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RESEARCH**

APPLICATION NUMBER:
20-784

MICROBIOLOGY REVIEW(S)

DEC 17 1997

REVIEW FOR DIVISION OF PULMONARY DRUG PRODUCTS, HFD-570
OFFICE OF NEW DRUG CHEMISTRY, MICROBIOLOGY STAFF, HFD-805
MICROBIOLOGIST'S REVIEW No. 2
December 16, 1997

MICROBIOLOGY REVIEWER: Carol K. Vincent

A. 1. NDA No.: 20-784

DRUG PRODUCT NAME: Nasacort® HFA-134a Nasal

APPLICANT: Rhône-Poulenc Rorer Pharmaceuticals, Inc.
500 Arcola Road
Collegeville, PA 19426-0107

2. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Nasal, metered dose inhaler.

3. METHOD(s) OF STERILIZATION: Non-sterile metered dose inhaler.

4. PHARMACOLOGICAL CATEGORY AND/OR PRINCIPAL INDICATION:
Nasacort, a glucocorticosteroid, is indicated for the treatment of seasonal perennial allergic rhinitis symptoms.

5. DRUG PRIORITY CLASSIFICATION: 3 S

B. 1. INITIAL SUBMISSION DOCUMENT DATE: December 16, 1996
2. AMENDMENT DATE: August 21, 1997
3. CONSULT REQUEST DATE: August 29, 1997
4. DOCUMENT RECEIVED FOR REVIEW: September 12, 1997

C. REMARKS: The Division of Pulmonary Drug Products, HFD-570, requested that the applicant provide _____
" This August 21, 1997 amendment conveys the applicants August 13, 1997 response the Division's May 19, 1997 CMC Comments letter. In that May 19, 1997 letter, only section 2 e concerned microbiological issues. The applicant's response to section 2 e is located at Attachment 4, [p 1-65 - 1-81] of the amendment.

D. CONCLUSION: Recommend approval on the basis of microbial quality for NDA 20-784.

See "E. REVIEW NOTES:", below.

cc:
Orig. NDA 20-784
HFD-160/Consult/CKVincent/NSweeney [HFD-805]
HFD-570/Bertha/Poochikian/Schumaker (Barnes)
Drafted by: CKVincent/12-11-97
R/D Init by: PHCooney/12-17-97

Filename: NDA20784.2nd


Carol K. Vincent
Review Microbiologist [HFD-805]

12-16-97
JWC 12/17/97

1 Page(s) Withheld

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 Draft Labeling

 Deliberative Process