

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-007

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

01 DECEMBER 2006

NDA: 22-007

Drug Product Name

Proprietary: N/A

Non-proprietary: Formoterol Fumarate Inhalation Solution

Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
6/28/2006	6/29/2006	8/10/2006	8/17/2006

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Dey LP

Address: 2751 Napa Valley Corporate Drive, Napa, CA 94558

Representative: Michele Carpenter, JD

Telephone: 707-224-3200 ext4750

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA [505(b)(2)]
 2. **SUBMISSION PROVIDES FOR:** Sterile inhalation solution
 3. **MANUFACTURING SITE:** Dey, L.P.
2751 Napa Valley Corporate Dr
Napa, CA 94558
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile aqueous, non-preserved, solution in unit-dose / _____ vial for inhalation, 20 mcg/2 mL **b(4)**
 5. **METHOD(S) OF STERILIZATION:** _____ **b(4)**
 6. **PHARMACOLOGICAL CATEGORY:** bronchodilator
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** N/A

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Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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/s/

Bryan Riley
12/4/2006 10:45:20 AM
MICROBIOLOGIST

James McVey
12/4/2006 11:28:31 AM
MICROBIOLOGIST