DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-375/S-026

APPROVAL LETTER

Bayer HealthCare Pharmaceuticals Inc.
Attention: Michael Niebo, RAC
Global Regulatory Affairs
P.O. Box 1000
Montville, NJ 07045-1000

Dear Mr. Niebo:

Please refer to your supplemental new drug application, received July 3, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Climara® (estradiol transdermal system).

We also acknowledge receipt of your submissions dated December 18, 19 and 26, 2007.

This "Changes Being Effected" supplemental new drug application provides for the inclusion of additional postmarketing safety information in the product labeling for Climara® (estradiol transdermal systems).

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. 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 George Lyght, R.Ph., Sr. Regulatory Project Manager, at (301) 796-0948.

Sincerely,

{See appended electronic signature page}

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

Enclosure :

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Scott Monroe

1/3/2008 07:04:28 PM