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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-484

Pharmacology Review(s)

PHARMACOLOGY/TOXICOLOGY COVER SHEET

NDA number: 21484

Review number: 1

Sequence number/date/type of submission: 000/ 19 February 2002/ original submission

Information to sponsor: Yes () No ()

Sponsor and/or agent: Ferring Pharmaceuticals Inc., 120 White Plains Road, Suite 400,
Tarrytown, New York 10591

Manufacturer for drug substance: Ferring Pharmaceuticals, Inc.

Reviewer name: Laurie McLeod-Flynn

Division name: Division of Reproductive and Urologic Drug Products

HFD-580

Review completion date: 04 September 2002

Drug:

Purified Urofollitropin

Relevant INDs/NDAs/DMFs: IND NDA 21289

Drug class: gonadotropin

Indication:

1. induction of ovulation and pregnancy in anovulatory, infertile women
2. stimulation of the development of multiple follicles in ovulatory women participating in an *in vitro* fertilization program

Clinical formulation: 75 IU FSH

Route of administration: subcutaneous and intramuscular

Executive Summary

I. Recommendations

Approval.

II. Summary of Nonclinical Findings

This is an administrative NDA, cross-referenced to NDA 21289, for which pre-clinical studies were reviewed by Alex Jordan on 3/10/01. No new pre-clinical studies were submitted.

III. Administrative

A. Reviewer signature: _____

/s/

B. Supervisor signature: Concurrence - _____

/s/

Non-Concurrence - _____
(see memo attached)

/s/

cc: ReddyA

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

/s/

Laurie McLeod
11/20/02 10:58:42 AM
PHARMACOLOGIST

Alexander W. Jordan
11/20/02 11:04:40 AM
PHARMACOLOGIST

Bravelle™ (urofollitropin for injection, purified)
Ferring Pharmaceuticals, Inc.
NDA 21-484

CAC/ECAC Report

This new drug application was not the subject of a CAC/ECAC report.

AR 12/08/02