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RESEARCH**

APPLICATION NUMBER:

21-273

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-273

Organon USA Inc.
Attention: Lawrence C. Starke, Ph.D.
Senior Director, Regulatory Affairs
56 Livingston Avenue
Roseland, NJ 07068

Dear Dr. Starke:

Please refer to your new drug application (NDA) dated July 21, 2000, received July 24, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Follistim[®] AQ (follitropin beta injection).

We acknowledge receipt of your submissions dated July 21, October 31, and November 14, 2000; March 13, April 20, May 3, 8, 11, and 16, 2001; October 17, 2002; February 21 and 26, March 4 and 26, April 11, 29, and 30, December 11 and 23, 2003; January 8 and 27, May 27, June 15, July 12, November 19, and December 6, 2004; February 8, March 10, 21, and 25, June 24, August 4, August 23 and 24, 2005.

The June 24, 2005, submission constituted a complete response to our May 17, 2005, action letter.

This new drug application provides for the use of Follistim[®] AQ (follitropin beta injection) for the development of multiple follicles in ovulatory patients participating in an Assisted Reproductive Technology (ART) program and for 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 completed our review of this application and as amended, it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert) and submitted labeling (immediate container and carton labels submitted August 4, 2005). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-273.**" Approval of this submission by FDA is not required before the labeling is used.

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. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call John Kim, R.Ph., J.D., Regulatory Health Project Manager, at (301) 827-3003.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug
Products, HFD-580
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Agreed-upon labeling (PI & PPI)