

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**75049**

**MEDICAL REVIEW**

DIVISION REVIEW SUMMARY

ANDA: 75-049

DRUG PRODUCT: Fluoxetine Hydrochloride

FIRM: Geneva

DOSAGE FORM: Capsules

STRENGTHS: 10 mg and 20 mg

CONTAINERS: Unit dose & 100's (both strengths)

CGMP STATEMENT/EIR UPDATE STATUS:

Acceptable dated 11/30/98.

BIO INFORMATION:

Acceptable dated 1/16/98.

VALIDATION

MV was found acceptable dated 11/12/97. Compendial product.

STABILITY

Lot nos. 6496034 and 6496022 were placed in accelerated (40°C/75% RH) and room temperature stability studies in the proposed marketing container configurations. The stability data appended are found to conform to the proposed stability specifications. Based upon the stability data submitted, the proposed 24 months expiration period should be granted.

The container/closure systems are described.

LABELING

Acceptable as is unless approved prior to 11/21/99. See review dated 9/22/98.

STERILIZATION VALIDATION

N/A

SIZE OF BIO/STABILITY BATCHES

Fluoxetine Hydrochloride is manufactured by \_\_\_\_\_ DMF  
DMF was reviewed and found to be acceptable (see chemist review #3).

|                       |              |               |
|-----------------------|--------------|---------------|
| 10 mg/lot no. 6496034 | theo. units/ | actual units. |
|-----------------------|--------------|---------------|

|                       |              |               |
|-----------------------|--------------|---------------|
| 20 mg/lot no. 6496022 | theo. Units/ | actual units. |
|-----------------------|--------------|---------------|

PROPOSED PRODUCTION BATCH

Blank batch record for the intended production batch sizes of \_\_\_\_\_ and \_\_\_\_\_ units for the 10 mg and 20 mg strengths, respectively, are included.

SPECIFICATIONS TO BE APPROVED:

Drug Substance

| Test parameter          | Specification                         |
|-------------------------|---------------------------------------|
| (A) Foreign Matter      | Acceptable                            |
| (A) Description         | White to off-white crystalline powder |
| Identification          |                                       |
| (B) Residual Solvents   |                                       |
| (A) Water               |                                       |
| Melting Range           |                                       |
| (B) Heavy Metals        |                                       |
| (B) Residue On Ignition |                                       |
| (A) Assay               |                                       |
| (A) Related Compounds   |                                       |
| Particle Size           |                                       |
| Tapped Density          |                                       |

DRUG PRODUCT:

| Test                     | Specification           | Method |
|--------------------------|-------------------------|--------|
| Assay                    | % of label claim        |        |
| Chromatographic Purity** | Total NMT %             |        |
| Content Uniformity       | Current USP <905>       |        |
| Description              | Conforms                |        |
| Dissolution/water*       | NLT % (Q) in 30 minutes |        |
| Identification           |                         |        |

\*\* Fluoxetine Related Compound "A": NMT %  
Fluoxetine Related Compound "B": NMT %

Any Individual Unknown: NMT %

**STABILITY:**

| Test              | Specification       | Method |
|-------------------|---------------------|--------|
| Assay             | %                   |        |
| Dissolution/Water | NLT % in 30 minutes |        |
| Chrom. Purity*    | Total NMT %         |        |
| Appearance        | Conforms            |        |

\* Fluoxetine Related Compound "A": NMT %  
Fluoxetine Related Compound "B": NMT %

Any Individual Unknown: NMT %

**RECOMMENDATION:**

Recommend TA letter to issue for Fluoxetine Hydrochloride Capsules, 10 mg and 20 mg.

SIGNATURE:

DATE: April 27, 1999

*SL* 5/18/99

NOTE: According to letter dated 1/28/99, Geneva cannot market until 12/2/03.