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RESEARCH**

APPLICATION NUMBER:

40166

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 2

2. ANDA # 40-166

3. NAME AND ADDRESS OF APPLICANT

Morton Grove Pharmaceuticals, Inc.
6451 West Main Street
Morton Grove, IL 60053

4. LEGAL BASIS FOR SUBMISSION

The firm has indicated that there are no patents for the listed drug and there is no exclusivity for this product.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Acetic Acid Otic Solution, USP

9. AMENDMENTS AND OTHER DATES:

Original 9/18/95
Amendment 9/28/95
Amendment 10/4/95
Amendment 11/14/95
Amendment 11/10/95
Amendment 12/21/95

10. PHARMACOLOGICAL CATEGORY

For the treatment of superficial infections of the external auditory canal caused by organisms susceptible to the action of the anti-microbial.

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF's

13. DOSAGE FORM

Solution

14. POTENCY

2%

15. CHEMICAL NAME AND STRUCTURE

Acetic Acid

16. RECORDS AND REPORTS

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

DATE COMPLETED:

Nashed E. Nashed, Ph.D.

7/15/96

Supervisor: Paul Schwartz, Ph.D.

7/15/96

20. COMPONENTS AND COMPOSITION