

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-714

MICROBIOLOGY REVIEW(S)

MAR 26 1997

**REVIEW FOR HFD-170
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF HFD-805**

**Microbiologist's Review # 1 of NDA 20-714 Amendments #3 & 4 & 5
March 26, 1997**

A. 1. **APPLICATION NUMBER:** NDA 20-714 Amendments #3 & 4 & 5

APPLICANT: Pharmacia & Upjohn Company
7000 Portage Road
Kalamazoo, MI 49001-0199

2. **PRODUCT NAMES:** Nicotrol Inhaler

3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:** 10 mg of nicotine per unit. It is administered by inhalation.

4. **METHOD(S) OF STERILIZATION:** non-sterile drug product

5. **PHARMACOLOGICAL CATEGORY:** Inhalation drug used in nicotine replacement therapy.

B. 1. **DATE OF INITIAL SUBMISSION:** May 1, 1996

2. **AMENDMENT:** Amendment #3: 12/5/97
Amendment #4: 1/13/97
Amendment #5: 1/29/97

3. **RELATED DOCUMENTS:** NDA 20-714

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

5. **DATE OF CONSULT REQUEST:** February 11, 1997

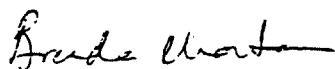
C. **REMARKS:**

The amendments respond to questions presented to the applicant as a result of Chemist's Review. The questions (#12 and 13) from the Chemist to the Applicant have been copied into the section of this review and the responses are individually reviewed.

MAR 27 1997

D. CONCLUSIONS:

From a microbiology standpoint, questions #12 and 13 are satisfactorily answered.



3/26/97

Brenda Uratani, Ph.D.
Review Microbiologist

He 3/26/97

cc:

NDA 20-714 Amendments # 3, 4, 5

HFD-170/ Div. File

HFD-805 /Uratani

HFD-170/CSO/McNeal

HFD-170/Chemist/ J. Ross

drafted by: Brenda Uratani, 2/26/97

R/D initialed by P.Cooney, 2/26/97