CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74496

BIOEQUIVALENCY REVIEW(S)

SEP 29 1994

Lorazepam Injection, USP
2 mg/ml & 4 mg/ml
ANDA # 74-496
Reviewer: Hoainhon Nguyen
WP # 74496w.594

Elkins-Sinn
Cherry Hill, New Jersey
Submission Date:
May 6, 1994

Review of a Waiver Request

The firm has requested a waiver from in vivo bioavailability requirements for its Lorazepam Injection, USP, 2 mg/ml and 4 mg/ml (syringes), in accordance with 21 CFR 320.22 (b) (1).

Comments:

1. The test product is a solution intended for intravenous and intramuscular injection.

2. The formulation of the test product is identical to that of the currently approved Ativan® Injection, USP, 2 mg/ml and 4 mg/ml, manufactured by Wyeth Laboratories, as shown below:

Ingredients	Ativan® Formulas	ESI's Formulas
Lorazepam, USP	2 mg/ml (and 4 mg/ml)	2 mg/ml (and 4 mg/ml)
Polyethylene Glycol 400	0.18 ml/ml	0.18 ml/ml
Propylene Glycol		
Benzyl Alcohol	2 %	2 %

Recommendation:

The Division of Bioequivalence agrees that the information submitted by Elkins-Sinn demonstrates that its Lorazepam Injection, USP, 2 mg/ml and 4 mg/ml, falls under 21 CFR 320.22 (b) (1) of the Bioavailability/Bioequivalence Regulations. The Division of Bioequivalence recommends that the waiver of in vivo bioavailability study be granted. The test product is deemed bioequivalent to the currently approved Ativan® Injection, 2 mg/ml and 4 mg/ml, manufactured by Wyeth Laboratories.

/S/
Hoainhon Nguyen
Division of Bioequivalence
Review Branch I

RD INITIALED AJJACKSON
FT INITIALED AJJACKSON /S/ Date: 9/29/94