CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75465

MEDICAL REVIEW

ANDA APPROVAL SUMMARY

ANDA: 75-755
DRUG PRODUCT: Fluoxetine
DOSAGE FORM: Tablets
STRENGTH: 10 mg and 20 mg
FIRM: Alphapharm Pty. Ltd.

CGMP STATEMENT/EIR UPDATE STATUS
An acceptable EIR was issued by the Office of Compliance, 8/8/2000.

BIO STUDY
Bioequivalence studies were found satisfactory, C. Chaurasia, 2/2/01.

VALIDATION
Drug substance is compendial. Drug product methods validation including Assay, Chromatographic Purity, and Dissolution was found satisfactory per Northeast Regional Laboratory, 8/28/00.

LABELING
Labeling was found satisfactory, A. Vezza, 5/8/01.

STERILIZATION VALIDATION (IF APPLICABLE)
N/A

DRUG SUBSTANCE
(pp. 18-19 of the 9/8/00 Amendment and pp. 3-18 of the 3/16/01 Amendment)

DMF for Fluoxetine Hydrochloride was found adequate on 8/2/01