

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
022439Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

16 March 2009

NDA: 22-439/N000

Drug Product Name

Proposed Proprietary:

(b) (4)

Non-proprietary:

Hydrocodone Bitartrate, USP
Pseudoephedrine Hydrochloride, USP
Chlorpheniramine Maleate, USP

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
06-NOV-2008	07-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

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:
 - 5.0 mg/5mL Hydrocodone bitrtrate
 - 60.0 mg/5 mL Pseudoephedrine hydrochloride
 - 4.0 mg/5mL Chlorpheniramine maleate
 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 - Original submission's proposed name  (b) (4) was withdrawn from consideration on 30-JAN-2009. Proposed proprietary name  (b) (4) still under consideration.

filename: N022439N000.R1

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

4 Page(s) has been Withheld in Full as B4 (CCI/TS) immediately following this page

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Denise Miller
3/16/2009 08:29:11 AM
MICROBIOLOGIST

Bryan Riley
3/16/2009 08:45:55 AM
MICROBIOLOGIST
I concur.