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RESEARCH**

*APPLICATION NUMBER:*  
**20950**

**MICROBIOLOGY REVIEW**

Hilfikar  
MAR - 1 1999

REVIEW FOR HFD-570  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF  
MICROBIOLOGIST'S REVIEW #1 OF NDA

February 23, 1999

A. 1. NDA 20-950

SPONSOR Dey Laboratories  
Napa, California

2. PRODUCT NAMES: Duovent (Albuterol Sulfate/ipratropium bromide combination)  
Inhalation Solution

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Inhalation solution  
without preservative, in a 3 mL (nominal) LDPE plastic vial. Vials are in groups of 5,  
packaged in a laminated overwrap.

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: A combination of bronchodilation agents.

6. DRUG PRIORITY CLASSIFICATION: 3S

B. 1. DATE OF INITIAL SUBMISSION: May 28, 1998

2. DATE OF AMENDMENT: (n/a)

3. RELATED DOCUMENTS: See Microbiologist's Review #1 of NDA 20-949.

4. ASSIGNED FOR REVIEW: November 18, 1998

C. REMARKS: This is an original NDA submission. The application provides for sterile,  
preservative-free inhalation solutions. Proposed FDA regulations will require inhalation  
solution products to be rendered sterile by their process of manufacture. -

This submission is very similar to NDA 20-949. Selected pages between 70 - 87 and  
selected sections from volume 4 were provided for review. The applicant, Dey  
Laboratories, has submitted applications for sterile products made by  
These include ANDAs \_\_\_\_\_ and 71-786, both of which are  
metaproterenol.

D. CONCLUSIONS: The submission is approvable. Comments to the applicant are provided at the end of the review.

/S/ 1 2-23-99  
\_\_\_\_\_  
David Hussong, Ph.D.  
Pae 3/1/99

cc:

HFD 160/Consult File  
HFD 570/CSO/D. Hilfikar/C. Shumaker  
HFD 820/Chemistry Reviewer/Kim  
HFD 805/D. Hussong

Drafted by: D. Hussong, 02/23/99  
R/D initialed by: P. Cooney

Filename, d:\nda\20-950r1.DOC

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information

manufacturing controls

Hilfiker

MAY 10 2000

REVIEW FOR HFD-570  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF  
MICROBIOLOGIST'S REVIEW #2 OF NDAs

May 9, 2000

- A. 1. NDA 20-949  
20-950
- APPLICANT Dey Laboratories  
Napa, California
2. PRODUCT NAMES: AccuNeb (NDA 20-949)  
DuoNeb (NDA 20-950)
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Sterile inhalation  
solutions without preservatives, in 2 mL LDPE plastic vials
4. METHOD(S) OF STERILIZATION:  
↓
5. PHARMACOLOGICAL CATEGORY: bronchodilators
6. DRUG PRIORITY CLASSIFICATION: 5S (20-949) and 3S (20-950)
- B. 1. DATE OF INITIAL SUBMISSION: March 27, 1998 (20-949) and May 28, 1998  
(20-950)
2. DATE OF AMENDMENT: 3 December 1999 (20-949), and 29 November 1999  
(20-950)
3. RELATED DOCUMENTS: none
4. ASSIGNED FOR REVIEW: January 24, 2000 (Microbiologist's questions), and  
May 5, 2000 (question 7 from NDA 20-949, 3 December 1999 amendment)
- C. REMARKS: Both applications were similar and contained similar deficiencies. The  
applicant responds to the same set of deficiency questions, except that the microbiology  
review of NDA 20-950 included a comment about a confusing notation in the sterility test  
method. Lastly, "Question 7" to NDA 20-949 (letter date 30 March 1999) was not

provided from the Microbiology Staff and, based on the nature of the drug substance and process controls, was not an appropriate question.

- D. **CONCLUSIONS:** The submission is recommended for APPROVAL. The applicant should be notified that routine tests for bioburden in the active ingredient may be discontinued.

5-9-2000

/S/

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David Hussong, Ph.D.

JHC 5/10/00

cc:

- Original NDAs 20-949 and 20-950
- HFD 570/Division Files
- HFD 160/Consult File
- HFD 570/CSO/Hilfiker
- HFD 570/Chemist/Kim
- HFD 570/Chemist/Shah
- HFD 805/D. Hussong

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