

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
ANDA 074286/S-016

Name: Desoximetasone Ointment USP
0.25%

Sponsor: Taro Pharmaceuticals, Inc.

Approval Date: March 15, 2010

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA 074286/S-016

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA 074286/S-016

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

DARKTS

Food and Drug Administration
Rockville, MD 20857

ANDAs (See Attachment)

5-016

Taro Pharmaceuticals USA, Inc.
Attention: Kavita Srivastava
Director, Regulatory Affairs
3 Skyline Drive
Hawthorne, NY 10532

Dear Madam:

This is in reference to your supplemental new drug applications dated February 4, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug applications listed in the attachment.

The supplemental applications, submitted as "Supplement - Changes Being Effected in 30 days" provide for the addition of the following site as an alternate testing site:

Taro Pharmaceutical Industries Ltd.
14 Hakitor Street
Haifa Bay, Israel
CFN: 9610271

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

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

The material submitted is being retained in our files.

Sincerely yours,

(See appended electronic signature page)

Paul Schwartz, Ph.D.
Acting Director
Division of Chemistry I
Office of Generic Drugs
Center for Drug Evaluation and Research

ATTACHMENT

Appplication #	Supplement #	Product Name	Dosage Form
074799	8	FLUOCINONIDE	Topical Solution USP, 0.05%
074580	11	CLOTRIMAZOLE	Topical Solution USP, 1%
076493	5	CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE	Lotion, 1%/ 0.05% (base)
075331	9	DIFLORASONE DIACETATE	Ointment USP, 0.05%
074254	7	DESONIDE	Ointment, 0.05%
040041	10	FLUOCINOLONE ACETONIDE	Ointment USP, 0.025%
075008	9	FLUOCINONIDE	Ointment USP, 0.05%
074286	16	DESOXIMETASONE	Ointment USP, 0.25%
040042	6	FLUOCINOLONE ACETONIDE	Cream USP, 0.025%
072494	11	FLUOCINONIDE	Cream USP, 0.05% (Emulsified Base)
075508	7	DIFLORASONE DIACETATE	Cream USP, 0.05%
073193	32	DESOXIMETASONE	Cream USP, 0.25%
073210	28	DESOXIMETASONE	Cream USP, 0.05%
076005	3	ECONAZOLE NITRATE	Cream, 1%
072641	25	CLOTRIMAZOLE	Vaginal Cream USP, 1%
072640	34	CLOTRIMAZOLE	Cream USP, 1%
040035	6	FLUOCINOLONE ACETONIDE	Cream USP, 0.01%
019117	33	FLUOCINONIDE	Cream USP, 0.05%
073548	23	DESONIDE	Cream, 0.05%
074935	10	FLUOCINONIDE	Gel USP, 0.05%
074904	14	DESOXIMETASONE	Gel USP, 0.05%

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
-----	-----	-----	-----
ANDA-76493	SUPPL-5	TARO PHARMACEUTICA LS USA INC	CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE
ANDA-76005	SUPPL-3	TARO PHARMACEUTICA LS USA INC	ECONAZOLE NITRATE
ANDA-75508	SUPPL-7	TARO PHARMACEUTICA LS USA INC	DIFLORASONE DIACETATE
ANDA-75331	SUPPL-9	TARO PHARMACEUTICA LS INC	DIFLORASONE DIACETATE
ANDA-75008	SUPPL-9	TARO PHARMACEUTICA LS INC	FLUOCINONIDE
ANDA-74935	SUPPL-10	TARO PHARMACEUTICA LS INC	FLUOCINONIDE
ANDA-74904	SUPPL-14	TARO PHARMACEUTICA LS INC	DESOXIMETASONE
ANDA-74799	SUPPL-8	TARO PHARMACEUTICA LS INC	FLUOCINONIDE
ANDA-74580	SUPPL-11	TARO PHARMACEUTICA LS INC	CLOTRIMAZOLE
ANDA-74286	SUPPL-16	TARO PHARMACEUTICA LS INC	DESOXIMETASONE
ANDA-74254	SUPPL-7	TARO PHARMACEUTICA LS USA INC	DESONIDE
ANDA-73548	SUPPL-23	TARO PHARMACEUTICA LS USA INC	DESONIDE
ANDA-73210	SUPPL-28	TARO PHARMACEUTICA LS INC	DESOXIMETASONE
ANDA-73193	SUPPL-32	TARO PHARMACEUTICA LS INC	DESOXIMETASONE
ANDA-72641	SUPPL-25	TARO PHARMACEUTICA LS INC	CLOTRIMAZOLE
ANDA-72640	SUPPL-34	TARO PHARMACEUTICA LS USA INC	CLOTRIMAZOLE

ANDA-72494	SUPPL-11	TARO PHARMACEUTICA LS USA INC	FLUOCINONIDE
ANDA-40042	SUPPL-6	TARO PHARMACEUTICA LS INC	FLUOCINOLONE ACETONIDE
ANDA-40041	SUPPL-10	TARO PHARMACEUTICA LS INC	FLUOCINOLONE ACETONIDE
ANDA-40035	SUPPL-6	TARO PHARMACEUTICA LS INC	FLUOCINOLONE ACETONIDE
ANDA-19117	SUPPL-33	TARO PHARMACEUTICA LS USA INC	FLUOCINONIDE

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/s/

PAUL SCHWARTZ
03/15/2010

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA 074286/S-016

CHEMISTRY REVIEWS

5-016

**Alternate Analytical Testing Laboratory Site Change
Abbreviated New Drug Supplemental Application Regulatory Assessment**

REVIEW#:

1

ANDA

(See Attachment)

SUPPLEMENT

(See Attachment)

NAME AND ADDRESS OF APPLICANT:

Taro Pharmaceuticals USA, Inc.
3 Skyline Drive
Hawthorne, NY 10532

PURPOSE OF AMENDMENT/SUPPLEMENT

SPECIAL SUPPLEMENT – CHANGES BEING EFFECTED IN 30 DAYS:

To add the following facility as an alternate testing laboratory:

Taro Pharmaceutical Industries Ltd.
14 Hakitor Street
Haifa Bay, Israel
CFN: 9610271

DATE(S) OF SUBMISSION(S)

February 4, 2010

NONPROPRIETARY NAME

(See Attachment)

DOSAGE FORM

(See Attachment)

POTENCY

(See Attachment)

Rx or OTC

Rx

DOCUMENTATION

In support of the proposed alternate analytical testing laboratory, the firm submitted the following:

- A commitment to use the same SOP's and test methods employed in the approved application.
- Certification that all post approval commitments relating to the test method(s) have been fulfilled.
- Certification that the testing laboratory has the capability to perform the intended testing.

- Certification that the testing laboratory is in conformance with cGMP's.
- A full description of the testing to be performed by the testing lab.

ESTABLISHMENT INSPECTION

Acceptable on March 1, 2010

REMARKS AND CONCLUSION

These supplements are approvable

PROJECT MANAGER:

Trang Q. Tran

DATE COMPLETED:

March 5, 2010

cc: ANDA
Division File
Field Copy

Endorsements:

HFD-617/T. Tran/ 3/5/10
HFD-620/J. Fan/ 3/11/10

V:\Chemistry Division I\Team 3\FIRMSNZ\TARO\LTRS&RVS\72640.S034 and Taro global
ALT_Test.doc

F/T by / TT

TYPE OF LETTER: Approval

ATTACHMENT

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074904	14	DESOXIMETASONE	Gel USP, 0.05%

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-75508	SUPPL-7	TARO PHARMACEUTICA LS USA INC	DIFLORASONE DIACETATE
ANDA-40042	SUPPL-6	TARO PHARMACEUTICA LS INC	FLUOCINOLONE ACETONIDE
ANDA-74904	SUPPL-14	TARO PHARMACEUTICA LS INC	DESOXIMETASONE
ANDA-72640	SUPPL-34	TARO PHARMACEUTICA LS USA INC	CLOTRIMAZOLE
ANDA-74286	SUPPL-16	TARO PHARMACEUTICA LS INC	DESOXIMETASONE
ANDA-19117	SUPPL-33	TARO PHARMACEUTICA LS USA INC	FLUOCINONIDE
ANDA-73193	SUPPL-32	TARO PHARMACEUTICA LS INC	DESOXIMETASONE
ANDA-72494	SUPPL-11	TARO PHARMACEUTICA LS USA INC	FLUOCINONIDE
ANDA-40035	SUPPL-6	TARO PHARMACEUTICA LS INC	FLUOCINOLONE ACETONIDE
ANDA-75008	SUPPL-9	TARO PHARMACEUTICA LS INC	FLUOCINONIDE
ANDA-74935	SUPPL-10	TARO PHARMACEUTICA LS INC	FLUOCINONIDE
ANDA-74799	SUPPL-8	TARO PHARMACEUTICA LS INC	FLUOCINONIDE
ANDA-40041	SUPPL-10	TARO PHARMACEUTICA LS INC	FLUOCINOLONE ACETONIDE
ANDA-76005	SUPPL-3	TARO PHARMACEUTICA LS USA INC	ECONAZOLE NITRATE
ANDA-75331	SUPPL-9	TARO PHARMACEUTICA LS INC	DIFLORASONE DIACETATE
ANDA-74580	SUPPL-11	TARO PHARMACEUTICA LS INC	CLOTRIMAZOLE

ANDA-72641	SUPPL-25	TARO PHARMACEUTICA LS INC	CLOTRIMAZOLE
ANDA-76493	SUPPL-5	TARO PHARMACEUTICA LS USA INC	CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE
ANDA-73548	SUPPL-23	TARO PHARMACEUTICA LS USA INC	DESONIDE
ANDA-74254	SUPPL-7	TARO PHARMACEUTICA LS USA INC	DESONIDE
ANDA-73210	SUPPL-28	TARO PHARMACEUTICA LS INC	DESOXIMETASONE

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/s/

TRANG Q TRAN
03/15/2010

JAMES M FAN
03/18/2010

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA 074286/S-016

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

Archival Copy



Taro Pharmaceuticals U.S.A., Inc.

SUPPL-16
SD# 55

February 4, 2010

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

**RE: ANDA 74-286
Desoximetasone Ointment USP, 0.25%**

**Changes Being Effectuated in 30 days (CBE-30) Supplement -
Addition of Alternate Testing Site – Taro
Pharmaceutical Industries Ltd. (Haifa Bay,
Israel)**

Dear Sir/Madam,

Taro Pharmaceuticals U.S.A. Inc. (Taro USA), hereby submits a CBE-30 Supplement for the above referenced ANDA, Desoximetasone Ointment USP, 0.25%.

This supplement is being submitted in accordance with the Guidance for Industry, Changes to an Approved NDA or ANDA, Section VI.C.1.d, dated April 2004. This CBE-30 Supplement provides for an alternate testing site, Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel (Taro Israel). Taro Israel is proposed to serve as a backup laboratory for Taro Pharmaceutical Inc., Canada (Taro Canada) to perform testing of API, excipients, finished drug products and packaging components.

The proposed site, Taro Israel, is identified and known to the FDA as Drug Establishment Registration No. 3002808385. The proposed site meets all the criteria established in the above mentioned guidance document for a CBE-30 submission: (1) the test procedure approved in the application or procedures that have been implemented via an annual report are used, (2) all post approval commitments made by the applicant relating to the test procedures have been fulfilled (e.g., providing method validation samples), and (3) the new testing facility has the capability to perform the intended testing.

Please note that Taro Israel has been approved as an alternate testing site for the following products manufactured at Taro Canada.

RECEIVED

FEB 05 2010

OGD

NDA # 22-067	Flo-Pred™ (Prednisolone Acetate Oral Suspension) 5 mg/5 mL and 15 mg/5 mL (as prednisolone)
ANDA # 78-668	Sulfacetamide Sodium Topical Suspension USP, 10%
ANDA # 40-718	Promethazine Hydrochloride Oral Solution USP, 6.25 mg/5 mL

The following documents are provided in support of this change:

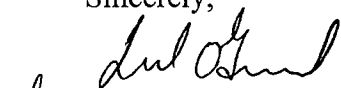
1. cGMP Certificate from Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel
2. GDEA Certificate from Taro Pharmaceutical Industries Ltd., Haifa Bay, Israel

This concludes the supplement to this application.

If there are any questions with regard to this supplement, please do not hesitate to contact the undersigned at:

Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive
Hawthorne, New York 10532
Tel.: (914) 345-9001 ext. 6160
Fax: (914) 593-0078

Sincerely,



Kavita Srivastava
Director, Regulatory Affairs
Taro Pharmaceuticals U.S.A., Inc.

cc: FDA, Office of International Programs

CBE Routing Form

5-010

This form is to accompany all CBE Supplements. Upon completion, File in DFS.

I. To be completed:

LETTER DATE: 2/4/10

APPLICATION: (See Attachment) SUPPLEMENT(S): (See Attachment)

Submitted as: ☐ CBE-Zero ☒ CBE-30 ☐ Labeling CBE

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

This qualifies as:

Chemistry and/or Micro PM	Chemistry and/or Micro TL	Chem. Div./ Deputy Div. Dir. *
CBE-30 Endorsement: TT 3/5/10 see below sec. 4 & 5	CBE-30 Endorsement: JF 3/1/10 see below sec. 4 & 5	SELECT CBE TYPE Endorsement:

* 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 Endorsement: _____ Decision Date: _____	

IV. **Basis for Decision/Comments:**

Proposes to provide the addition of the following site as an alternate testing site:

Taro Pharmaceutical Industries Ltd. (CFN: 9610271)

14 Hakitor Street

Haifa Bay, Israel

EES CTL profile AC on 3/1/2010

Supported by "Guidance for Industry", Section VI.C.1.d.

V. **Approval By Inspection:**

Upon review at the Team level it was determined that the supportive data provided for the proposed change is sufficient for the approval of the supplement and needs no further input from the primary reviewer.

Changes deemed via TL: Acceptable By-Inspection: ☒ YES

Comments/Endorsement:

VI. Project Manager Chemistry Team: SELECT TEAM #

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: _____

VII. 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: GRANTED (GR)

DATE: 3/11/10

ATTACHMENT

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ANDA-75508	SUPPL-7	TARO PHARMACEUTICA LS USA INC	DIFLORASONE DIACETATE
ANDA-75331	SUPPL-9	TARO PHARMACEUTICA LS INC	DIFLORASONE DIACETATE
ANDA-75008	SUPPL-9	TARO PHARMACEUTICA LS INC	FLUOCINONIDE
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ANDA-19117	SUPPL-33	TARO PHARMACEUTICA LS USA INC	FLUOCINONIDE

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/s/

TRANG Q TRAN
03/11/2010

JAMES M FAN
03/12/2010