

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75633

CHEMISTRY REVIEW(S)

OFFICE OF GENERIC DRUGS

ABBREVIATED NEW DRUG APPLICATION CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. CHEMIST'S REVIEW NUMBER

2 (two)

2. ANDA NUMBER

75-633

3. NAME AND ADDRESS OF APPLICANT

Taro Pharmaceuticals USA Inc.
Attention: Lorraine Sachs
5 Skyline Drive
Hawthorne, NY 10532

4. LEGAL BASIS for ANDA SUBMISSION

The basis of Taro's proposed ANDA for Clobetasol Propionate Emollient Cream USP, 0.05%, is the reference listed drug, Temovate E[®] Emollient, 0.05% (NDA 20340) manufactured by Glaxo Wellcome. According to information published in the list of Approved Drug Products 18th Ed., Temovate E[®] Emollient, 0.05% is not covered by any patents and marketing exclusivities.

5. SUPPLEMENT(s)

None

6. NAME OF DRUG

Clobetasol Propionate Emollient Cream USP

7. NONPROPRIETARY NAME

Clobetasol Propionate Emollient Cream USP

8. SUPPLEMENT(s) PROVIDE(s) FOR

None

9. AMENDMENTS AND OTHER DATES

5/7/1999	Original submission
12/15/99	Major amendment
3/8/00	Correspondence (change of ownership)
4/18/00	Amendment
5/10/00	Telephone amendment

10. PHARMACOLOGICAL CATEGORY

Anti-inflammatory

11. HOW DISPENSED

Prescription

12. RELATED IND/NDA/DMF(s)

Product	Holder	DMF No	LOA
			V1.3, p1117
			V1.4, p1321
			V1.4, p1352
			V1.4, p1355
			V1.4, p1359
			V1.4, p1362

13. DOSAGE FORM

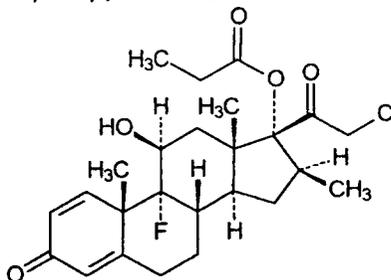
Cream

14. POTENCY

0.05%

15. CHEMICAL NAME AND STRUCTURE

Clobetasol Propionate. Pregna-1,4-diene-3,20-dione, 21-chloro-9-fluoro-11-hydroxy-16-methyl-17-(1-oxopropoxy)-, (11 β ,16 β)-. C₂₅H₃₂ClFO₅. 466.99. 25122-46-7.

**16. RECORDS AND REPORTS**

None

17. COMMENTS

New owner: Taro Pharmaceuticals USA Inc.
The application is approvable.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER AND DATE COMPLETED

Liang-Lii Huang, Ph.D. / May 4, 2000
Endorsed by Paul Schwartz, Ph.D. / May 4, 2000

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