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RESEARCH**

APPLICATION NUMBER:
21-565

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Consult review for HFD-550

11 April, 2003

NDA: NDA 21-565

Name of Drug: RELESTAT™ 0.05%

Review Number: 1

Submission Date: December 19, 2002

Applicant: Allergan

Name of Reviewer: Vinayak Pawar

Conclusion: The application is recommended for approval from microbiological standpoint.

Executive Summary**I. Recommendations****A. Recommendation on Approvability -**

The sterilization validation and the preservative effectiveness adequately assure the safety of the product from microbiological standpoint. The proposal is recommended for approval.

B. Recommendation on Phase 4 Commitments and/or Agreements, if Approvable

NA

II. Summary of Microbiology Assessments**A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology**

Edetate Disodium, Sodium Chloride, Monobasic Sodium Phosphate _____, Epinastine hydrochloride, Benzalkonium Chloride and _____ Sodium Hydroxide are added to Purified Water and the pH adjusted to _____ The batch is _____ and filled _____ into pre-sterilized containers to _____ 5mL and 10mL fills and labeled. The process is summarized in Fig 1.

B. Brief Description of Microbiology Deficiencies

None

C. Assessment of Risk Due to Microbiology Deficiencies-

None

III. Administrative**A. Reviewer's Signature _____****B. Endorsement Block**

Vinayak Pawar/11 April 2003

Peter H. Cooney/

C. CC Block

cc:

Original NDA 21-565

HFD-550/Division File/Raphael Rodriguez

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/s/

Vinayak Pawar
5/1/03 10:29:58 AM
MICROBIOLOGIST

Peter Cooney
5/2/03 10:00:30 AM
MICROBIOLOGIST