

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER **75042**

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO.4

2. ANDA # 75-042

*see addendum
firm's response of 8/19/98*

3. NAME AND ADDRESS OF APPLICANT

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

4. LEGAL BASIS FOR SUBMISSION

The firm certifies that in their opinion and to their knowledge there are no U.S. Patents that claim the listed drug referred to this application Westcort, or that claim a use of the listed drug. Also 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 3/5/97
Amendment 11/7/97
Amendment 3/30/98
Amendment 4/16/98
Amendment 5/11/98
Amendment 6/15/98
Amendment 6/16/98
Amendment 7/30/98

Amendment 8/19/98

10. PHARMACOLOGICAL CATEGORY

Anti-inflammatory

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM

Cream

14. POTENCY

0.2%

15. CHEMICAL NAME AND STRUCTURE

Pregn-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:

/S/
Nashed E. Nashed, Ph.D.

8/17/98
8/3/98

Supervisor: Paul Schwartz, Ph.D.

8/3/98

PS 8/11/98, 8/20/98