DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-683/S-004, S-006, S-007

Wyeth Pharmaceuticals
Attention: Robert DiGregorio
Director, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. DiGregorio:

Please refer to your supplemental new drug applications dated October 11, 2001 received October 15, 2001 (S-004), October 22, 2002 received October 25, 2002 (S-006), November 1, 2002 received November 7, 2002 (S-007) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ALESSE® (levonorgestrel and ethinyl estradiol) Tablets.

Your submission of August 2, 2007, constituted a complete response to our June 25, 2007 Approvable Letter.

These supplemental new drug applications provide for revisions to the physician package insert and patient package inserts.

We have 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, as enclosed.

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 Kassandra Sherrod, R.Ph., Regulatory Project Manager, at (301) 796-0997.

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

1/31/2008 08:34:55 PM