DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-907/S-009
NDA 20-907/S-011

APPROVAL LETTER

Novo Nordisk, Inc.
Attention: Mary Ann McElligott, Ph.D.
Associate Vice President, Regulatory Affairs
100 College Road West
Princeton, NJ 08540

Dear Dr. McElligott:

Please refer to your supplemental new drug applications dated February 28, 2006 (serial # 009) and June 28, 2006 (serial # 011), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Activella® (estradiol/norethindrone acetate) tablets.

We also acknowledge receipt of your submissions dated August 2, September 12 and 19, November 15, and December 19, 22, and 27, 2006.

Supplement 009 provides for the use of Activella® (estradiol/norethindrone acetate) tablets 0.5 mg/0.1 mg for the treatment of moderate to severe vasomotor symptoms associated with menopause in women who have a uterus.

Supplement 011 "Changes Being Effected" provides for revisions to the physician insert and patient leaflet for Activella® according to the FDA draft guidance, dated November 2005, entitled "*Guidance for Industry: Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms - Recommended Prescribing Information for Health Care Providers and Patient Labeling*."

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted December 27, 2006, text for the patient leaflet submitted December 22, 2006) and submitted labeling (immediate container and carton labels submitted December 19, 2006).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplements NDA 20-907/S-009, S-011.**" Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

If you have any questions, call Ayoub Suliman, Pharm.D., Regulatory Health Project Manager, at (301) 796-0630.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Acting Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: agreed-upon text for package insert and patient leaflet

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/s/

Scott Monroe

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