CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74496

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS, HFD640

Microbiologists Review #1

October 24, 1994

A. 1. ANDA **74 - 496**

APPLICANT Elkins - Sinn
Attention: Thelma C. Hildebrand
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

2. PRODUCT NAMES: Lorazepam Injection, USP

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 2 mg/mL and 4 mg/mL syringes for IM and IV injection.

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: sedative.

B. 1. DATE OF INITIAL SUBMISSION: May 24, 1994

2. DATE OF AMENDMENT: None

3. RELATED DOCUMENTS: N.A.

4. ASSIGNED FOR REVIEW: 10/21/94

C. REMARKS: Although a Microbiology volume is provided as a white bound desk copy, the reviewer needed to refer to the official jacket to get all the information necessary. For instance the applicant did not include the layout drawings or equipment list in the white volume.

D. CONCLUSIONS: The submissions are not recommended for approval on the basis of sterility assurance.

/S/ 10/24/94
James L. McVey

11/2/94

cc:
Original ANDA
Field Copy
HFD 615 /CSO/W.P. Rickman
HFD 640 drafted by: J. McVey
HFD 640 initialed by C.G. Guyer or F Fang

OFFICE OF GENERIC DRUGS, HFD640

Microbiologists Review #2

August 29, 1995

A. 1. ANDA **74 - 496**

APPLICANT Elkins - Sinn
Attention: Thelma C. Hildebrand
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

2. PRODUCT NAMES: Lorazepam Injection, USP

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 2 mg/mL and 4 mg/mL syringes for IM and IV injection.

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: sedative.

B. 1. DATE OF INITIAL SUBMISSION: May 24, 1994

2. DATE OF AMENDMENT:
May 3, 1995 Correspondence - **Subject of this review.**
March 29, 1995 - **Subject of this review.**

3. RELATED DOCUMENTS: N.A.

4. ASSIGNED FOR REVIEW: 08/29/95

C. REMARKS: Filtration validation needed. C/C stability issue.

D. CONCLUSIONS: The submissions are not recommended for approval on the basis of sterility assurance.

/S/

James L. McVey 8/29/95

HFD 640 initialed by or F Fang or F Holcombe

cc:

Original ANDA
Duplicate ANDA
Field Copy
HFD 640 drafted by: J. McVey

OFFICE OF GENERIC DRUGS, HFD640

Microbiologists Review #3

August 9, 1996

A. 1. ANDA **74 - 496**

APPLICANT Elkins - Sinn
Attention: Thelma C. Hildebrand
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

2. PRODUCT NAMES: Lorazepam Injection, USP

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 2 mg/mL and 4 mg/mL syringes for IM and IV injection.

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: sedative.

B. 1. DATE OF INITIAL SUBMISSION: May 24, 1994

2. DATE OF AMENDMENT:
May 3, 1995 Correspondence
March 29, 1995
July 17, 1996 - Subject of this review.

3. RELATED DOCUMENTS: N.A.

4. ASSIGNED FOR REVIEW: August 7, 1996

C. REMARKS: Millipore validation of filtration. Container stability addressed.

D. CONCLUSIONS: The submission is recommended for approval on the basis of sterility assurance.

/S/ 8/9/96
James L. McVey

8/14/96

HFD 640 initialed by or F Fang or F Holcombe

cc:

Original ANDA
Duplicate ANDA
Field Copy
HFD 640 drafted by: J. McVey 74496ap3.m

OFFICE OF GENERIC DRUGS, HFD620

Microbiologists Review #4

November 17, 1997

A. 1. ANDA **74 - 496**

APPLICANT Elkins - Sinn
Attention: Thelma C. Hildebrand
2 Esterbrook Lane
Cherry Hill, NJ 08003-4099

2. PRODUCT NAMES: Lorazepam Injection, USP
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 2 mg/mL and 4 mg/mL syringes for IM and IV injection.
4. METHOD(S) OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY: sedative.

B. 1. DATE OF INITIAL SUBMISSION: May 24, 1994
2. DATE OF AMENDMENT:
May 3, 1995 Correspondence
March 29, 1995
July 17, 1996
September 3, 1997 - Subject of this review.
October 16, 1997 - Subject of this review.
3. RELATED DOCUMENTS: N.A.
4. ASSIGNED FOR REVIEW: November 17, 1997

C. REMARKS: The Master Batch Production Record is amended on Sept. 3, 1997 in anticipation of District office investigation. Also in anticipation of District Review, revised Finished Product, Bulk Solution/In-Process and Drug Substance Specifications and Testing Procedures (SATs) are submitted in the October 16, 1997 Amendment.

D. CONCLUSIONS: The submission is recommended for approval on the basis of sterility assurance.

/S/ 11/17/97
James L. McVey

HFD 620 initialed by Rashmikant M. Patel 11/17/97

cc:

Original ANDA
Duplicate ANDA
Field Copy
HFD 640 drafted by: J. McVey 74496ap4.m