

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-484

Approval Letter(s)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-484

Ferring Pharmaceuticals, Inc.
Attention: Kenneth Kashkin, M.D.
Vice President, Medical and Regulatory Affairs
400 Rella Boulevard
Suite 300
Suffern, NY 10901

Dear Dr. Kashkin:

Please refer to your new drug application (NDA) dated February 15, 2002 received on February 19, 2002 submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for Bravelle™ (urofollitropin for injection, purified).

We acknowledge receipt of your submissions dated May 1, July 19, 25, August 19, November 15, 26, 27, December 16, 17, and 18, 2002.

This new drug application provides for the use of Bravelle™ (urofollitropin for injection, purified) for multiple follicular development (controlled ovarian stimulation) during assisted reproductive technology cycles in patients who have previously received pituitary suppression.

We completed our review of this application, 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, immediate container and carton labels). 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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-484.**" Approval of this submission by FDA is not required before the labeling is used.

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 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-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, call Archana Reddy, M.P.H., Regulatory Project Manager, at (301) 827 - 4260.

Sincerely,

 *{See appended electronic signature page}*

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

Enclosure (Final Revised Labeling)

**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
12/19/02 02:55:58 PM