CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:NDA 21047

CHEMISTRY REVIEW(S)

DIVISION OF METABOLISM AND ENDOCRINE DRUG PRODUCTS - HFD-510
Review of Chemistry, Manufacturing, and Controls

NDA #: 21-047 **DATE REVIEWED:** July 21, 1999

CHEMISTRY REVIEW #: 1 **REVIEWER:** Martin Haber, Ph.D.

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	10/26/98	10/28/98	11/7/98

NAME & ADDRESS OF SPONSOR: Ferring Pharmaceuticals Inc.
120 White Plains Road, Suite 400
Tarrytown, NY 10591 (914) 333-8900

DRUG PRODUCT NAME:

Proprietary:	Repronex
Nonproprietary:	Menotropins for Injection, USP
Chem.Type/Therapeutic.Class:	Type 6/ Class S

PHARMACOL. CATEGORY/INDICATION:	Induction of ovulation
DOSAGE FORM:	Lyophilized powder in vial
STRENGTHS:	75 and 150 IU/vial
ROUTE OF ADMINISTRATION:	Injection (intramuscular or subcutaneous)
Rx/OTC:	X Rx __ OTC

CHEMICAL NAME, MOLECULAR FORMULA, MOLECULAR WEIGHT:
Extract of human postmenopausal urine containing Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH), glycoprotein hormones each containing two subunits of about 20 KDa molecular weight. The common α subunit is 92 amino acids. The β subunit of FSH and LH is 111 and 141 amino acids, respectively.

REMARKS:
This is a consult review for HFD-580. This NDA was filed to allow for a subcutaneous route of administration of the approved product, Repronex (ANDA 73-598/599) which is currently marketed by the applicant for intramuscular administration only. The applicant referred to the approved ANDA 73-598/599 for CMC information, including the microbiology section and environmental assessment. No chemistry review is needed as no chemistry or formulation changes to the product were made. The EER status is acceptable as of 6/25/99,

Sample carton labels, immediate container labels and package insert refer to both intramuscular and subcutaneous injection and are satisfactory from a chemistry viewpoint. The approved Tradename Repronex is being used for the same product and indication. There is no regulation prohibiting the use of one name for two applications. User fee date is 8/26/99.

CONCLUSIONS & RECOMMENDATIONS:
From a chemistry viewpoint the application is approvable.

Orig. NDA # 21-047
cc: HFD-510/D-G.Wu/M.Haber/Consults File
HFD-580/Division file/M-J.Rhee/D.Moore

/S/
Martin Haber, Ph.D.
Review Chemist

R/D Init by: Dr. D-G. Wu, Team Leader Chemist

/S/
for Dee-Gang Wu 7-21-99

SUPPORTING DOCUMENTS: NDA 21-047

IND
DMF
DMF
DMF
DMF

RELATED DOCUMENTS: N/A

CONSULTS: None

Chemist's Review Summary NDA 21-047

A: **Drug Substance:** **Satisfactory** See ANDA Chem. Rev. #5, 10/29/93

B: **Drug Product:** **Satisfactory** See ANDA Chem. Rev. #5, 10/29/93

C: **Investigational Formulations:** **NA**

D: **Labeling:** **Satisfactory**

E: **Environmental Impact Analysis Report:** **NA**

F: **Methods Validation:** **NA**

G: **Establishment Inspections:** **Satisfactory**