CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-663

Statistical Review(s)

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: October 27, 2004

FROM: Biometrics Team Leader (HFD-715)

TO: Martin Kaufman, R.Ph. (HFD-580)

SUBJECT: NDA 21-663, Menopur

I provided statistical support for the following three studies contained in NDA 21-663:

1. An open-label, randomized, parallel group, comparative Phase III trial to study the efficacy and safety of HP Menotropin versus recombinant FSH administered subcutaneously to female patients in an IVF/ICSI program.

2. A randomized, open-label, parallel group, multi-center, efficacy study comparing purified Repronex® SC, purified Repronex® IM and Repronex® SC in female patients undergoing in vitro fertilization

3. [ ]

I provided the analyses of the primary study endpoints, the results of which are included in Appendix 2 of the medical officer's review. I also recommended the use of Dunnet's procedure to calculate two-sided 95% confidence intervals adjusted for two comparisons with an active comparator in the two studies containing three treatment arms.

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/s/

Lisa A. Kammerman
10/27/04 04:51:01 PM
BIOMETRICS

NDA 21-663

Menopur (menotropins for injection, USP)

Ferring Pharmaceuticals

Statistical Review (Carci)

N/A

10/09/24