DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 20-843/S-008
19-781/S-008

Solvay Pharmaceuticals, Inc.
Attention: Cicely N. Vaughn, MPH
901 Sawyer Rd.
Marietta, GA 30062

Dear Ms. Vaughn:

Please refer to your supplemental new drug application dated September 11, 2003, received September 12, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROMETRIUM® (progesterone, USP) capsules.

These "Changes Being Effected" supplemental new drug applications provide for the addition of a Geriatric Use subsection, as a part of the **PRECAUTIONS** section of the label.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter.

The geriatric labeling changes will be incorporated into the final printed labeling (FPL) after agreement is obtained on amendments to labeling supplements S-005 and S-006 for these applications. It must be identical to the agreed upon labeling at that time and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 20-843/S-008 and NDA 19-781/S-008." Approval of these submissions by FDA is not required before the labeling is used.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

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) 827-4260.

Sincerely,

{See appended electronic signature page}

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

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

/s/

Daniel A. Shames

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