

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
20983

MICROBIOLOGY REVIEW

MAY 28 1999

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

May 28, 1999

A. 1. NDA 20-983

SPONSOR Glaxo Wellcome, Inc.

2. PRODUCT NAMES: Ventolin[®] HFA (Albuterol Sulfate, USP Inhalation Aerosol)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Inhalation Aerosol

4. METHOD(S) OF STERILIZATION: NA

5. PHARMACOLOGICAL CATEGORY: Bronchodilator

6. DRUG PRIORITY CLASSIFICATION: 3

B. 1. DATE OF INITIAL SUBMISSION: June 30, 1998

2. DATE OF AMENDMENT: not provided

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: May 25, 1999

C. REMARKS: This review addresses the need for a microbial limit specification for the drug product. This NDA is an original application for an HFA-134a (1,1,1,2-tetrafluoroethane) propellant based version of an older CFC propellant based Ventolin product. The sponsor has submitted an amendment containing data indicating that the propellant (HFA-134a) has anti-microbial activity.

D. CONCLUSIONS: The switch from CFC to HFA-134a propellant adds no microbiological concerns.

/S/

5-28-99

Bryan Riley, Ph.D.

PRC

5/28/99

cc:

Original NDA 20-983
HFD 570/Consult File
HFD 570/C. Bertha/G. Poochikian/C. Schumaker/ P. Jani
HFD 805/Consult File
HFD 805/B. Riley

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