CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-929

MICROBIOLOGY REVIEW

Trout

SEP 15 1998

REVIEW FOR HFD-570

OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review #2 of NDA 20-929
September 2, 1998

A. 1. APPLICATION NUMBER: 20-929

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

2. PRODUCT NAME: Pulmicort® Respules™

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Sterile single-dose budesonide ——— 0.25, and 0.5 mg/mL) nebulizing preservative-free suspension packaged in clea, ——— ampules (respules) containers with 2 mL fill volume.

4. METHODS OF STERILIZATION: ———

5. PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION: Anti-inflammatory corticosteroid treatment for asthma in pediatric patients.

6. DRUG PRIORITY CLASSIFICATION: 1P

B. 1. DATE OF INITIAL SUBMISSION: November 18, 1997

2. DATE OF AMENDMENT: May 12, 1998

3. DATE OF CONSULT: May 19, 1998

4. ASSIGNED FOR REVIEW: May 21, 1998

C. REMARKS:

Microbiologist's Review #1 resulted in three questions conveyed (via FAX) to the applicant on April 21, 1998. The applicant's responses are the subject of this review.

During a November 20, 1996 pre-NDA CMC meeting held between Astra and the Division of Pulmonary Drug Products, the FDA requested that Astra produce sterile Pulmicort Respules. A non-sterile product, used primarily in the European market, has been manufactured at Astra, Sweden since 1987.

D. CONCLUSIONS:

The submission is recommended for approval for microbiology issues concerning sterility assurance. Specific comments are provided in "E. Review Notes".

/S/

Neal Sweeney, Ph.D.

cc: NDA 20-929
HFD-570/Division File
HFD-570/CSO/G. Trout
HFD-570/Chemist/Chong-Ho Kim
HFD-805/Consult File/N. Sweeney

Drafted by: N. Sweeney, March 4, 1998
R/D initialed by P. Cooney, March 4, 1998

2 Page(s) Withheld

CONCLUSIONS:

The submission is recommended for approval for microbiology issues concerning sterility assurance. Specific comments are provided in "E. Review Notes".

/S/ 9/2/98

Neal Sweeney, Ph.D.

Date 9/15/98

cc: NDA 20-929
HFD-570/Division File
HFD-570/CSO/G. Trout
HFD-570/Chemist/Chong-Ho Kim
HFD-805/Consult File/N. Sweeney

Drafted by: N. Sweeney, March 4, 1998
R/D initialed by P. Cooney, March 4, 1998

MAR 16 1998

REVIEW FOR HFD-570

OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review #1 of NDA 20-929
March 4, 1998

A. 1. **APPLICATION NUMBER:** 20-929

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

2. **PRODUCT NAME:** Pulmicort® Respules™

3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Sterile single-dose budesonide [redacted] 0.25, and 0.5 mg/mL) nebulizing preservative-free suspension packaged in clear [redacted] ampules (respules) containers with 2 mL fill volume.

4. **METHODS OF STERILIZATION:** [redacted]

5. **PHARMALOGICAL CATAGORY and/or PRINCIPLE INDICATION:** Anti-inflammatory corticosteroid treatment for asthma in pediatric patients.

6. **DRUG PRIORITY CLASSIFICATION:** 1P

B. 1. **DATE OF INITIAL SUBMISSION:** November 18, 1997

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

3. **DATE OF CONSULT:** December 11, 1997

4. **ASSIGNED FOR REVIEW:** December 22, 1997

C. **REMARKS:** During a November 20, 1996 pre-NDA CMC meeting held between Astra and the Division of Pulmonary Drug Products, the FDA requested that Astra produce sterile Pulmicort Respules. A non-sterile product, used primarily in the European market, has been manufactured at Astra, Sweden since 1987.

D. CONCLUSIONS:

The submission is approvable for microbiology issues concerning sterility assurance. Specific comments are provided in "E. Review Notes" and "List of Microbiology Deficiencies and Comments".

/S/ 3/4/98

Neal Sweeney, Ph.D.

/S/ 3/16/98

cc: NDA 20-929
HFD-570/Division File
HFD-570/CSO/G. Trout
HFD-570/Chemist/Chong-Ho Kim
HFD-805/Consult File/N. Sweeney

Drafted by: N. Sweeney, March 4, 1998
R/D initialed by P. Cooney, March 4, 1998

14 Page(s) Withheld