

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-912

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

07 JULY 2006

NDA: 21-912

Drug Product Name

Proprietary: N/A.

Non-proprietary: arformoterol tartrate.

Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
8 DEC 2005	12 DEC 2005	15 FEB 2006	28 FEB 2006
23 JUNE 2006	26 JUNE 2006	N/A	N/A

Applicant/Sponsor

Name: Sepracor Inc.

Address: 84 Waterford Drive.
Marlborough, MA. 01752-7010

Representative: Renee M. Carroll

Telephone: 508-357-7598

Name of Reviewer: John W. Metcalfe, Ph.D.

Conclusion: Recommended for Approval.

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA.
 2. **SUBMISSION PROVIDES FOR:** A new drug product.
 3. **MANUFACTURING SITE:**
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[]
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Inhalation Solution.
 - Oral Inhalation.
 - 15 µg/ 2 mL.
 5. **METHOD(S) OF STERILIZATION:** [] b(4)
[]
 6. **PHARMACOLOGICAL CATEGORY:** The drug product is indicated for the long term maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.
- B. **SUPPORTING/RELATED DOCUMENTS:** None.
- C. **REMARKS:**
A facsimile was forwarded to the applicant on 05 June 2006 for the purpose of conveying several questions regarding the subject submission. The questions posed to the applicant are as follows:
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The applicant provided a response to each of the above questions in an amendment to the subject submission dated 23 June 2006. The applicant responses are included in appropriate sections of this review.

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On Original

File Name: N021912R1.doc

Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – NDA 21-912 is recommended for approval on the basis of microbiological product quality.
- 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 proposed commercial manufacturing process begins with

[
C]
= Vials

b(4)

are later overwrapped in foil pouches and then placed in cartons and shipper cases.

- B. **Brief Description of Microbiology Deficiencies** – There are no microbiology deficiencies identified.
- C. **Assessment of Risk Due to Microbiology Deficiencies** – Not applicable.

III. Administrative

- A. **Reviewer's Signature** _____
- B. **Endorsement Block**
Stephen E. Langille, Ph.D.
- C. **CC Block**
N/A

14 Page(s) Withheld

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 Draft Labeling

 Deliberative Process

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

/s/

John Metcalfe
7/12/2006 03:10:05 PM
MICROBIOLOGIST

Stephen Langille
7/12/2006 03:16:42 PM
MICROBIOLOGIST