

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 75043

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 4

2. ANDA # 75-043

3. NAME AND ADDRESS OF APPLICANT

Taro Pharmaceuticals Inc.
130 East Drive
Bramalea, Ontario
L6T 1C3 Canada

4. LEGAL BASIS FOR SUBMISSION

In the firm opinion and to the best of their knowledge there are no U.S. Patents that claim the listed drug referred in this application and the reference listed drug is not entitled to a period of marketing exclusivity.

5. SUPPLEMENT(s)

Original 12/23/96

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Hydrocortisone Valerate

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

N/A

9. AMENDMENTS AND OTHER DATES:

Amendment 3/26/97

Amendment 4/17/97

Amendment 11/7/97

Amendment 3/30/98

Amendment 4/16/98

Amendment 6/29/98

Amendment 7/30/98

9/19/98, 9/21/98

10. PHARMACOLOGICAL CATEGORY

Anti-inflammatory

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM 14. POTENCY

Ointment

0.2%

15. CHEMICAL NAME AND STRUCTURE

Pergn-4-ene-3,20-dione,21-dihydroxy-7-[(1-oxopentyl)oxy]-, (11 β)

16. RECORDS AND REPORTS

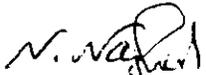
17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

DATE COMPLETED:


Nashed E. Nashed, Ph.D.

8/17/98
7/31/98

Supervisor: Paul Schwartz, Ph.D.

8/3/98 *ps 8/10/98*

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