTENCY: 1%

13. ROUTE OF ADMINISTRATION: Topical

14. Rx/OTC DISPENSED: x Rx ___ OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)[Note26]:
    _____ SPOTS product – Form Completed
    x Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:
Molecular formula: CsH65ClNO11
Mol. Wt.: 810.47
Systematic Chemical Names:

IUPAC


CAS

(3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-3-{[(1E)-2-[(1R,3R,4S)-4-chloro-3-methoxycyclobexyl]-1-methylvinyl]-6-ethyl-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-3H-pyrrole[2,1-c][1,4]oxazacyclotricosine-1,7,20,21(4H,23H)-tetrone

(PCI)

2.1.2. Other names

{3S,3R*[(E,3S,4R*)]4S*,5R*,8S*,9E,12R*,14R*,15S*,16R*,18S*,19S*,26aR*]-3-[(4-chloro-3-methoxycyclobexyl)-1-methylvinyl]-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-3H-pyrrole[2,1-c][1,4]oxazacyclotricosine-1,7,20,21(4H,23H)-tetrone

33-epi-chloro-33-desoxyascomycin
17. RELATED/SUPPORTING DOCUMENTS:

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¹ Action codes for DMF Table:
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Other codes indicate why the DMF was not reviewed, as follows:
2 – Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

² Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents: (related)

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The Chemistry Review for NDA 21-307

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

This NDA can be approved from a Chemistry standpoint.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if approvable

None

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

(1) Drug Product:

The drug product, Elidel (pimecrolimus) Cream 1%, is packaged in tubes with a white, propylene, piercing screw cap. This drug product was submitted as an NME since the active pharmaceutical was first of its class in this country for the treatment of atopic dermatitis. This NDA has a 1S classification.
The applicant proposed a 24-month expiration date for the product to be marketed in ~ 15 g, 30 g, and 100 g tubes. Acceptable stability data were submitted to support the proposed expiration date. In this regard, a 24-month expiry date has been granted for the finished product.

The tradename, Elidel, has been found acceptable by OPDRA. This labeling information, as well as the labels of the container and carton, is acceptable from a technical standpoint. The storage condition of 25 \(^\circ\) C (77 \(^\circ\) F), with excursions permitted between 15 \(^\circ\) C-30 \(^\circ\) C (59 \(^\circ\) F-86 \(^\circ\) F) and “Do not freeze” statement has found to be appropriate for the Elidel Cream 1%.

The labeling was reviewed and found acceptable by DDMAC.

Establishment Inspection: All facilities, as indicated in the NDA, were found acceptable for CGMPs. An overall recommendation of approvable was received from the Office of Compliance on 28-Aug-2001.

Environmental Assessment: The applicant’s claim of categorical exclusion under regulation 21 CFR 25.31 (b) is acceptable since the EIC projection was found to be at a level well below 1 ppb.

(2) Drug Substance:

The drug substance, pimecrolimus, is an NME. The manufacture of pimecrolimus API consists of In this regard, starting material results from This process has been found to be acceptable (see Micro Review dated 31-Oct-2001). The synthesis and purification of the pimecrolimus was adequately described in the NDA (see chemistry review #1, pg. 29).
The structure and physicochemical characteristic are adequately described in the NDA to assure the identity, strength, quality and purity of the pimecrolimus API.

Pimecrolimus is essentially insoluble in water. It is highly soluble in various alcohols, and it is somewhat less soluble in less hydrophilic solvents.

B. Description of How the Drug Product is Intended to be Used

The drug product is to be administered topically as anti-infective agent for the treatment of atopic dermatitis.

C. Basis for Approvability or Not-Approval Recommendation

The manufacturing and controls as identified above are sufficient to assure the consistent identity, strength, quality and purity of the drug.
III. Administrative

A. Reviewer's Signature

B. Endorsement Block

C. CC Block
WITHHOLD 5 PAGE (S)
III. INVESTIGATIONAL FORMULATIONS
Acceptable per Chemistry review #1, 01-Nov-2001

IV. ENVIRONMENTAL ASSESSMENT
Acceptable per Chemistry review #1, 01-Nov-2001

V. METHODS VALIDATION
Methods validation packages were sent the laboratories on 11-Nov-2001. Waiting validation report.

VI. LABELING
Acceptable per Chemistry review #1, 01-Nov-2001
VII. ESTABLISHMENT INSPECTION

Application: MDA 21302/000
Priority: 1S
Org Code: 540
Stamp: 15-DEC-2000
Regulatory Due: 15-OCT-2001
Action Goal: District Goal:
16-AUG-2001

Applicant: NOVARTIS PHARMACEUTICALS CO
Brand Name: ELIDEL (PIMECROLIMUS) CREAM 1%
NO CITY, XX

Established Name:
Generic Name: PIMECROLIMUS
Dosage Form: CRM (CREAM)
Strength: 1%
301-827-2020, Project Manager
301-827-2066, Review Chemist
301-827-2041, Team Leader

FDA Contacts: M. WRIGHT (HFD-540)
E. PAPPAS (HFD-540)
W. HECAMP II (HFD-540)

Overall Recommendation:
ACCEPTABLE on 27-AUG-2001 by J. D. AMBROGIO (HFD-324) 301-827-0062

Establishment: NOVARTIS PHARMA GmbH
ORELINGER STRASSE 44
WEHR, BADEN, GM D-79664

Profile: CFN OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 26-JAN-2001
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

Establishment: 9617734
NOVARTIS PHARMA INC (CIBA)
SCHAFFHAUSERSTRASSE
CH-4332 STEIN, SZ

Profile: OIN OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 24-AUG-2001
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

Establishment: 9692043
NOVARTIS PHARMA INC (CIBA)
SCHAFFHAUSERSTRASSE
CH-4332 STEIN, SZ

Profile: CRU OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 02-AUG-2001

Responsibilities:
FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE PACKAGER

Responsibilities:
DRUG SUBSTANCE
FINISHED DOSAGE RELEASE TESTER

APPEARS THIS WAY ON ORIGINAL
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION
Profile: CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 02-AUG-2001
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION
Establishment: 9611204
DMF No: NOVARTIS PHARMA INC (SANDOZ) AADA No: LICHSTRASSE 35, ST. JOHANN SITE BASEL, SZ 4002
Profile: CRU OAI Status: NONE Responsibilities: DRUG SUBSTANCE MANUFACTURER FINISHED DOSAGE RELEASE TESTER
Last Milestone: OC RECOMMENDATION
Milestone Date: 02-AUG-2001
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION
Profile: CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 02-AUG-2001
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION
Establishment: 9612715
DMF No: NOVARTIS PHARMA INC (SANDOZ) AADA No: RINGASKIDDY/CORK, RINGASKIDD RELEASE
Profile: CTL OAI Status: NONE Responsibilities: DRUG SUBSTANCE TESTER
Last Milestone: OC RECOMMENDATION
Milestone Date: 25-JAN-2001
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION
Establishment: 9614433
DMF No: NOVARTIS PHARMANALYTICA SA AADA No: LOCARNO, SZ
Profile: CTL OAI Status: NONE Responsibilities: DRUG SUBSTANCE STABILITY TESTER
Last Milestone: OC RECOMMENDATION
Milestone Date: 11-JAN-2001
Decision: ACCEPTABLE
Reason: BASED ON PROFILE
Establishment: [ ]
DMF No: AADA No: 
Profile: OIN OAI Status: NONE Responsibilities: 
Last Milestone: OC RECOMMENDATION
Milestone Date: 07-FEB-2001
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION
Establishment: [ ]
DMF No: AADA No: 
Profile: CTL OAI Status: NONE Responsibilities: 

VIII. DRAFT DEFICIENCY LETTER

Not applicable
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Ernest G. Pappas
12/6/01 08:30:04 AM
CHEMIST
recommend approval

Wilson H. DeCamp
12/6/01 08:32:28 AM
CHEMIST
concur with review

APPEARS THIS WAY
ON ORIGINAL