CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-746

MICROBIOLOGY REVIEW(S)

MAY 29 1998

REVIEW FOR HFD-570
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA 20-746
28 May 1998

A. 1. NDA 20-746

APPLICANT: Astra USA, Inc.
50 Otis Street
Westborough, MA 01581-4500

2. PRODUCT NAME: Rhinocort Nasal Spray

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is a nasal spray.

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 product is indicated for the management of symptoms of seasonal or perennial allergic rhinitis in adults and children.

B. 1. DATE OF INITIAL SUBMISSION: 27 February 1998

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS: (none)

4. ASSIGNED FOR REVIEW: 17 May 1998

C. REMARKS: A single page of the application (page 178) was received for review. Therefore, this review is only applicable to microbial limits test protocol found on this page of the document. The review chemist has requested that the adequacy of the protocol as a regulatory test procedure for microbial limits be determined. No other information is reviewed here.

E. CONCLUSIONS: The procedure as described on page 178 of the application is adequate to determine the total counts of bacterial and fungal organisms present in the drug product.

/S/ 28 May 1998
Paul Stinavage, Ph.D.

/S/ 5/29/98

cc: Original NDA 20-746
HFD-570/Div. Files/Ng
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 28 May 1998
R/D initialed by P. Cooney

APPEARS THIS WAY
ON ORIGINAL

Team

REVIEW FOR HFD-570

AUG 20 1997

OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review #2 of NDA 20-746
August 14, 1997

A. 1. **APPLICATION NUMBER:** NDA 20-746

APPLICANT: Astra USA
(Address not provided in consult review package)

2. **PRODUCT NAME:** Rhinocort® Aqua Nasal Spray

3. **DOSAGE FORM:** Budesonide 32 µg/dose (0.64 mg/mL) and 64 µg/dose (1.28 mg/mL) in 10 mL glass spray bottles.

4. **METHOD OF STERILIZATION:** None (non-sterile product). The product is preserved with potassium sorbate ( ) disodium edetate ( )

5. **PHARMACOLOGICAL CATAGORY and/or PRINCIPLE INDICATION:** Not provided in the consult request review package.

6. **DRUG PRIORITY CLASSIFICATION:** S

B. 1. **DATE OF INITIAL SUBMISSION:** July 29, 1996

2. **DATE OF AMENDMENT:** June 16, 1997

3. **DATE OF CONSULT:** February 12, 1997 July 11, 1997

4. **ASSIGNED FOR REVIEW:** February 13, 1997 July 16, 1997

C. **REMARKS:** Microbiologist's Review yielded one comment which was sent to Astra via facsimile on March 18, 1997.

APPEARS THIS WAY
ON ORIGINAL

D. CONCLUSIONS:

The application is recommended for approval for issues concerning microbiology.

/S/ 8/14/97

APPEARS THIS WAY
ON ORIGINAL

Neal Sweeney, Ph.D.

/S/ 8/20/97

cc:

Original NDA 20-746
HFD-570/Division File
HFD-570/CSO/G. Trout
HFD-570/Schumaker, Ng, Poochikian, Anthracite
HFD-805/Consult File/N. Sweeney

Drafted by: Neal Sweeney, August 14, 1997
R/D initialed by P. Cooney August 14, 1997

APPEARS THIS WAY
ON ORIGINAL

MAR 7 1997

REVIEW FOR HFD-570

OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review #1 of NDA 20-746
March 7, 1997

A. 1. **APPLICATION NUMBER:** NDA 20-746

APPLICANT: Astra USA
(Address not provided in consult review package)

2. **PRODUCT NAME:** Rhinocort® Aqua Nasal Spray

3. **DOSAGE FORM:** Budesonide 32 µg/dose (0.64 mg/mL) and 64 µg/dose (1.28 mg/mL) in 10 mL glass spray bottles.

4. **METHOD OF STERILIZATION:** None (non-sterile product). The product is preserved with potassium sorbate [redacted] disodium edetate [redacted]

5. **PHARMACOLOGICAL CATAGORY and/or PRINCIPLE INDICATION:** Not provided in the consult request review package.

6. **DRUG PRIORITY CLASSIFICATION:** S

B. 1. **DATE OF INITIAL SUBMISSION:** July 29, 1996

2. **DATE OF CONSULT:** February 12, 1997

3. **RELATED DOCUMENTS:** (none)

4. **ASSIGNED FOR REVIEW:** February 13, 1997

C. **REMARKS:** Consult request is for (1) the evaluation of microbial limits testing, (2) preservative effectiveness validation, and (3) storage of the bulk drug product. The consultation review package did not contain manufacturing control or drug product stability information.

APPEARS THIS WAY
ON ORIGINAL

MAR 10 1997

D. CONCLUSIONS:

The application is recommended for approval for issues concerning microbiology. Comments concerning microbial limits methodology are to be conveyed as an information request to the applicant.

/S/ 3/7/97
Neal Sweeney, Ph.D.

cc:
Original NDA 20-746
HFD-570/Division File
HFD-570/CSO/G. Trout
HFD-570/Chemist/L. Ng
HFD-805/Consult File/N. Sweeney

Drafted by: Neal Sweeney, March 7, 1997
R/D initialed by P. Cooney March 7, 1997

/S/ for PHCooney 3/7/97

APPEARS THIS WAY
ON ORIGINAL