CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 074286/S-010

Name: Desoximetasone Ointment USP 0.25%

Sponsor: Taro Pharmaceuticals, Inc.

Approval Date: September 15, 2005

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-010

CONTENTS

Reviews / Information Included in this Review	
Approval Letter	X
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Labeling	
Labeling Review(s)	
Medical Review(s)	
Chemistry Review(s)	X
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Statistical Review(s)	
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-010

APPROVAL LETTER

ANDA 73-193/S-024 (0.25%, Cream)
73-210/S-019 (0.05%, Cream)
74-286/S-010 (0.25%, Ointment)

Taro Pharmaceuticals U.S.A. Inc.
Attention: Kalpana Rao
5 Skyline Drive
Hawthorne, NY 10532

SEP 15 2005

Dear Madam:

This refers to your supplemental new drug applications dated February 8, 2005 submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Desoximetasone drug products.

The supplemental applications, submitted as "Supplement-Changes Being Effected in 30 Days", provide for the change in the drug substance manufacturing site from Taro Pharmaceutical Industries Ltd., (Taro Israel) to (b) (4).

We have completed the review of the 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,

Paul Shrewsbury for 9/15/05

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

cc:

ANDA 73-193/S-024 (0.25%)
73-210/S-019 (0.05%)
74-286/S-010 (0.25%)
ANDA DUP
DIV FILE
Field Copy

Endorsements (Draft and Final with Dates):
HFD-627/Liang-Lii Huang, Ph.D./8/16/05, 8/29/05 L Huang 9/13/05

HFD-627/James Fan, Team Leader/9/7/05 9/13/05

HFD-617/Ann Vu, Project Manager/9/8/05 9/14/05

F/T:ard/9/9/05

V:\FIRMSNZ\TARO\LTRS&REV\73193 S024 LAP.doc
Date: August 16, 2005

CHEMISTRY REVIEW - APPROVABLE

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-010

CHEMISTRY REVIEWS

1. CHEMISTRY REVIEW NO. 1 (one)

2. ANDA # 73-193/S-024
73-210/S-019
74-286/S-010

3. NAME AND ADDRESS OF APPLICANT
Taro Pharmaceuticals Inc
130 East Drive
Bramalea, Ontario, Canada L6T IC3

US agent: Taro Pharmaceuticals U.S.A. Inc.
Attention: Kalpana Rao
5 Skyline Drive
Hawthorne, NY 10532
(914) 345-9001

4. LEGAL BASIS FOR SUBMISSION
N/A

5. SUPPLEMENT(s)
73-193/S-024
73-210/S-019
74-286/s-010

6. PROPRIETARY NAME
none

7. NONPROPRIETARY NAME
73-193/S-024 Desoximetasone Cream USP, 0.25%
73-210/S-019 Desoximetasone Cream USP, 0.05%
74-286/S-010 Desoximetasone Ointment USP, 0.25%

8. SUPPLEMENT(s) PROVIDE(s) FOR:
CBE-30:
the change in the API manufacturing site from Taro Pharmaceutical Industires Ltd., (Taro Israel) to (b) (4)

9. AMENDMENTS AND OTHER DATES:
Date of submission: February 8, 2005

10. PHARMACOLOGICAL CATEGORY
Glucocorticoid; anti-inflammatory

11. Rx or OTC
RX

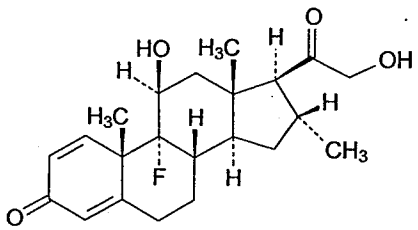
12. RELATED IND/NDA/DMF(s)
N/A

13. DOSAGE FORM
Cream (topical)

14. POTENCY
0.25% and 0.05%

15. CHEMICAL NAME AND STRUCTURE

Desoximetasone. Pregna-1,4-diene-3,20-dione, 9-fluoro-11,21-dihydroxy-16-methyl-,(11β, 16α)-. $C_{22}H_{29}FO_4$. 376.47. 382-67-2. Anti-inflammatory.



16. RECORDS AND REPORTS
none

17. COMMENTS
These applications are approvable.

18. CONCLUSIONS AND RECOMMENDATIONS
These applications are approvable.

19. REVIEWER:
Liang-Lii Huang, Ph.D.
Endorsed by James Fan
Team Leader

DATE COMPLETED:
August 15, 2005
August 16, 2005

Following this page, 4 pages withheld in full (b)(4)-CCI/TS

31. SAMPLES AND RESULTS
N/A

32. LABELING

N/A

33. ESTABLISHMENT INSPECTION
Acceptable 2/25/05

34. BIOEQUIVALENCY 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__XX_____
No _____

If no, explain reason(s) below:

37. **DMF CHECKLIST FOR ANDA # 73-193/S-024, 73-210/S-019, 74-286/S-010** **REVIEW # 1**

DMF #	DMF TYPE/SUBJECT/HOLDER	ACTION CODE	RESULT OF REVIEW	DATE REVIEW COMPLETED
13861	II/Desoximetasone USP / (b) (4)	1	adequate	8/29/05

Comments:

Comments:

Comments:

Comments:

Comments:

Comments:

Comments:

ACTION CODES: (1) DMF Reviewed. Other codes indicate why the DMF was not reviewed, as follows:

(2) Type 1 DMF;
(3) Reviewed previously and no revision since last review;
(4) Sufficient information in application;
(5) Authority to reference not granted;
(6) DMF not available;
(7) Other (explain under"Comments").

Liang-Lii Huang
Reviewer Signature

9/13/05
Date

cc: ANDA 73-193/S-024, 73-210/S-019, 74-286/S-010
DIV FILE
Field Copy

Endorsements (Draft and Final with Dates):

HFD-627/Liang-Lii Huang, Ph.D./8/15/05;8/29/05 L Huang 9/13/05

HFD-627/James Fan, Team Leader/8/16/05;9/2/05

HFD-617/Ann Vu, PM/8/29/05

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August 29, 2005

F/T by:ard/9/13/05

CHEMISTRY REVIEW - APPROVABLE

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-010

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

ARCHIVAL COPY

February 8, 2005

EER entered 2/25/05. DMS

Taro Pharmaceuticals U.S.A., Inc.

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room, Metro Park North II
7500 Standish Place, Room 150
Rockville MD 20857
USA

NDA NO 74-286 REF NO. SCB-010-AT
NDA SUPPL FOR Facility Add

REF: ANDA 74-286
Desoximetasone Ointment USP, 0.25%
CBE-30 Supplement

Change in the Manufacturing Site of Active Pharmaceutical Ingredient (API)— Desoximetasone USP.

Dear Sir/Madam:

Reference is made to our approved ANDA for Desoximetasone Ointment USP, 0.25%, approved on June 7, 1996. Pursuant to 21 CFR 314.70(c), Taro Pharmaceuticals U.S.A. Inc., (henceforth referred as Taro), wishes to supplement the application to provide for the change in the API manufacturing site from Taro Pharmaceutical Industries Ltd. (Taro Israel) to (b) (4).

(b) (4) was approved as the manufacturer of the API, Desoximetasone USP, in the original ANDA, and Taro Israel was approved as the API Manufacturer in the supplement S-004 on May 19, 2000. (b) (4) will manufacture Desoximetasone USP according to their process and according to Taro Israel's process. The two processes will be differentiated by product control numbers.

The address of the (b) (4) manufacturing site which will manufacture Desoximetasone USP according to Taro Israel's process is as follows:

(b) (4)

RECEIVED
FEB 09 2005
OGD / CDER

Please refer to Taro Israel's DMF 13861 for additional information regarding the manufacturing site change.

Desoximetasone USP, as manufactured by (b) (4) using Taro Israel's manufacturing process, will be tested and released by Taro according to the ANDA approved specification for this material. Hence, the specification for the drug substance has not been revised.

In support of the proposed change in the API manufacturing site, Taro has manufactured a (b) (4) batch of Desoximetasone Ointment USP, 0.25% using the drug substance manufactured at the (b) (4) site and has placed it on stability under accelerated and room temperature conditions.

The following documentation has been provided:

i. DMF access letter from Taro Pharmaceutical Industries Ltd. authorizing access to their Drug Master File for Desoximetasone USP, DMF No. 13861 (Attachment 1). Also provided in this attachment is (b) (4) GMP Certification.

ii. Taro's and (b) (4) certificates of analysis for the Desoximetasone USP raw material, (L) RM040797R, used in the manufacture of the exhibit batch of Desoximetasone Ointment USP, 0.25%, (L) 4H035 (Attachment 2).

iii. Executed manufacturing records for the manufacture of a (b) (4) batch of Desoximetasone Ointment USP, 0.25%, (L) 4H035E (the letter E indicates the exhibit batch) and test results for in-process testing / bulk product testing (Attachment 3). The master formula and manufacturing directions are as currently approved for this application.

iv. Executed packaging work orders for the packaging of 5 g, 15 g and 60 g samples of (L) 4H035E, packaged into aluminum tubes. (Note: The entire batch was fully packaged into approved market containers and pack sizes). (Attachment 4).

v. Finished packaged product certificates of analysis for Desoximetasone Ointment USP, 0.25% for 5 g, 15 g and 60 g aluminum tubes, (L) 4H035 (Attachment 5). The finished product met all ANDA release criteria.

vi. Three (3) months accelerated (40°C±2°C, 75%±5%RH) and three (3) months room temperature (25°C±2°C, 60%±5%RH) stability data, for the 5 g, 15 g and 30 g aluminum tubes, (L) 4H035 (Attachment 6). The finished product meets all the ANDA stability specifications for the periods tested.

The stability protocol remains as approved in the original application. Taro commits to monitor commercial batches manufactured with the new supplier according to the stability protocol approved in the original ANDA.

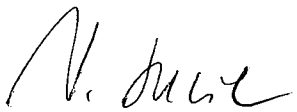
This concludes the CBE-30 supplement for the Desoximetasone USP manufacturing site change. No other changes have been made to or are proposed for this product.

Please note that Taro is concomitantly supplementing the following applications to provide for the change in the manufacturing site for Desoximetasone USP from Taro Israel to (b) (4): Desoximetasone Cream USP, 0.05%, ANDA 73-210, and Desoximetasone Cream USP, 0.25%, ANDA 73-193.

If you have any further concerns, please do not hesitate to contact us at:

Taro Pharmaceuticals U.S.A. Inc.
Attn: Kalpana Rao
Vice President, Regulatory Affairs (Global)
5 Skyline Drive,
Hawthorne, New York 10532
(914) 345-9001

Sincerely yours,



Vesna Lucic
Director, Regulatory Affairs

\ ml

cc: FDA Office of International Programs

CBE Routing Form

This form is to accompany all CBE Supplements. Upon completion, return to the OGD Document Room.

I. To be completed by the OGD Document Room:

LETTER DATE: 2/8/05

APPLICATION: 74-286 SUPPLEMENT(S): SCB-610-AT

Submitted as: **CBE-Zero** **CBE-30** **Labeling CBE**

II. To be completed by the Chemistry/Micro Division Staff:

A. This qualifies as:

Chemistry and/or Micro PM	Chemistry and/or Micro TL	Chem. Div./ Deputy Div. Dir. *
CBE-Zero / CBE-30	CBE-Zero / CBE-30	CBE-Zero / CBE-30

B. Does not qualify. This is Annual Reportable.

Chemistry and/or Micro PM	Chemistry and/or Micro TL	Chem. Div./ Deputy Div. Dir. *

C. Does not qualify. This is a Prior Approval Supplement.

Chemistry and/or Micro PM	Chemistry and/or Micro TL	Chem. Div./ Deputy Div. Dir. *
2/25/05	2/27/05	

* Div/ Deputy Director signature needed only when: 1.) CBE is elevated to a PAS or 2.) PM/TL recommend different actions

III. Labeling CBE

Granted: _____ Denied: _____

Team Leader Signature: _____ Decision Date: _____

IV. Basis for Decision/Comments:

V. Project Manager Chemistry Team: 3

Prepare letter and notify applicant by telephone when CBE is denied because it is a Prior Approval Supplement. DATE: _____

Notify applicant by telephone that inappropriate CBE category used. DATE: _____

Request that applicant withdraw supplement, and submit the changes with the next Annual Report. DATE: _____

VI. Document Room: Record appropriate CBE code and file in archival submission.
Granted (GR); Doesn't qualify, inappropriate CBE category (DC); Doesn't qualify, it's AR (DA); Doesn't qualify, it's a PAS (DN)

FINAL DECISION: GR DATE: 2/28/05

CBE Zero____ CBE 30 X Prior Approval____ Annual Report____

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Application : ANDA 74286/010
Org Code : 600
Priority :

Sponsor: TARO PHARMS (CA)
5 SKYLINE DR
HAWTHORNE, NY 10532

Stamp Date : 09-FEB-2005
PDUFA Date :
Action Goal :
District Goal: 09-JUL-2005

Brand Name :
Estab. Name: DESOXIMETASONE
Generic Name:
Dosage Form: (OINTMENT)
Strength : 0.25%

FDA Contacts:	T. VU	Project Manager (HFD-615)	301-827-5754
	J. FAN	Team Leader (HFD-623)	301-827-5848

Overall Recommendation: ACCEPTABLE on 25-FEB-2005by S. ADAMS (HFD-322) 301-827-9051

Establishment : CFN : (b) (4) FEI : (b) (4)

(b) (4)

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE MANUFACTURER

Profile : CSN OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 25-FEB-05
Decision : ACCEPTABLE
Reason : BASED ON PROFILE
