DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-123/SCS-014

Wyeth Pharmaceuticals
Attention: Susan B. Wilson
Senior Regulatory Coordinator
Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Wilson:

Please refer to your supplemental new drug application dated March 20, 2002, received March 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Factrel (gonadorelin HCl).

We acknowledge receipt of your submission dated July 10, 2002.

This supplemental new drug application provides for a change in the site of the manufacture, packaging, testing, and release of the Diluent for Factrel Injectable.

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Archana Reddy, MPH, Consumer Safety Officer, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Moo-Jhong Rhee, Ph.D.
Chemistry Team Leader, for the
Division of Reproductive and Urologic Drug Products,
(HFD-580)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Moo-Jhong Rhee

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