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RESEARCH**

*APPLICATION NUMBER:*  
**22442Orig1s000**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

16 March 2009

**NDA:** 22-442/N000

**Drug Product Name**

**Proposed Proprietary:**

REZIRA (b) (4)

**Non-proprietary:**

Hydrocodone Bitartrate, USP

Pseudoephedrine Hydrochloride, USP

**Review Number:** 1

**Dates of Submission(s) Covered by this Review**

Letter	Stamp	Review Request	Assigned to Reviewer
07-NOV-2008	10-NOV-2008	15-JAN-2009	23-JAN-2009

**Submission History (for amendments only) N/A**

**Applicant/Sponsor**

**Name:**

Cypress Pharmaceuticals

**Address:**

135 Industrial Blvd.

Madison, MS 39110

**Representative:**

William Putnam

**Telephone:**

(913) 451-3955

**Name of Reviewer:**

Denise Miller

**Conclusion:**

Approve

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## Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA
  2. **SUBMISSION PROVIDES FOR:** new drug product
  3. **MANUFACTURING SITE:**  

(b) (4)
  4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
    - (b) (4) aqueous solution
    - Oral
    - Strength:
      - 5 mg/5mL Hydrocodone bitrtrate
      - 60 mg/5 mL Pseudoephedrine hydrochloride
  5. **METHOD(S) OF STERILIZATION:** not a sterile drug product
  6. **PHARMACOLOGICAL CATEGORY:** Relief of cough and nasal congestion
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:**
- Submission is an electronic document in the CTD format.
  - Original submission's proposed name REZIRA  (b) (4) was withdrawn from consideration on 04-MAR-2009. Proposed proprietary name REZIRA™ still under consideration.

**filename:** N022439N000.R1

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## **Executive Summary**

### **I. Recommendations**

- A. Recommendation on Approvability** – Recommend to approve from a quality microbiology standpoint.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A

### **II. Summary of Microbiology Assessments**

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – Non-sterile oral pharmaceutical product. Assessment of [REDACTED] (b) (4) [REDACTED] performed.
- B. Brief Description of Microbiology Deficiencies** - None
- C. Assessment of Risk Due to Microbiology Deficiencies** – N/A

### **III. Administrative**

- A. Reviewer's Signature** \_\_\_\_\_  
Denise Miller, Microbiologist
- B. Endorsement Block** \_\_\_\_\_  
Bryan S. Riley, Ph.D.
- C. CC Block**  
N/A

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/s/

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Denise Miller  
3/19/2009 01:18:13 PM  
MICROBIOLOGIST

Bryan Riley  
3/19/2009 01:21:51 PM  
MICROBIOLOGIST  
I concur.