

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER: 20-831**

**MICROBIOLOGY REVIEW(S)**

REVIEW FOR HFD-570  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF  
MICROBIOLOGIST'S REVIEW #1 OF NDA 20-831  
8 December 1998

## A. 1. NDA 20-831 BC

APPLICANT: Novartis Pharma AG  
Basel, Switzerland

2. PRODUCT NAME: Foradil Aerolizer™ Powder for Inhalation

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:

The product is an inhalant.

4. METHODS OF STERILIZATION:

The product is not a sterile product, but should conform to microbial and preservative effectiveness specifications.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE  
INDICATION:

The indications for product use were not provided in the materials received for review.

B. 1. DATE OF INITIAL SUBMISSION: unknown

2. DATE OF AMENDMENT: 1 June and 19 October 1998 (Subjects  
of this Review)

3. RELATED DOCUMENTS: (none)

4. ASSIGNED FOR REVIEW: 17 November 1998

C. REMARKS: The original application did not receive a microbiology review. The materials received for review are a portion of the applicant's response (amendment) to questions posed by the review chemist. Therefore, this review does not address any other part of the submission.

The intent of many of the questions is unclear to the reviewer. Background material was requested from the

consulting division in order to clarify the intent of the questions. These were not received at the time of this review. Therefore, this review represents the best judgement of the microbiology reviewer based on the information received.

E. CONCLUSIONS: The responses to the chemist's questions appear adequate. Based on these responses, the application is recommended for approval.

  
/S/ 8 December 1998  
~~Paul Stinavage, Ph.D.~~  
/S/ 12/14/98

cc: Original NDA 20-831  
HFD-570/Div. Files/P. Jani/C. Shumaker/J.C. Leak/G. Poochikian  
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 8 December 1998  
R/D initialed by P. Cooney

APPEARS THIS WAY  
ON ORIGINAL