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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-566

Microbiology Review(s)

04/08/03

Product Quality Microbiology Review
Review for HFD-180
03 April 2003

NDA: NDA 21-566

Drug Product Name

Proprietary: Prevacid I.V. for Injection

Non-proprietary: lansoprazole for injection

Drug Product Classification: Short Term Treatment of Erosive
Esophagitis

Review Number: 1

Subject of this Review

Submission Date: 20 December 2002

Receipt Date: 23 December 2002

Consult Date: 22 January 2003

Date Assigned for Review: 23 January 2003

Submission History (for amendments only)

Date(s) of Previous Submission(s):

Date(s) of Previous Micro Review(s):

Applicant/Sponsor

Name: Tap Pharmaceutical Products, Inc.

Address: 675 North Field Drive, Lake Forest, IL 60045

Representative: Nancianne Knipfer

Telephone: (847) 236-2193

Name of Reviewer: Paul Stinavage

Conclusion: The application is recommended for approval on the basis of
sterility assurance.

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUPPLEMENT:** Not Applicable
2. **SUPPLEMENT PROVIDES FOR:** Not Applicable
3. **MANUFACTURING SITE:** []
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** 30 mg/vial
5. **METHOD(S) OF STERILIZATION:** []
6. **PHARMACOLOGICAL CATEGORY:** Treatment for erosive esphagitis
- B. **SUPPORTING/RELATED DOCUMENTS:** IND's [] 41,938; NDA 20-406; DMF's []
- C. **REMARKS:** The product will be manufactured, tested, released, and tested on stability by: []

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Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – The submission is recommended for approval on the basis of sterility assurance.
- B. **Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**

II. Summary of Microbiology Assessments

- A. **Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – []
- B. **Brief Description of Microbiology Deficiencies** –
- C. **Assessment of Risk Due to Microbiology Deficiencies** –

III. Administrative

- A. **Reviewer's Signature** _____
- B. **Endorsement Block**
Paul Stinavage
Peter H. Cooney
- C. **CC Block**
cc: Melissa Hancock Furness
Original NDA 21-566
HFD-180/Division File/NDA 21-566

6 Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

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/s/

Paul Stinavage
4/8/03 12:47:17 PM
MICROBIOLOGIST
Product manufactured L J

Peter Cooney
4/8/03 02:53:01 PM
MICROBIOLOGIST