CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-319

MICROBIOLOGY REVIEW

REVIEW TO HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF/HFD-805
MICROBIOLOGY REVIEW #1 OF NDA

8 August 2001

A. 1. NDA: 21-319

2. TYPE OF SUPPLEMENT: N/A

3. SUPPLEMENT PROVIDES FOR: N/A

4. APPLICANT/SPONSOR: Glaxo Wellcome
Five Moore Drive
Research Triangle Park, NC 27709

5. MANUFACTURING SITE:

6. DRUG PRODUCT NAME:
Proprietary:
Nonproprietary: Dutasteride
Drug Priority Classification:

7. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Soft Gelatin Capsules, Oral, 0.5 mg

8. METHOD(S) OF STERILIZATION: N/A

9. PHARMACOLOGICAL CATEGORY: Benign Prostatic Hyperplasia

B. 1. DOCUMENT/LETTER DATE: December 21, 2000
2. RECEIPT DATE: December 21, 2000
3. CONSULT DATE: April 12, 2001
4. DATE OF AMENDMENT: N/A
5. ASSIGNED FOR REVIEW: May 8, 2001
6. SUPPORTING/RELATED DOCUMENTS:

C. REMARKS: The applicant proposes not performing microbial limit testing for this non-sterile, non-aqueous, oral dosage form.

D. CONCLUSIONS: This submission is recommended for approval on the basis of product quality microbiology.

Bryan S. Riley, Ph.D.
Microbiology Reviewer

cc.: Original NDA 21-319
HFD 580/Division File
HFD 580/Project Manager
HFD 580/Other
HFD 805/Consult File
HFD 805/ B. Riley

Drafted by: Bryan Riley, Ph.D.
R/D initialed by: Peter Cooney, Ph.D.