CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74-793

ADMINISTRATIVE DOCUMENTS

MOVA PHARMACEUTICAL CORPORATION
P. O. Box 8639
Caguas, Puerto Rico 00626
(809) 746-8500

MOVA

November 22, 1995

Dr. Charles Ganley - Director
FDA - OGD
Document Control Room - MPN II
7500 Standish Place - Room 150
Rockville, MD 20855-2773

RE: LORAZEPAM INJECTION, USP, 2 mg/mL, 4 mg/mL
ORIGINAL ABBREVIATED NEW DRUG APPLICATION

Dear Dr. Ganley:

As required by Section 505 (j) of the Federal Food, Drug and Cosmetics Act, MOVA Pharmaceutical Corporation hereby submits for your review an Abbreviated New Drug Application for Lorazepam Injection, USP, 2 mg/mL, 4 mg/mL. The listed drug product is Ativan[R] Injection, 2 mg/mL, 4 mg/mL, NDA # N18140001, N18140002, by Wyeth Laboratories, Inc.

The content and format of this ANDA is in accordance with 21 CFR 314.94. We are enclosing an Archival Copy and a Review Copy of this Application. A certified true copy of the Chemistry, Manufacturing and Controls Section has been concurrently filed with the San Juan District Office of FDA (Field Copy).

We trust that the enclosed information is satisfactory. If you have any questions regarding this Application, do not hesitate to contact either Mr. Angel L. Rodriguez or the undersigned at (809) 746-8500, ext. 347, and 182, respectively.

Sincerely,

Dale Robson
Vice President
Regulatory Affairs & QA Administration

RECEIVED
NOV 27 1995
GENERIC DRUGS

APPROVAL PACKAGE SUMMARY FOR 74-793

ANDA: 74-793

FIRM: Mova Pharmaceutical Corporation

DRUG: Lorazepam

DOSAGE: Parenteral

STRENGTH: 2 mg/mL, 4 mg/mL

CGMP STATEMENT/EIR UPDATE STATUS: EER is PENDING

BIO STUDY/BIOEQUIVALENCE STATUS: Bio waiver was granted 7/28/97

METHODS VALIDATION: The drug product is compendial

STABILITY: The firm has submitted three months accelerated stability data at 27.5±2.5°C and 24 months at refrigerated temperatures (2-8°C) in upright and inverted positions for 1 cc and 10 cc packaging sizes of both strengths.

LABELING REVIEW STATUS: Labeling is satisfactory 6/10/98

STERILIZATION VALIDATION: The microbiological portion of the application Is satisfactory 7/1/97.

BATCH SIZES: The firm has submitted the master formula and manufacturing procedure for the maximum batch for Lorazepam injection 2 mg/mL which will be liters and liters for 4 mg/mL. Also, provided copies of the executed manufacturing batch records for 2 mg/mL, 1cc liters), 2 mg/mL, 10cc liters), 4 mg/mL, 1cc batch liters) and 4 mg/mL, 10cc liters). The firm will be using the same drug substance manufacture, same manufacturing procedure and same equipment.

COMMENTS: The application is approvable PENDING ACCEPTABLE EER.

N. Nashed 12/28/99

REVIEWER: Nashed E. Nashed, Ph.D. DATE: 12/16/99

SUPERVISOR: Paul Schwartz, Ph.D.

MAR 8 1996

Lorazepam Injection, USP
2 mg/ml & 4 mg/ml (1 and 10 ml vials)
ANDA # 74-793
Reviewer: A.P. Patel
WP # x:\apatel\ 74793w.n95

Mova Pharmaceutical Corp.
Cagus, Puerto Rico
Submission Date:
Nov. 22, 1995

Review of a Waiver Request

Introduction:

Lorazepam is used as a preanesthetic medication, producing sedation, relief of anxiety, and a decreased ability to recall events related to the day of surgery.

Objective:

The firm has requested a waiver from *in vivo* Bioavailability requirements for its Lorazepam Injection, USP, 2 mg/ml and 4 mg/ml (1 ml single dose vials and 10 ml multiple dose vials), in accordance with 21 CFR 320.22 (b) (1). The approved reference product is Ativan[R] Injection, USP, 2 mg/ml and 4 mg/ml, manufactured by Wyeth Laboratories, Inc. The test product is a solution intended for intravenous and intramuscular injection.

Comments:

1. The comparative formulations of the test product and RLD are in Table 1.

2. The test product meets the criteria for waiver as specified in 21 CFR §320.22 (b)(1) : (i) the product is a parenteral solution intended for intravenous administration; and (ii) the product contains the same active and inactive ingredients in the same concentrations as the reference listed drug.

Deficiencies: None

Recommendation:

The Division of Bioequivalence agrees that the information submitted by Mova Pharmaceuticals, Corp. demonstrates that Lorazepam injection 2 and 4 mg/ml (1- and 10-ml vials) falls under 21 CFR Section 320.22(b)(1) of the Bioavailability/Bioequivalence Regulations. The waiver of *in vivo* bioequivalence study for the 2 and 4 mg/ml strengths of the test product is granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test injectable formulation to be bioequivalent to Ativan[R] Injection 2 and 4 mg/ml manufactured by Wyeth Laboratories, Inc.

The firm should be informed of the recommendation.

3/7/96

A.P.Patel
Division of Bioequivalence
Review Branch III

RD Initialed R.M. Mhatre
FT Initialed R.M. Mhatre Ramakant M. Mhatre Date: 3/8/96

Ramakant M. Mhatre, Ph.D.
Chief, Branch III
Division of Bioequivalence

cc: P.Patel),