

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 21-254

MICROBIOLOGY REVIEW(S)

REVIEW FOR HFD-820

**OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805
Microbiologist's Review #1 of NDA 21-254**

June 21, 2001

- A. 1. APPLICATION NUMBER:** NDA 21-254
- APPLICANT:** Glaxo Wellcome Inc.
5 Moore Drive
Research Triangle Park, NC 27709
Phone: 919-483-2100
FAX: 919-483-5063
- 2. PRODUCT NAME:** ADVAIR™ HFA Inhalation Aerosol
- 3. DOSAGE FORM:** Fluticasone propionate (44 µg, 110 µg, and 220 µg) and salmeterol xinafoate (21 µg) HFA metered dose inhalant.
- 4. METHOD OF STERILIZATION:** None (non-sterile product).
- 5. PHARMACOLOGICAL CATAGORY and/or PRINCIPLE INDICATION:** Anti-inflammatory (fluticasone propionate) and beta₂-adrenergic bronchodilator (salmeterol xinafoate) indicated for maintenance of asthma in patients 12 years of age and older.
- B. 1. DATE OF INITIAL SUBMISSION:** 12/20/00
- 2. DATE OF CONSULT:** 3/19/01
- 3. ASSIGNED FOR REVIEW:** 6/15/01
- C. REMARKS:** The consult request was for an evaluation of the drug product _____ method and _____ study.

D. CONCLUSIONS:

The application is recommended for approval for issues concerning product quality microbiology. Specific comments are provided in section "E. REVIEW NOTES".

Neal Sweeney, Ph.D.

cc:

Original NDA 21-254
HFD-820/Division File
HFD-820/A. Schroeder
HFD-805/Consult File/N. Sweeney

Drafted by: Neal Sweeney, June 21, 2001
R/D initialed by P. Cooney, June 21, 2001

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/s/

Neal Sweeney
7/23/01 11:08:16 AM
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