CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74-793

CORRESPONDENCE

MOVA PHARMACEUTICAL CORPORATION
P.O. Box 8639
Caguas, Puerto Rico 00726
(787) 746-8500

MOVA

November 5, 1999

ORIG AMENDMENT
N/APM

Mr. Douglas Sporn
Food and Drug Administration
Office of Generic Drugs
Center for Drug Evaluation & Research
7500 Standish Place
Metro Park North II, Room 150
Rockville, Maryland 20855

RE: ANDA 74-793, Lorazepam Injection, USP, 2 mg/mL and 4 mg/mL

MINOR AMENDMENT

Dear Mr. Sporn:

In response to FDA's Not Approvable letter dated May 27, 1998 MOVA Pharmaceutical Corporation is submitting a MINOR amendment to our pending Abbreviated New Drug Application for Lorazepam Injection, USP, 2 mg/mL and 4 mg/mL. This amendment contains revisions to release specifications and revisions to the stability protocol as requested. Regarding final printed labeling for the container, reference is made to labeling amendment submitted on May 26, 1998.

MOVA Pharmaceutical Corporation acknowledges that the firms referenced in this application regarding manufacturing and testing of the drug product should be in compliance with CGMP's at the time of the approval.

A true copy of this amendment has been sent to the FDA San Juan District Office.

If you should have any questions regarding this submission, please contact me at (787)746-8500 Ext. 2119.

Cordially,

Mayra Garcia
Regulatory Affairs Associate

Enclosure

11-11-99

ORIG AMENDMENT
N/A m

MOVA PHARMACEUTICAL CORPORATION
Regulatory Affairs and Corporate Compliance Department

March 31, 1998

Mr. Jerry Phillips, Acting Director - OGD
U. S. Food and Drug Administration
7500 Standish Place
Rockville, MD 20857

RE: ANDA 74-793 Lorazepam Injection, USP, 2 mg per mL, 4 mg per mL

MINOR LABELING AMENDMENT

Dear Mr. Phillips:

In response to FDA's fax non-approvable letter dated January 13, 1998, MOVA Pharmaceutical Corporation is submitting a *Minor Labeling Amendment* to the above referenced ANDA .

MOVA Pharmaceutical Corporation hereby submits 12 copies of the final printed package insert labeling, and the sise-by-side comparison.

If there are any questions regarding this submission, please contact me at (787)746-8500 ext. 1421.

Cordially,

Debbie Navarro

Debbie Navarro
Regulatory Affairs Associate

Microbiology Comments to be Provided to the Applicant

ANDA: 74-793 APPLICANT: MOVA Pharmaceutical Corporation

DRUG PRODUCT: Lorazepam Injection, USP, 2 mg/mL & 4 mg/mL

A. Microbiology Deficiencies:

1. [redacted]

1

Injection is not an aqueous-based product. Also, the drug products used to bracket Lorazepam Injection were not identified.

B. In addition to responding to the deficiency presented above, please note and acknowledge the following comment in your response:

1. We recommend that breached positive controls, e.g., vials with a small hole through the stopper that are immersed like the test units, should be employed in future experiments.

Please clearly identify your amendment to this facsimile as "RESPONSE TO MICROBIOLOGY DEFICIENCIES."

Sincerely yours,

Rashmikant M. Patel, Ph.D.

Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

3/13/00

MOVA PHARMACEUTICAL CORPORATION
P.O. Box 8639
Caguas, Puerto Rico 00726
(787) 746-8500

MOVA

NDA ORIG AMENDMENT

June 9, 1997

Mr. Douglas Sporn
Food and Drug Administration
Office of Generic Drugs
Center for Drug Evaluation & Research
7500 Standish Place,
Metro Park North II
Rockville, Maryland 20855

RE: ANDA 74-793, Lorazepam Injection, USP, 2 mg/mL, 4 mg/mL

MINOR AMENDMENT

Dear Mr. Sporn:

MOVA Pharmaceutical Corporation herewith submits a MINOR Amendment to our pending Abbreviated New Drug Application for Lorazepam Injection, USP, 2 mg/mL, 4 mg/mL. Reference is made to your Not Approvable Letter dated June 7, 1996, in which you requested, among other items, Full Term Stability Data. A copy of this communication is provided for your convenience. This amendment contains the answers for each of the Chemistry, Labeling, and Microbiology observations made on the Jun 7 communication. Enclosed are also the supporting documents for each of the responses as needed. MOVA Pharmaceutical Corporation acknowledges that the firms referenced in this application regarding manufacturing and testing of the drug product should be in compliance with cGMP's at the time of the approval. A true copy of this amendment has been sent to FDA San Juan District Office.

Should you have any questions pertaining to this Amendment, or the original application, do not hesitate to contact me at 787-746-8500, ext. 234.

Sincerely Yours,

Angel L. Rodriguez-Arce
Sr. Reg. Affairs Associate

RECEIVED
JUN 16 1997
GENERIC DRUGS

ANDA 74-793

MOVA Pharmaceutical Corporation
Attention: Dale Robson
Calle A (Zafiro) Carr. 1 Km. 34.18 Urb. Industrial
Villa Blanca Caguas Puerto Rico 00725

MAR 12 1996

Dear Sir:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505 (j) of the Federal Food, Drug and Cosmetic Act for Lorazepam Injection USP, 2 mg/mL and 4 mg/mL.

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments expressed in this letter are preliminary. The above bioequivalency comments may be revised after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling or other scientific or regulatory issues. A revised determination may require additional information and/or studies, or may conclude that the proposed formulation is not approvable.

Sincerely yours,

Keith K. Chan, Ph.D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research