



NDA 21-166/S-005

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 dated July 13, 2006, received July 14, 2006, 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 February 5 and 15, 2007.

Your submission of February 5, 2007 constituted a complete response to our January 12, 2007 action letter.

This supplemental new drug application provides for changes to the distributor's name and NDC number on carton/container labeling and changes to the physician and patient labeling to include information from the Women's Health Initiative (WHI) Study.

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.

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text. Upon receipt and verification, 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).

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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.
Acting 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

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