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RESEARCH**

APPLICATION NUMBER:

21-730

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Review for HFD 570

1-March-2005

NDA: 21-730

Drug Product Name
Proprietary: Xopenex™ HFA Inhalation Aerosol
Non-proprietary: levalbuterol tartrate

Drug Product Classification: Standard

Review Number: 1

Subject of this Review
Submission Date: May 11, 2004
Receipt Date: May 12, 2004
Consult Date: July 23, 2004
Date Assigned for Review: August 3, 2004

Submission History (for amendments only)
Date(s) of Previous Submission(s): Not applicable
Date(s) of Previous Micro Review(s): Not applicable

Applicant/Sponsor
Name: Sepracor Inc.
Address: 84 Waterford Drive
Marlborough, MA
508-481-6700

Representative: Ms. Renee Carroll
Telephone: 508-357-7598

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** New Drug Application
 2. **SUBMISSION PROVIDES FOR:** Product quality microbiology information for a metered dose inhalation product
 3. **MANUFACTURING SITE:**
3M Pharmaceuticals
19901 Nordhoff Street
Northridge, CA 91324-3298
Establishment Registration
Number CFI-2010441
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Inhalant
 - Oral
 - 45 ug/actuation
 5. **METHOD(S) OF STERILIZATION:** Non-sterile
 6. **PHARMACOLOGICAL CATEGORY:** Treatment for bronchospasms
- B. **SUPPORTING/RELATED DOCUMENTS:** None
- C. **REMARKS:**

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Executive Summary

I. Recommendations

- A. Recommendation on Approvability -**
NDA 21-730 is recommended for approval from the standpoint 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 -**
The applicant will perform microbial limits testing on a non-sterile aqueous inhalation product packaged in a metered dose inhaler.
- B. Brief Description of Microbiology Deficiencies -**
No microbiology deficiencies were identified based upon the information provided in this application.
- C. Assessment of Risk Due to Microbiology Deficiencies -**
Not applicable

III. Administrative

- A. Reviewer's Signature** _____
- B. Endorsement Block**
Stephen E. Langille, Ph.D.
David Hussong, Ph.D.
- C. CC Block**
In DFS

3 Page(s) Withheld

1 § 552(b)(4) Trade Secret / Confidential

1 § 552(b)(5) Deliberative Process

1 § 552(b)(4) Draft Labeling

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/s/

Stephen Langille
3/4/05 09:06:30 AM
MICROBIOLOGIST

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3/4/05 09:58:49 AM
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