

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

202450Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

06 DEC 2011

NDA: 202-450

Drug Product Name

Proprietary: (b) (4) (proposed)

Non-proprietary: Acridinium bromide

Review Number: 1

Dates of Submission(s) Covered by this Review

| Submit | Received | Review Request | Assigned to Reviewer |
|-------------|-------------|----------------|----------------------|
| 23 JUN 2011 | 23 JUN 2011 | 13 OCT 2011 | 13 OCT 2011 |
| 23 SEP 2011 | 23 SEP 2011 | N/A | N/A |
| 19 OCT 2011 | 19 OCT 2011 | N/A | N/A |
| 02 DEC 2011 | 02 DEC 2011 | N/A | N/A |

Applicant/Sponsor

Name: Forest Laboratories

Address: Harborside Financial Center
Plaza V, Suite 1900
Jersey City, NJ 07311

Representative: Amjad M. Iqbal

Telephone: 201-386-2117

Name of Reviewer: Jessica G. Cole, Ph.D.

Conclusion: This application is recommended for approval.

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** 505(b)(1) NDA
 2. **SUBMISSION PROVIDES FOR:** A non-sterile dry powder in a (b) (4)
[REDACTED]
 3. **MANUFACTURING SITE:** Forest Laboratories, Ireland Limited
Clonsaugh Business & Technology Park
Dublin 17 Ireland
FEI: 3002806993
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Non-sterile dry powder in a (b) (4)
 - Oral inhalation
 - 400 µg aclidinium bromide
 5. **METHOD(S) OF STERILIZATION:** This is a non-sterile drug product
 6. **PHARMACOLOGICAL CATEGORY:** Indicated for the maintenance treatment of chronic obstructive pulmonary disease

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

C. **REMARKS:** This submission was in the eCTD format. The following information request was sent to applicant on 21 November 2011 and a response was received on 02 December 2011.

Microbiology Comment:

Provide the results of verification studies for the microbial enumeration tests demonstrating that the proposed methods are suitable for use with the drug product.

filename: N202450R1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – This application is recommended for approval on the basis of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – Not applicable.

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – This drug product is (b) (4) and has established microbial limits which insure the safety of the final dosage form.
- B. Brief Description of Microbiology Deficiencies** – Not applicable.
- C. Assessment of Risk Due to Microbiology Deficiencies** – Not applicable.

III. Administrative

- A. Reviewer's Signature** _____
Jessica G. Cole, Ph.D.
- B. Endorsement Block** _____
Stephen Langille, Ph.D.
Senior Microbiology Reviewer
- C. CC Block**
N/A

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

/s/

JESSICA COLE
12/12/2011

STEPHEN E LANGILLE
12/12/2011