

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 75-684

MICROBIOLOGY REVIEW(S)

OFFICE OF GENERIC DRUGS, HFD-640

Microbiologists Review #1

April 3, 2001

Addendum:

ANDA: 75-684

Gratuitous Amendment Dated:
March 23, 2001 (Received March 26, 2001)

Subject of this Review

Conclusions: The above ANDAs are inclusive of the following NDAs Review and found **acceptable** by P Stinavich in HFD-805. The conclusion was initialed by P. Cooney. The same data applies to the above ANDAs.

ASL
Andrea S. High, Ph. D.

cc: Original **ANDA**

Duplicate ANDA

Division Copy

Field Copy

Drafted by A. High, HFD 600 V:\microrev\75-684g

Initialed M. Fanning

4/2/01^U

**9 pages have been withheld in
full from this document.**

OFFICE OF GENERIC DRUGS, HFD-640
Microbiology Review #3
January 2, 2001

- A. 1. ANDA 75-684
- APPLICANT Bedford Laboratories
270 Northfield Road,
Bedford, OH 44146
2. PRODUCT NAME: Famotidine Injection
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
10 mg/mL, 50-mL Pharmacy Bulk Vial
4. METHOD(S) OF STERILIZATION: _____
5. PHARMACOLOGICAL CATEGORY: Inhibitor of histamine
receptors.
- B. 1. DATE OF INITIAL SUBMISSION: July 30, 1999
2. DATE OF AMENDMENT: December 22, 2000
Subject of this Review (Received December 26, 2000)
3. RELATED DOCUMENTS: None
4. ASSIGNED FOR REVIEW: January 2, 2001
- C. REMARKS: The subject amendment provides for the response to microbiology deficiencies in the correspondence dated December 21, 2000.
- D. CONCLUSIONS: The submission is recommended for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes".

151

Nrapendra Nath, Ph. D.

CC: Original ANDA
Duplicate ANDA
Division Copy
Field Copy
Drafted by N. Nath, HFD 600; V:\microrev\75684a3.doc
Initialed by A. High

1/9/01

**2 pages have been withheld in
full from this document.**

7

OFFICE OF GENERIC DRUGS, HFD-640
Microbiology Review #2
December 13, 2000

A. 1. ANDA 75-684

APPLICANT Bedford Laboratories
270 Northfield Road,
Bedford, OH 44146

2. PRODUCT NAME: Famotidine Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
10 mg/mL, 50-mL Pharmacy Bulk Vial

4. METHOD(S) OF STERILIZATION: _____

5. PHARMACOLOGICAL CATEGORY: Inhibitor of histamine
receptors.

B. 1. DATE OF INITIAL SUBMISSION: July 30, 1999

2. DATE OF AMENDMENT: November 3, 2000
Subject of this Review (Received November 6, 2000)

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: December 13, 2000

C. REMARKS: The subject amendment provides for the response to microbiology deficiencies in the correspondence dated August 10, 2000.

D. CONCLUSIONS: The submission is not recommended for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiology Comments to be Provided to the Applicant" found at the end of this review. The deficiencies represent a Fax amendment.

151

Nrapendra Nath, Ph. D.

CC: Original ANDA
Duplicate ANDA
Division Copy
Field Copy
Drafted by N. Nath, HFD 600; V:\microrev\75684a2.doc
Initialed by A. High

12/13/00

**2 pages have been withheld in
full from this document.**

11

OFFICE OF GENERIC DRUGS, HFD-640
Microbiology Review #1
August 3, 2000

A. 1. ANDA 75-684

APPLICANT Bedford Laboratories
270 Northfield Road,
Bedford, OH 44146

2. PRODUCT NAME: Famotidine Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
10 mg/mL, 50-mL Pharmacy Bulk Vial

4. METHOD(S) OF STERILIZATION: _____

5. PHARMACOLOGICAL CATEGORY: Inhibitor of histamine
receptors.

B. 1. DATE OF INITIAL SUBMISSION: July 30, 1999
Subject of this Review (Received August 3, 1999)

2. DATE OF AMENDMENT: None

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: August 3, 2000

C. REMARKS: The subject drug product is manufactured at Ben
Venue Laboratories' manufacturing facilities in Bedford, OH
_____. The subject drug
product is sterile filtered and aseptically filled in Type I
glass vials and fitted with rubber stoppers.

D. CONCLUSIONS: The submission is not recommended for
approval on the basis of sterility assurance. Specific
comments are provided in "E. Review Notes" and "Microbiology
Comments to be Provided to the Applicant" found at the end
of this review. The deficiencies represent a minor
amendment.

131

Nrapendra Nath, Ph. D.

CC: Original ANDA
Duplicate ANDA
Division Copy
Field Copy
Drafted by N. Nath, HFD 600; V:\microrev\75684.doc
Initialed by A. High

8/8/00

**10 pages have been withheld in
full from this document.**