DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-781/S-013
NDA 20-843/S-010

Solvay Pharmaceuticals, Inc.
Attention: Naran Patel, R.A.C.
Manager, Regulatory Affairs
901 Sawyer Road
Marietta, Georgia 30062

Dear Mr. Patel:

Please refer to your supplemental new drug applications (NDAs) dated March 5, 2008, received March 6, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROMETRIUM® (progesterone, USP) Capsules, 100 mg and 200 mg.

We also acknowledge receipt of your submissions dated September 4 and 15, and November 14, 2008, May 28 and 29, 2009.

Your submission of November 14, 2008, constituted a complete response to our September 6, 2008, Complete Response letter.

These "Changes Being Effected" supplemental new drug applications provide for changes to the physician and patient package inserts that include updating labeling (1) to conform with class labeling for progestin drug products when progestins are used in conjunction with estrogens and (2) with published analyses and information from the Women's Health Initiative (WHI) Postmenopausal Hormone Therapy Trials.

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 enclosed, agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed physician and patient package inserts.

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. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions, "SPL for approved NDA 19-781/S-013, and NDA 20-843/S-010."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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, please call Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 796-0875.

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

6/30/2009 05:26:07 PM