# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

**204307Orig1s000**

# MICROBIOLOGY REVIEW(S)

# Product Quality Microbiology Review

**October 29, 2012**

**NDA: 204307**

**Drug Product Name**

**Proprietary:** (b) (4) oral solution

**Non-proprietary:** hydrocodone bitartrate and chlorpheniramine maleate/Solution

**Review Number:** 1

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

| Submit | Received | Review Request | Assigned to Reviewer |
|---|---|---|---|
| 4/23/2012 | 4/24/2012 | 7/06/2012 | 7/13/2012 |
| 8/02/2012 | 8/02/2012 | N/A | N/A |
| 10/29/2012 | 10/29/2012 | N/A | N/A |

**Submission History (for amendments only):** None

**Applicant/Sponsor**

**Name:** Cypress Pharmaceutical, Inc.

**Address:** 135 Industrial Boulevard, Madison, MS 39110

**Representative:** Janet K. DeLeon, RAC, Director of Product Development, 2944 W 143rd Terrace, Leawood, KS 66224

**Telephone:** 913 681-0667

**Name of Reviewer:** Steven P. Donald, M.S.

**Conclusion:** Recommended for approval.

# Product Quality Microbiology Data Sheet

**A. 1. TYPE OF SUBMISSION:** Original NDA

**2. SUBMISSION PROVIDES FOR:** Manufacture of an oral solution

**3. MANUFACTURING SITE:** Great Southern Laboratories, 10863 Rockley Rd. Houston, TX 77099

**4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Solution, (b) (4) in multi-dose bottle, oral, 5mg hydrocodone bitartrate/4mg chlorpheniramine maleate per 5 ml

**5. METHOD(S) OF STERILIZATION:** (b)

**6. PHARMACOLOGICAL CATEGORY:** Narcotic analgesic and antihistamine

**B. SUPPORTING/RELATED DOCUMENTS:** None

**C. REMARKS:** The CMC Micro review request pertains to an information request made by the CMC Quality reviewer in the 74 day letter and the subsequent responses by the applicant. The filing review and information request was drafted by Quality reviewer L Hann and is dated July 6, 2012. The responses received on 8/02/2012 and 10/29/2012 are reviewed herein along with the complete NDA submission, by the Product Quality Microbiology reviewer.

**filename:** N204307r1.doc

# Executive Summary

**I. Recommendations**

**A. Recommendation on Approvability –**
NDA 204307 is recommended for approval from the standpoint of product quality microbiology.

**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 –** The drug product is an oral solution prepared by the addition of the API in an excipient/ water solution.

**B. Brief Description of Microbiology Deficiencies –** No product quality microbiology deficiencies were identified based upon the information provided.

**C. Assessment of Risk Due to Microbiology Deficiencies -** N/A

**III. Administrative**

**A. Reviewer's Signature _____**
Steven P. Donald, M.S.

**B. Endorsement Block_____**
Bryan Riley, Ph.D.
Team Leader

**C. CC Block**
N/A

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/s/

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STEVEN P DONALD
11/01/2012

BRYAN S RILEY
11/01/2012
I concur.