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

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<td>23 JUNE 2006</td>
<td>26 JUNE 2006</td>
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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:
   ❖ ❖

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:
   - Inhalation Solution.
   - Oral Inhalation.
   - 15 µg/2 mL.

5. METHOD(S) OF STERILIZATION:
   ❖

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:

❖

Page 2 of 18
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.
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
   \[
   \begin{align*}
   &\text{Container} \\
   \Downarrow &\text{Vials}
   \end{align*}
   \]
   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

D(4) Trade Secret / Confidential

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

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