# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**74803**

# MEDICAL REVIEW

ANDA APPROVAL SUMMARY

ANDA: 74-803 DRUG PRODUCT: Fluoxetine Hydrochloride USP

FIRM: Barr DOSAGE FORM: Capsule STRENGTHS: 10 mg
2 Quaker Road 20 mg
P.O. Box 2900
Pomona, New York 10970-051

CGMP STATEMENT/EIR UPDATE STATUS:

CGMP statement (p. 09-00026) in original submission. Paragraph 306(k) certification submitted (p. 01-00006).

EIR acceptable for drug product manufacturer (withold, 7-26-99) and drug substance manufacturer (OK, 5/27/98).

Facilities included:

Compounding and encapsulation:

Barr Laboratories, Inc.
265 Livingston Street
Northvale, New Jersey 07647-0008.

Packaging and labeling:

Barr Laboratories, Inc.
246 Pegasus Avenue
Northvale, New Jersey 07647-0008.

Shipping:

Barr Laboratories, Inc.
Arco Building
232 Pegasus Avenue
Northvale, New Jersey 07647-0008.

Analytical and stability testing:

Barr Laboratories, Inc.
Building #1
2 Quaker Road
Pomona, New York 10970-0591.

Drug Substance Manufacturer:

BIO STUDY:

Bioequivalence study conducted on 20 mg capsule Lot #5R87719, batch size capsules, was found acceptable by the Division of Bioequivalence per Z. Wahba, 8/21/98.

Waiver granted for the 10 mg product as it has been shown to be proportional to the 20 mg product.

*In-vitro* dissolution study was found acceptable, Z. Wahba, 8/21/98.

VALIDATION - (DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):

Drug substance and drug product compendial.

STABILITY - ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE IN CONTAINER SECTION?:

Stability for the following included:

| Lot # | Batch Size | Sample | Test Conditions |
|---|---|---|---|
| 5R87618 | capsules | 100's | 40°C/75% RH/3 months |
| | | | 25°C/60% RH/24 months |
| 5R87719 | capsules | 100's | 40°C/75% RH/3 months |
| | | | 25°C/60% RH/24 months |
| 308769R01 | capsules | 100's | 40°C/75% RH/3 months |
| | | | 25°C/60% RH/6 months |
| 308779R01 | capsules | 100's | 40°C/75% RH/3 months |
| | | | 25°C/60% RH/6 months |

Container/Closure system, 10 mg and 20 mg capsules:

100 capsules/container - 60 cc round white HDPE bottle, 33 mm metal screw cap or 33 mm metal/plastic child resistant cap with polyethylene coated paper liner, PS-22 Innerseal.

All container/closure systems are as described in the Container/Closure section.

Expiration date: 24 months based on accelerated stability data.

LABELING:

Description in package insert satisfactory for molecular structure, molecular formula, formula weight, inactive ingredients, product description and package size.

Professional labeling - satisfactory, A. Vezza,

STERILIZATION VALIDATION (IF APPLICABLE):

N/A

SIZE OF BIO BATCH (FIRM'S SOURCE OF NDS OK?):

Bio batch: 20 mg product, Lot #5R87719, batch size capsules, stability data included.

DMF Fluoxetine Hydrochloride, Laboratori MAG, satisfactory, L. Tang, 5/16/2000.

SIZE OF STABILITY BATCHES - (IF DIFFERENT FROM BIO BATCH, WERE THEY MANUFACTURED VIA THE SAME PROCESS?):

See above.

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?:

Executed batch records for the 10 mg x capsules Lot #5R87618 and the 20 mg x capsules Lot #5R87719 (bio/stability batches) included. Blank batch records were submitted in the application for 195.000 kilogram granulation and filling for 10 mg x capsules and 20 mg x capsules. All scale-ups consistent with current Office policy. Proposed manufacturing processes are the same as the bio/stability batches.

CHEMIST: Lucia C. Tang DATE: 5-16-2000 6-7-2000

SUPERVISOR: U.V. Venkataram IST DATE: 5-18-2000 6/8/00.