

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

***APPLICATION NUMBER:* 20-938**

MICROBIOLOGY REVIEW(S)

D:-
MAR 9 1999

REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA

March 5, 1999

A. 1. NDA 20-938

SPONSOR Boehringer Ingelheim Pharmaceuticals
900 Ridgebury Rd
P.O. Box 368
Ridgefield, CT 06877

2. PRODUCT NAMES: MOBIC® (Meloxicam)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Tablet, Oral

4. METHOD(S) OF STERILIZATION: N/A

5. PHARMACOLOGICAL CATEGORY: Non-steroidal Anti-Inflammatory

6. DRUG PRIORITY CLASSIFICATION:

B. 1. DATE OF INITIAL SUBMISSION: December 15, 1998

2. DATE OF AMENDMENT:

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: February 3, 1999

C. REMARKS: Meloxicam is a non-steroidal anti-inflammatory of the oxicam class. The drug product is a non-sterile tablet containing 7.5 mg of the drug substance. This review addresses the Microbial Limits specifications of the product.

D. CONCLUSIONS: The application is approvable pending resolution of the deficiencies listed in the "Microbiologists List of Deficiencies".

*Not
checked in
this review*

/S/

3-5-99

Bryan Riley, Ph.D.

3/9/99

cc:

Original NDA 20-938
HFD 550/Consult File
HFD 550/D. Gunter
HFD 550/Rev Chemist
HFD 805/Consult File
HFD 805/B. Riley

Drafted by: B. Riley, 3/5/99
R/D initialed by: P. Cooney,

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL