NDA 21-057

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

Dear Mr. Mayo:

Please refer to your new drug application (NDA) dated January 28, 1999, received January 29, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Antagon™ (ganirelix acetate) 250 ug/0.5 mL.

We acknowledge receipt of your submissions dated February 2, 9, 23, March 8, 10, 29, April 12, 27, May 19, June 4 (telefacsimilie) 7, 8, 9 (2-telefacsimilies), 10, 10 (telefacsimilie), 11 (telefacsimilie), 14, 18, 18 (telefacsimile), 30 (telefacsimilie), July 1, 1 (telefacsimilie), 2, 6 (telefacsimilie), 8, 9, 9 (2-telefacsimilies), 11, 12, 12 (telefacsimilie), July 19 (2-telefacsimilies), 22, 28 (telefacsimilie) and 29 (telefacsimilie), 1999.

This new drug application provides for the use of Antagon (ganirelix acetate) 250 µg/0.5 mL injection for the inhibition of premature LH surges in women undergoing controlled ovarian hyperstimulation.

We have completed the review of this application, as amended, 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 agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling submitted on July 29, 1999, (text for the package insert), and immediate container and carton labels submitted on July 23, 1999. Marketing the product with FPL that is not identical to the approved labeling text 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 "FPL for approved NDA 21-057." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitment specified in a teleconference on June 17, 1999, and confirmed by you in writing on June 18, 1999. This commitment, along with any completion dates agreed upon, is listed below.

> Organon, Inc. commits to submit the final report for the mouse micronucleus assay by September 30, 1999.

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. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, 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.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Reproductive and Urologic Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this application at this time.

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, contact Diane Moore, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

Florence Houn, M.D., M.P.H., F.A.C.P.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research