

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-726

MICROBIOLOGY REVIEW(S)

JAN 17 1997

DeTye

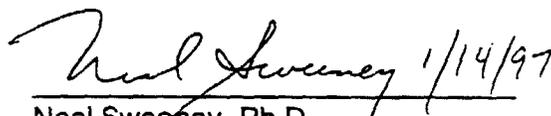
REVIEW FOR HFD-150

OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review # 2 of NDA 20-726
January 14, 1997

- A. 1. APPLICATION NUMBER: NDA 20-726
- APPLICANT: Ciba-Geigy Corporation
56 Morris Avenue
Summit, NJ 07901-1398
2. PRODUCT NAME: Femara (letrozole) tablets
3. DOSAGE FORM: 100 mg film-coated tablets containing 2.5 mg letrozole (non-sterile oral dosage)
4. METHOD OF STERILIZATION: None (non-sterile product).
5. PHARMACOLOGICAL CATAGORY and/or PRINCIPLE INDICATION:
Femara (letrozole) is a nonsteroidal aromatase inhibitor indicated for the treatment of advanced breast cancer in women with natural or artificially induced postmenopausal status.
6. DRUG PRIORITY CLASSIFICATION: 1S
- B. 1. DATE OF INITIAL SUBMISSION: July 24, 1996 (Subject of Microbiologist's Review #1)
2. DATE OF CONSULT: August 22, 1996
3. DATE OF AMENDMENT: December 30, 1996 (Subject of Microbiologist's Review #2)
4. RELATED DOCUMENTS: (none)
5. ASSIGNED FOR REVIEW: January 8, 1997
- C. REMARKS: Microbiologist's Review #1 (Oct. 17, 1996) resulted in two questions which were conveyed to the applicant on November 12, 1996 via Fax. The applicant's responses to the issues are provided below and follow the italicized questions from Microbiologist's Review #1.

D. CONCLUSIONS:

The application is recommended for approval for issues concerning drug substance/product microbial limits specifications, microbial limits method validation and specifications, and microbiology stability testing.


Neal Sweeney, Ph.D.
DHC 1/17/97

cc:

Original NDA 20-726
HFD-150/ Division File
HFD-150/CSO/D.Spillman
HFD-150/P.Dietz/L.Zhou/E.Tolgyesi
HFD-805/Consult File/N. Sweeney

Drafted by: Neal Sweeney, January 14, 1997
R/D initialed by P. Cooney, January 14, 1997

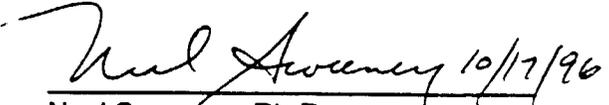
REVIEW FOR HFD-150

OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review # 1 of NDA 20-726
October 17, 1996

- A. 1. APPLICATION NUMBER: NDA 20-726
- APPLICANT: Ciba-Geigy Corporation
56 Morris Avenue
Summit, NJ 07901-1398
2. PRODUCT NAME: Femara (letrozole) tablets
3. DOSAGE FORM: 100 mg film-coated tablets containing 2.5 mg letrozole (non-sterile oral dosage)
4. METHOD OF STERILIZATION: None (non-sterile product).
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Femara (letrozole) is a nonsteroidal aromatase inhibitor indicated for the treatment of advanced breast cancer in women with natural or artificially induced postmenopausal status.
6. DRUG PRIORITY CLASSIFICATION: 1S
- B. 1. DATE OF INITIAL SUBMISSION: July 24, 1996
2. DATE OF CONSULT: August 22, 1996
3. RELATED DOCUMENTS: (none)
4. ASSIGNED FOR REVIEW: September 4, 1996
- C. REMARKS: The consult request is for evaluations of (1) the microbial limit specifications for the drug substance and drug product, and (2) the respective validations of the microbial limit methodologies. This review also considers the microbiology aspects of the proposed stability protocol.

D. CONCLUSIONS:

The application is recommended as "approvable" for issues concerning drug substance/product microbial limits specifications, and microbial limits method validation.


Neal Sweeney, Ph.D.
 10/21/96

cc:

Original NDA 20-726
HFD-150/ Division File
HFD-150/CSO/D.Spillman
HFD-150/P.Dietz/L.Zhou/E.Tolgyesi
HFD-805/Consult File/N. Sweeney

Drafted by: Neal Sweeney, October 17, 1996
R/D initialed by P. Cooney October 17, 1996