

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 21047

PHARMACOLOGY REVIEW(S)

REVIEW AND EVALUATION OF PHARMACOLOGY/TOXICOLOGY DATA:

KEY WORDS:

Reviewer Name: Alex Jordan
Division Name: DRUDP
HFD#: 580
Review Completion Date: 3/24/99

Review number: 1
IND/NDA number: 21-047
Serial number/date/type of submission: 10/22/98
Information to sponsor: Yes () No (X)
Sponsor (or agent): Ferring Pharm
Manufacturer for drug substance:

Drug:

Code Name:
Generic Name: menotropins
Trade Name: Repronex
Chemical Name:
CAS Registry Number:
Molecular Formula/ Molecular Weight:
Structure:

Relevant INDs/NDAs/DMFs: IND _____ ANDA 73-598 and 73-599

OVERALL SUMMARY AND EVALUATION:

Introduction: This is a 505(b)(2) application for subcutaneous injection. The sponsor references previously approved ANDA's for the intramuscular injection. The drug product itself is identical. In an earlier meeting with the sponsor, we agreed to allow for cross reference to the ANDA's and that no preclinical toxicology studies would be necessary for this NDA.

Safety Evaluation: there are no safety concerns

Conclusions:

Communication Review:

- Labeling Review (NDA): satisfactory

RECOMMENDATIONS: The NDA is approvable from the pharm/tox standpoint.

Reviewer signature/team leader signature [Concurrence/Non-concurrence]

cc: list HFD-580 AJordan

1/S/ 3/24