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RESEARCH**

APPLICATION NUMBER:

21-494

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Review for HFD-180

01 August 2002

NDA: 21-494

Drug Product Name

Proprietary: Axid®

Non-proprietary: Nizatidine Syrup

Drug Product Classification: Oral dosage form

Review Number: 1

Subject of this Review

Submission Date: 10 April 2002

Receipt Date: 11 April 2002

Consult Date: 28 May 2002

Date Assigned for Review: 25 June 2002

Applicant/Sponsor

Name: Reliant Pharmaceuticals

Address: 110 Allen Road, Liberty Corner, NJ 07938

Representative: Keith Rotenberg

Telephone: (908)542-4423

Name of Reviewer: Paul Stinavage

Conclusion: The application is approvable pending resolution of product quality microbiology concerns.

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUPPLEMENT:** N/A
 2. **SUPPLEMENT PROVIDES FOR:** N/A
 3. **MANUFACTURING SITE:** Brockton, MA
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Oral Dosage Form
 5. **METHOD(S) OF STERILIZATION:** Non-sterile product
 6. **PHARMACOLOGICAL CATEGORY:** The product is intended for treatment of endoscopically diagnosed esophagitis, including erosive and ulcerative esophagitis and associated heartburn due to GERD.
- B. **SUPPORTING/RELATED DOCUMENTS:**
- C. **REMARKS:** Chemistry, Manufacturing, and Controls information for this application were cross referenced to the data contained in the efficacy supplement

[_____]

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Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – The application is approvable pending resolution of product quality microbiology concerns.
- 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 – none**

III. Administrative

- A. **Reviewer's Signature** _____
- B. **Endorsement Block**
 - P. Stinavage
 - P.H. Cooney
- C. **CC Block**
 - cc:
 - Original NDA 21-494
 - HFD-180/Division File/NDA 21-494/P. Levine

2 Page(s) Withheld

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

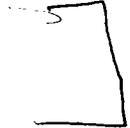
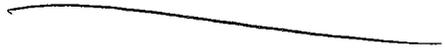
§ 552(b)(4) Draft Labeling

§ 552(b)(5) Deliberative Process

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/s/

Paul Stinavage
8/12/02 09:06:23 AM
MICROBIOLOGIST



Robert Cooney
8/12/02 11:01:34 AM
MICROBIOLOGIST