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APPLICATION NUMBER:

22-348

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

May 6, 2009

NDA: 22-348

Drug Product Name
Proprietary: Amelior
Non-proprietary: ibuprofen IV

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
December 11, 2008	December 11, 2008	January 13, 2009	January 13, 2009

Submission History (for amendments only) – N/A

Applicant/Sponsor
Name: Cumberland Pharmaceuticals
Address: 2525 West End Ave, Nashville, TN 37203
Representative: Amy D. Rock, Ph.D., Senior Manager, R A
Telephone: 615-255-0068

Name of Reviewer: Vinayak B. Pawar, Ph.D.

Conclusion: NDA 22-348 is recommended for approval from microbiology product quality standpoint.

Product Quality Microbiology Data Sheet

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

2. **SUBMISSION PROVIDES FOR:** Intravenous Ibuprofen

3. **MANUFACTURING SITES:**
(b) (4)

(b) (4)

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Intravenous injection, 400mg, 800mg (100mg/mL)

5. **METHOD(S) OF STERILIZATION:** (b) (4)

6. **PHARMACOLOGICAL CATEGORY:** Management of Pain and reduction of fever.

B. **SUPPORTING/RELATED DOCUMENTS:** N/A

C. **REMARKS:** An original NDA 22-348 is submitted for the drug product Amelior (Ibuprofen IV). This product will be manufactured by (b) (4) will manufacture both, 400mg/vial and 800mg/vial configurations, while (b) (4) will currently manufacture only 400mg/vial configuration. This is a fast track electronic submission. (b) (4) manufacturing site at (b) (4), was last inspected by FDA in February 2007. (b) (4) manufacturing site at (b) (4), was last inspected by FDA in January, 2007. The IQA was filed by Danae Christodoulou on February 4, 2009.

filename: C:\my documents\review\NDA\N022348R1

Executive Summary

I. Recommendations

A. Recommendation on Approvability – The application is recommended for approval from microbiology product quality 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 –
Ibuprofen Injection is sterilized using a (b) (4) sterilization process. To ensure that the production environment is not compromised, all equipment and components required for manufacture of Ibuprofen Injection are (b) (4) prior to use. (b) (4)

B. Brief Description of Microbiology Deficiencies - None

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

III. Administrative

A. Reviewer's Signature _____
Vinayak B. Pawar, Ph.D.
Reviewer, CDER/OPS/NDMS

B. Endorsement Block _____
David Hussong, Ph.D.
Assoc. Director., CDER/OPS/NDMS

C. CC Block
N/A

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/s/

Vinayak Pawar
5/11/2009 03:57:46 PM
MICROBIOLOGIST

The application is recommended for approval from microbiology product quality standpoint.

David Hussong
5/11/2009 08:34:48 PM
MICROBIOLOGIST
I concur with the reviewer's recommendation for approval of this new drug application.