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RESEARCH**

APPLICATION NUMBER:

74-793

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 3

2. ANDA # 74-793

3. NAME AND ADDRESS OF APPLICANT

Mova Pharmaceutical Corporation
P.O. Box 8639
Caguas, Puerto Rico 00626

4. LEGAL BASIS FOR SUBMISSION

The firm certifies that in their opinion and to the best of their knowledge, patent 4,017,616 assigned to the reference drug product Ativan Injection, from Wyeth Ayerst, expired on April 12, 1994. Hence, currently there are no patents that claim the listed drug referred to in this application or that claim a use of the listed drug product.

The firm has indicated that the reference listed drug product is not entitled to a period of marketing exclusivity under 21 USC section 505 (j)(4)(D) of the Food, Drug and Cosmetic Act, as amended September 24, 1984.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Lorazepam

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Original 11/17/95
Amendment 6/9/97
Amendment 3/31/98
Amendment 11/5/99
Amendment 12/17/99

10. PHARMACOLOGICAL CATEGORY

Anti-anxiety

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF's

13. DOSAGE FORM

Parenteral

14. POTENCY

2 mg/mL, 4 mg/mL

15. CHEMICAL NAME AND STRUCTURE

7-chloro-5-(o-chlorophenyl)-1,3-dihydro-3-hydroxy-2H-1,4-benzodiazepin-2-one

16. RECORDS AND REPORTS

17. COMMENTS

The microbiological portion of the application is satisfactory 7/1/97.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable PENDING ACCEPTABLE EER.

19. REVIEWER:

Nashed E. Nashed, Ph.D.

Supervisor: Paul Schwartz, Ph.D.

DATE COMPLETED:

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