

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-281

MICROBIOLOGY REVIEW

MAR 26 2001

REVIEW FOR HFD-180

OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review # 1 of NDA 21-281

March 14, 2001

- A. 1. **APPLICATION NUMBER:** NDA 21-281
- APPLICANT:** TAP Pharmaceuticals
675 North Field Drive
Lake Forest IL, 60045
Phone: 847-317-5781
FAX: 847-317-5795
2. **PRODUCT NAME:** Prevacid®
3. **DOSAGE FORM:** Prevacid (lansoprazole) Sachet for Suspension, 15 mg and 30 mg unit dose sachets.
4. **METHOD OF STERILIZATION:** None (non-sterile product).
5. **PHARMACOLOGICAL CATAGORY and/or PRINCIPLE INDICATION:** Proton pump inhibitor which inhibits gastric acid secretion. Indicated for treatment of gastric and duodenal ulcers.
6. **DRUG PRIORITY CLASSIFICATION:** Standard
- B. 1. **DATE OF INITIAL SUBMISSION:** 06/30/00
2. **DATE OF CONSULT:** 02/02/01
3. **ASSIGNED FOR REVIEW:** 02/08/01
4. **RELATED DOCUMENT:** NDA 20-406 (Prevacid Delayed-Release Capsules)
- C. **REMARKS:** NDA 21-281 provides for a new dosage form (Sachet for Suspension) for Prevacid®.

D. CONCLUSIONS:

The application is approvable pending resolution of microbiology issues concerning microbiological attributes of the drug product. Specific comments are provided in "E. REVIEW NOTES" and "List of Microbiology Comments and Deficiencies".

APPEARS THIS WAY
ON ORIGINAL

Neal Sweeney, Ph.D.

APPEARS THIS WAY
ON ORIGINAL

cc:

NDA 21-281
HFD-180/ Division File
HFD-180/J. Sieczkowski/C. Perry
HFD-805/Consult File/N. Sweeney

Drafted by: Neal Sweeney, March 14, 2001
R/D initialed by P. Cooney March 14, 2001