DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-582/S-006

Organon, Inc.
Attention: John Leach
Associate Director, Regulatory Affairs
375 Mt. Pleasant Avenue
West Orange, NJ 07052

Dear Mr. Leach:

Please refer to your supplemental new drug application dated April 6, 2001, received April 9, 2001, submitted under section 505(b) pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) for Follistim® (follitropin beta for injection).

We refer to the approval letter sent to you on February 7, 2002. That approval was issued in error because it did not recognize an existing orphan drug exclusivity. This letter rescinds the February 7, 2002, approval for the supplement and provides a tentative approval for the use of Follistim® (follitropin beta for injection) for the induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure.

Our conclusions regarding the data in the application are unchanged and the drug is safe and effective for use as recommended in the agreed upon labeling (refer to the FDA approval letter dated February 7, 2002**). However,** the Orphan Drug provisions of the Act, 21 U.S.C. §§ 360aa-360dd, provide for a grant of seven years of market exclusivity for drug products that are approved for the treatment of diseases or conditions affecting fewer than 200,000 persons in the U.S. Orphan drug exclusivity blocks approval of any other application for the same drug for the same indication for the seven year period. Orphan exclusivity was granted to Serono Laboratories, Inc. on May 24, 2000, for their product, Gonal F® (gametotropin beta for injection). The agency has determined that your product is the same as Gonal F® under the standards described in FDA's regulation at 21 CFR 316.3(b)(13)(A). Therefore, your supplemental application for Follistim® (follitropin beta for injection) may not be finally approved for marketing under Section 505 of the Act until May 24, 2007.

Accordingly, your application is tentatively approved under 21 CFR 314.105. This determination is contingent upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in manufacturing and testing of the drug product) and is, therefore, subject to change on the basis of new information that may come to our attention.

Please provide the Agency, 60 days prior to May 24, 2007, an amendment to this application identifying any changes in the conditions under which your product was tentatively approved. This information should include updated final printed labeling, chemistry, manufacturing and control data, and a safety update as appropriate. This submission should be designated as a minor amendment in your cover letter.

In addition to, or instead of, the amendment requested above, the Agency may, at any time prior to the final date of approval, request that you submit an amendment containing the information described above. Failure to submit any such amendment requested by the Agency, will prompt a review of the application that may result in rescission of the tentative approval letter.

Any significant change in the conditions outlined in this supplemental new drug application requires Agency review before final approval may be granted.

Prior to the issuance of a final approval letter by the Agency, this supplemental new drug application is not approved. If you believe that there are grounds for issuing the final approval letter prior to May 24, 2007, you should amend your application accordingly.

We apologize for any inconvenience this error may have caused. If you have any questions, call Freshnie DeGuia, Regulatory Project Manager, at (301) 827-4260**.**

Sincerely,

Daniel Shames, M.D.
Acting Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames

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