CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
21-238

Microbiology Review(s)

Validation of the regulatory methods will be completed after approval.

(S)

5/24/01

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

REVIEW TO HFD-180
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF/HFD-805
MICROBIOLOGY REVIEW #1 OF NDA

27 March 2001

A. 1. NDA: 21-238

2. TYPE OF SUPPLEMENT: N/A

3. SUPPLEMENT PROVIDES FOR: N/A

4. APPLICANT/SPONSOR: Glaxo SmithKline
1250 S. Collegeville Road
PO Box 5089
Collegeville, PA 19426

5. MANUFACTURING SITE:

6. DRUG PRODUCT NAME:
Proprietary: Kytril
Nonproprietary: granisetron hydrochloride
Drug Priority Classification: Standard

7. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Non-Sterile, Preserved Oral Solution, 0.2 mg/mL

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

9. PHARMACOLOGICAL CATEGORY: Anti-Emetic

B. 1. DOCUMENT/LETTER DATE: August 30, 2000
2. RECEIPT DATE: September 1, 2000
3. CONSULT DATE: February 5, 2001
4. DATE OF AMENDMENT: N/A
5. ASSIGNED FOR REVIEW: February 7, 2001
6. SUPPORTING/RELATED DOCUMENTS:

C. REMARKS: The drug product contains sodium benzoate as a preservative, and is acidic (pH 2.8-3.2) which also inhibits microbial contaminants.

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

/S/

Bryan S. Riley, Ph.D.
Microbiology Reviewer

cc.: Original NDA 21-238
HFD 180/Division File
HFD 180/Project Manager
HFD 180/Other
HFD 805/Consult File
HFD 805/ B. Riley

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

Redacted 2

pages of trade

secret and/or

confidential

commercial

information