CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20-582

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-582

SEP 29 1997

Organon, Inc.
Attention: Albert P. Mayo
Director, Regulatory Affairs
375 Mt. Pleasant Ave.
West Orange, NJ 07052

Dear Mr. Mayo:

Please refer to your new drug application dated January 10, 1996, received January 11, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Follistim (follitropin beta for injection), 75 IU and 150 IU vials.

We acknowledge receipt of your submissions dated April 18, May 14 and 22, June 3 and 12, July 11, 24 and 30, August 21 and 28, and September 19, 24, 25, 26 and 29, 1997, submitted in response to our not approvable letter dated April 10, 1997. The User Fee goal date for this application is November 14, 1997.

This new drug application provides for:

1. the development of multiple follicles in ovulatory patients participating in Assisted Reproductive Technologies; and
2. the induction of ovulation and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submission dated September 29, 1997. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on September 29, 1997. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-582. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We wish to remind you that approval of the established name, follitropin beta, for your product does not imply that the Agency recognizes that follitropin beta is a different chemical entity than the other recombinant DNA-derived FSH, follitropin alfa. Data from physico-chemical tests and bioassays have demonstrated that follitropin alfa and beta are indistinguishable. However, the Agency will allow your use of the established name, follitropin beta, to provide for consistency with your identical, already marketed European product.

We remind you of your Phase 4 commitments specified in your submissions dated May 14 and July 30, 1997. These commitments are listed below.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment. The status summary should include expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

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, please contact Lana L. Pauls, M.P.H., Chief, Project Management Staff, at (301) 827-4260.

Sincerely,

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research