SOLVAY PHARMACEUTICALS

31 March 2003

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re:
Federal Register January 31, 2003 (Volume 68, Number 21) Docket No. 03D-0007
Federal Register February 3, 2003 (Volume 68, Number 22) Docket No. 9[redacted]

Dear Dockets Management:

Reference is made to the January 31, 2003 Federal Register Notice containing Docket 03D-007 entitled "Draft Guidance for Industry on Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms--Recommendations for Clinical Evaluation; Availability." Reference is also made to the February 3, 2003 Federal Register Notice containing Docket 98D-0834 entitled "Draft Guidance for Industry on Labeling for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms--Prescribing Information for Health Care Providers and Patient Labeling; Availability."

The following comments are submitted in response to the referenced notice. Solvay Phamaceuticals Inc., reserves all rights under the Administrative Procedures Act.

Attachment 1 contains comments pertaining to the clinical study design and clinical study analysis components of the "Draft Guidance for Industry on Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms--Recommendations for Clinical Evaluation; Availability." Attachment 2 contains general comments on both guidance documents with respect the proper classification for Progestogens.

If there are any questions or concerns regarding these comments, please contact me at 770 578 5684.

Sincerely,

Cicely N. Vaughn, MPH
Manager, Regulatory Affairs

cc: Margaret Kober

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