CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 074286/S-003

Name: Desoximetasone Ointment USP 0.25%

Sponsor: Taro Pharmaceuticals, Inc.

Approval Date: April 9, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-003

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Statistical Review(s)	
Microbiology Review(s)	
Administrative & Correspondence Documents	X

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APPLICATION NUMBER:

ANDA 074286/S-003

APPROVAL LETTER

ANDA 74-286/S-003 (Ointment)
74-904/S-002 (Gel)

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

APR - 9 1999

Dear Ms. Sachs:

This refers to your supplemental new drug applications dated November 27, 1998, submitted pursuant to 21 CFR 314.70, for Desoximetasone Ointment (0.25%) and Desoximetasone Gel (0.05%), USP.

The supplemental applications provide for the use of an alternate analytical testing method for assay and determination of impurities in the active drug substance.

We have completed the review of these supplemental applications and they are approved.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

R Patel 4/9/99

Rashmikant M. Patel, Ph.D.
Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA #74286/S-003 and 74904/S-002
Division File
Field Copy
HFD-92

Endorsements:

HFD-627/Neeru B.Takiar/03-26-99 NT 4/1/99
HFD-627/P.Schwartz, Ph.D./3-29-99 NM for PS 4/1/99
HFD-617/J.Buccine, PM/M.Anderson for/3-31-99
V:\firmsnz\Taro\Ltrs&rev\74286S003.RV1
F/T: bc/4-1-99

4/6/99

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APPLICATION NUMBER:

ANDA 074286/S-003

CHEMISTRY REVIEWS

1. CHEMISTRY REVIEW NO. # 1

2. ANDA # 74-286/S-003 (0.25%)
74-904/S-002 (0.05%)

3. NAME AND ADDRESS OF APPLICANT:
Taro Pharmaceuticals USA, Inc.
Attention: Lorraine Sachs
5 Skyline Drive
Hawthorne, NY 10532

4. LEGAL BASIS OF SUBMISSION:
74-286: This drug product, Desoximetasone Ointment USP, 0.25% was approved June 7, 1996.

74-904: This drug product, Desoximetasone Gel USP, 0.05% was approved July 14, 1998.

5. Supplements:
74-286/S-003 (0.25%)
74-904/S-002 (0.05%)

6. PROPRIETARY NAME: None

7. NONPROPRIETARY NAME:
74-286: Desoximetasone Ointment USP, 0.25%
74-904: Desoximetasone Gel USP, 0.05%

8. SUPPLEMENT(s) PROVIDE (s) FOR:
The use of an alternate analytical testing method for assay and determination of impurities in the active drug substance.

9. AMENDMENTS AND OTHER DATES:
11-27-98 Supplements were submitted.

10. PHARMACOLOGICAL CATEGORY:
Synthetic topical corticosteroid

11. Rx or OTC: Rx

12. RELATED IND/NDA/DMF(s): N/A

13. DOSAGE FORM: 74-286 (Ointment)
74-904 (Gel)

14. STRENGTH: 74-286 (0.25%)
74-904 (0.05%)

15. CHEMICAL NAME AND STRUCTURE: N/A

16. RECORDS AND REPORTS: N/A

17. COMMENTS: None

18. CONCLUSIONS AND RECOMMENDATIONS:
The supplemental applications are Approvable.

19. REVIEWER: Neeru B. Takiar DATE COMPLETED: 03/26/99
Endorsed by P.Schwartz, Ph.D.

20. COMPONENTS AND COMPOSITION: N/A

21. FACILITIES AND PERSONNEL: N/A

22. SYNTHESIS: N/A

23. RAW MATERIAL:
Review status: Satisfactory

The supplemental applications provide for the use of an alternate analytical testing method (SOP A-137) for assay and determination of impurities/degradation in the active drug substance. This analytical procedure provides better separation of all the potential degradants and synthetic precursors.

The method has demonstrated equivalency with the USP method for assay and chromatographic purity. Comparable results for three different lots of raw material have been submitted in the Validation Report RD-MV025 (page 10).

Taro has submitted the following information in support of these supplemental applications:

- HPLC method -SOP A137-4: HPLC method for the assay of Desoximetasone and Impurities in Desoximetasone Cream 0.05% and 0.25% and Desoximetasone Raw Material (page 1-5).

- Method Validation Report - RD-MV025: Validation of an HPLC method for the assay of Desoximetasone Raw Material: Using the method outlined in SOP A-137, Revision 1(page 6-48).

24. OTHER FIRM(s): N/A

25. MANUFACTURING AND PROCESSING: N/A

26. CONTAINER: N/A

27. PACKAGING AND LABELING: N/A

28. LABORATORY CONTROLS and (IN-PROCESS)(FINISHED DOSAGE FORM):
N/A

29. STABILITY: N/A

30. CONTROL NUMBERS: N/A

31. SAMPLES AND RESULTS: N/A

32. LABELING: N/A

33. ESTABLISHMENT INSPECTION: N/A

34. BIOEQUIVALENCE STATUS: N/A

35. ENVIRONMENTAL IMPACT CONSIDERATIONS/CATEGORICAL EXCLUSION:
N/A

36. ORDER OF REVIEW:
The application submission(s) covered by this review was taken in the date order of receipt Yes X
No _____

If no, explain reason(s) below:

cc: cc: ANDA #74286/S-003 and 74904/S-002
Division File
Field Copy

Endorsements:

HFD-627/Neeru B.Takiar/03-26-99 NT 4/1/99
HFD-627/P.Schwartz, Ph.D./ PS 3/29/99
\\CDV008\WP51F99\FIRMSNZ\TARO\LTRS&REV\74286S003.RV1.doc
F/T:

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-003

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

TARO PHARMACEUTICALS INC.
130 EAST DRIVE
BRAMALEA, ONTARIO
L6T 1C3

NDA NO. 74286 REF NO. SC-003
NDA SUPPL FOR Control Revision

November 27, 1998

Office of Generic Drugs, CDER
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
U.S.A.

Re: ANDA 74-286 Desoximetasone Ointment USP, 0.25%
Supplement

Active Raw Material - Alternate test method for assay and impurities

Dear Sirs,

Reference is made to our ANDA for Taro's Desoximetasone Ointment, USP 0.25%, approved June 7, 1996.

At this time we wish to supplement our approved applications to use an alternate analytical method (SOP A-137) for assay and determination of impurities in the active raw material. This analytical procedure is better able to separate all potential impurities and synthetic precursors.

The method demonstrated equivalency with the USP method for assay and chromatographic purity, giving comparable results for three different lots of raw material (please see page 10 of the attached Validation Report RD-MV025).

In support of this supplemental application, please find enclosed the following documents:

- HPLC method - SOP A137-4: HPLC method for the assay of Desoximetasone and Impurities in Desoximetasone Cream 0.05% and 0.25% and Desoximetasone Raw Material.

- Method Validation Report - RD-MV025: Validation of an HPLC method for the assay of Desoximetasone Raw Material: Using the method outlined in SOP A-137 (Revision 1).

Please note that we are simultaneously submitting this information in the supplements to ANDAs for Desoximetasone Gel USP, 0.25% ANDA 74-904 and Desoximetasone Cream USP, 0.05% - ANDA 73-210 and Desoximetasone Cream USP 0.25% - ANDA 74-193.

This concludes the supplement to this applications. If there are any questions with regard to this supplement, please do not hesitate to contact the undersigned or our U.S. agent.

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DEC 0 1 1998
GENERIC DRUGS

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Taro Pharmaceuticals U.S.A., Inc.
5 Skyline Drive
Hawthorne, New York 10532
(914) 345-9001
Attn: Lorraine W. Sachs, RAC
Associate Director, Regulatory Affairs

Sincerely,
Taro Pharmaceuticals Inc.

Derek Ganes, Ph.D.
VP, Regulatory Affairs

/L. Ogbaghebriel

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