

**REVIEW FOR HFD-120
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805**

Microbiologist's Review #1 of NDA 20-990
November 18, 1998

A. 1. **APPLICATION NUMBER:** 20-990

APPLICANT: Pfizer Pharmaceuticals
235 East 42nd Street
New York, NY 10017-5755

2. **PRODUCT NAMES:** Zoloft (sertraline hydrochloride) Oral Concentrate

3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:** 20 mg/ml of sertraline. It is packaged in a 60 ml amber glass bottle (60 ml fill volume) with an accompanying calibrated dropper. The drug product is diluted with approximately 120 ml of diluent (water, gingerale, lemon/lime soda or orange juice) prior to oral administration.

4. **METHOD(S) OF STERILIZATION:**

5. **PHARMACOLOGICAL CATEGORY:** Zoloft is indicated for treatment of depression.

B. 1. **DATE OF INITIAL SUBMISSION:** April 15, 1998

2. **AMENDMENT:** none

3. **RELATED DOCUMENTS:**

4. **ASSIGNED FOR REVIEW:** August 17, 1998

5. **DATE OF CONSULT REQUEST:** August 14, 1998

C. **REMARKS:**

Zoloft was originally approved in December of 1991 for the treatment of depression. The original approval covered a tablet formulation. This submission requests approval of a new formulation of sertraline, the oral liquid concentrate.

D. CONCLUSIONS:

The application is approvable pending resolution of microbiology issues

APPEARS THIS WAY
ON ORIGINAL

/S/

11/18/98

Brenda Uratani, Ph.D.
Review Microbiologist

/S/

11/19/98

APPEARS THIS WAY
ON ORIGINAL

cc:

NDA 20-990

HFD-120/ Div. File

HFD-805/ Uratani

HFD-120/Klein

drafted by: Brenda Uratani, 11/18/98

R/D initialed by P. Cooney, 11/18/98