# CENTER FOR DRUG EVALUATION AND RESEARCH

# Approval Package for:

# APPLICATION NUMBER:

# 20-907/S-006

Trade Name: Activella 1mg/0.5mg Tablets

Generic Name: estradiol / norethindrone acetate

Sponsor: Novo Nordisk

Approval Date: September 13, 2002

# CENTER FOR DRUG EVALUATION AND RESEARCH

# APPLICATION NUMBER:

# 20-907/S-006

**CONTENTS**

Reviews / Information Included in this NDA Review.

| | |
|---|---|
| Approval Letter(s) | X |
| Tentative Approval Letter(s) | |
| Final Printed Labeling | |
| CSO Labeling Review(s) | |
| Medical Officer Review(s) | |
| Chemistry Review(s) | X |
| Microbiology Review(s) | |
| Bioequivalence Review(s) | |
| Administrative Document(s) | |
| Correspondence | X |

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# APPLICATION NUMBER:

# 20-907/S-006

# APPROVAL LETTER

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-907/S-006

**APPROVAL LETTER**

Novo Nordisk Pharmaceuticals, Inc.
Attention: Barry Reit, Ph.D.
Vice President, Regulatory Affairs
100 College Road West
Princeton, NJ 08540

Dear Dr. Reit:

Please refer to your supplemental new drug application dated March 13, 2002, received March 14, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Activella™ (estradiol/norethindrone acetate).

This "Changes Being Effected in 30 Days" supplemental new drug application provides for [redacted] to the [redacted]

We completed our review of this supplemental new drug application and it is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Dornette Spell-LeSane, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

David Lin, Ph.D.
Chemistry Team Leader, for the
Division of Reproductive and Urologic Drug Products, (HFD-580)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/
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David T. Lin
9/13/02 10:09:29 AM
I concur.

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# CENTER FOR DRUG EVALUATION AND RESEARCH

# APPLICATION NUMBER:

# 20-907/S-006

# CHEMISTRY REVIEW(S)

CHEMIST REVIEW
OF **SUPPLEMENT**

1. **ORGANIZATION**: DRUDP HFD-580
2. **NDA NUMBER:** 20-907/ SCM 006

3. **SUPPLEMENT DATES:**
   **Letter Date:** 13-Mar-2002
   **Stamp Date:** 14-Mar-2002
4. **AMENDMENTS/REPORTS/DATES:**
   **Letter Date**: n/a
5. **RECEIVED BY CHEMIST:** March 2002

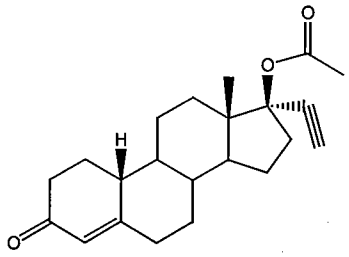
6. **SPONSOR NAME AND ADDRESS**
   Novo Nordisk Pharmaceuticals
   100 College Road West
   Princeton, NJ 08540

7. **DRUG PRODUCT NAME:** Activella

8. **NONPROPRIETARY NAME:** estradiol/norethindrone acetate tablet

9. **DRUG SUBSTANCES NAMES/STRUCTURES**
   Estradiol: Estra-1,3,5(10)-triene-3,17-diol. See USP 24 for the chemical structure.

   Norethindrone acetate (NETA): 17-beta-acetoxy-17-alpha-ethynyl-4-estren-3-one




10. **DOSAGE FORM(S):** Tablet

11. **STRENGTH:** 1 mg NETA/ 0.5 mg estradiol

12. **PHARMACOLOGICAL CATEGORY:** estrogen/progestin: for the treatment of VMS

13. **HOW DISPENSED:** Rx

14. **RECORDS AND REPORTS CURRENT:** Yes

15. **RELATED IND/NDA/DMF:**
    - DMF [redacted]
    - DMF [redacted]

- NDA 20-908/SCM 007 (Vagifem)
- ANDA 40-312 (Innofem)

**16. SUPPLEMENT PROVIDES FOR:**

**17. COMMENTS:**

**18. SPECIAL PRODUCTS**: No _X

**19. CONCLUSIONS AND RECOMMENDATIONS:**
As the DMFs for and are adequate, and the Office of Compliance has recommended approval for the new site, this CBE-30 supplement can be approved. **Issue an Approval Letter.**

**20.**

| REVIEWER NAME | SIGNATURE | DATE COMPLETED |
|---|---|---|
| J. Salemme, Ph.D.<br>Review Chemist | | |

INIT by DLin___
Project Mgr: Mercier

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**Page(s) of trade secret and /or confidential commercial information**

25-MAR-2002 FDA CDER EES Page 1 of 1
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 20907/006
Stamp: 14-MAR-2002
Regulatory Due: 14-JUL-2002
Applicant: NOVO NORDISK PHARM
100 COLLEGE RD WEST
PRINCETON, NJ 08540
Priority: 4S
Org Code: 580

Action Goal:
District Goal: 09-JUN-2002
Brand Name: ACTIVELLE
Estab. Name:
Generic Name: ESTRADIOL; NORETHINDRONATE ACETATE

Dosage Form: (AEROSOL)
Strength: 1 MG/0.5 MG

Application Comment: THIS SUPPLEMENT IS FOR [redacted] (on 21-MAR-2002 by J. SALEMME (HFD-580) 301-827-7270)

FDA Contacts: D. SPELL LESANE , Project Manager
J. SALEMME (HFD-580) 301-827-7270 , Review Chemist
D. LIN (HFD-580) 301-827-4230 , Team Leader

Overall Recommendation: ACCEPTABLE on 25-MAR-2002 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: [redacted]

DMF No: [redacted] AADA:
Responsibilities: [redacted]
Profile: CSN OAI Status: NONE
Estab. Comment:

| Milestone Name | Date | Req. Type | Insp. Date | Decision & Reason | Creator |
|---|---|---|---|---|---|
| SUBMITTED TO OC | 21-MAR-2002 | | | | SALEMMEJ |
| OC RECOMMENDATION | 25-MAR-2002 | | | ACCEPTABLE BASED ON PROFILE | DAMBROGIOJ |

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/s/
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Jean Salemme
9/12/02 02:43:41 PM
CHEMIST

David T. Lin
9/12/02 03:24:34 PM
CHEMIST
I concur.

# CENTER FOR DRUG EVALUATION AND RESEARCH

# APPLICATION NUMBER:

# 20-907/S-006

# CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-907/S-006

**CBE-30 SUPPLEMENT**

Novo Nordisk Pharmaceuticals, Inc.
Attention: Barry Reit, Ph.D.
Vice President, Regulatory Affairs
100 College Road West
Princeton, NJ 08540

Dear Dr. Reit:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

| | |
|---|---|
| Name of Drug: | Activella™ |
| NDA Number: | 20-907 |
| Supplement number: | SCM-006 |
| Date of supplement: | March 13, 2002 |
| Date of receipt: | March 14, 2002 |

This supplemental application, submitted as "Supplement - Changes Being Effected in 30 days" proposes the following change:

The implementation of the [redacted]

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on May 12, 2002 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Reproductive and, Urologic Drug Products HFD-580
Office of Drug Evaluation III
Attention: Division Document Room 17B-20

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Reproductive and, Urologic Drug Products HFD-580
Office of Drug Evaluation III

5600 Fishers Lane
If you have any question, call me at (301) 827-4260.

Attention: Document Room 17B-20

Sincerely,

Dornette Spell-LeSane, NP-C, MHA,
Regulatory Project Manager
Division of Reproductive and Urologic
Drug Products, HFD-580
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

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Dornette Spell-LeSane
4/11/02 01:43:46 PM

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