DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-166/S-007

APPROVAL LETTER

Ascend Therapeutics, Inc.
Attention: Thomas W. MacAllister, J.D., Ph.D.
Senior Vice President and General Counsel
607 Herndon Parkway, Suite 210
Herndon, VA 22170

Dear Dr. MacAllister:

Please refer to your supplemental new drug application received July 27, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EstroGel® (estradiol gel) 0.06%.

We also acknowledge receipt of your submissions dated January 16 and 23, 2008.

This "Changes Being Effected" supplemental new drug application provides for the inclusion of the description of the 25 gram and 50 gram canisters, revised patient priming instructions, corresponding carton and container labels for EstroGel®, and updated class labeling of the Physician Insert and Patient Package Insert.

We have 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 attached.

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(l)] 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 Health 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

1/25/2008 12:05:45 PM