

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**74496**

**MICROBIOLOGY REVIEW**

OFFICE OF GENERIC DRUGS, HFD640

Microbiologists Review #1

October 24, 1994

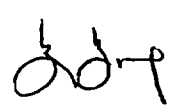
- A. 1. ANDA 74 - 496
- APPLICANT Elkins - Sinn  
Attention: Thelma C. Hildebrand  
2 Esterbrook Lane  
Cherry Hill, NJ 08003-4099
2. PRODUCT NAMES: Lorazepam Injection, USP
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 2 mg/mL and 4 mg/mL syringes for IM and IV injection.
4. METHOD(S) OF STERILIZATION:
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.

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

  
James L. McVey

10/24/94

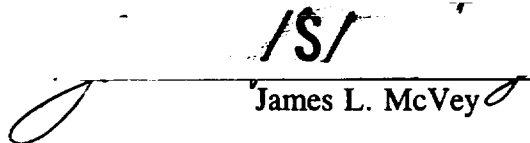
 11/2/94

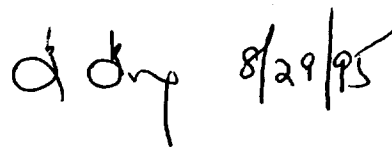
OFFICE OF GENERIC DRUGS, HFD640

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.

  
James L. McVey

  
d dnp 8/29/95

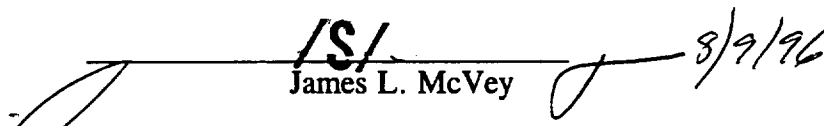
HFD 640 initialed by or F Fang or F Holcombe

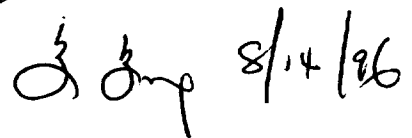
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Original ANDA  
Duplicate ANDA  
Field Copy  
HFD 640 drafted by: J. McVey

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.

  
James L. McVey 8/9/96

  
8/14/96

cc:

HFD 640 initialed by or F Fang or F Holcombe

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.

*IS/*  
James L. McVey *11/17/97*

HFD 620 initialed by Rashmikant M. Patel

cc:

Original ANDA

Duplicate ANDA

Field Copy

HFD 640 drafted by: J. McVey 74496ap4.m

*REC'D  
11/17/97*