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Worldwide Regulatory Affairs

Wyeth

2081 '03 APR 16 A9

April 4, 2003

Dockets Management Branch (HFD-240)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Docket No. 98D-0834, "Draft Guidance for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms – Prescribing Information for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"

Dear Sir or Madam:

Reference is made to the February 3, 2003 Federal Register Notice (68FR22) which announced the availability of the Draft Guidance for Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms – Prescribing Information for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.

Wyeth Pharmaceuticals, a division of Wyeth, appreciates the opportunity to provide comments on this Draft Guidance for Industry. Wyeth is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing, and marketing of pharmaceuticals, vaccines, biotechnology products, and nonprescription medicines that improve the quality of life for people worldwide. The Company's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Health Care, and Fort Dodge Animal Health.

The purpose of this correspondence is to provide the Agency with Wyeth's comments to this draft guidance. Wyeth's comments are found in Attachment 1 to this letter, a copy of the Draft Guidance is found in Attachment 2, and relevant justification documents and references are found in Attachments A through G.

98D-0834

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Should you have any questions regarding the information provided, please contact the undersigned at 610-902-3775 or Ms. Christine Rosser at 610-902-3120.

Sincerely,

WYETH PHARMACEUTICALS INC.

Christine M. Rosser for NEH

Nanette E. Holston
Director, Global Brand Management
Worldwide Regulatory Affairs