CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 074286/S-009

Name: Desoximetasone Ointment USP 0.25%

Sponsor: Taro Pharmaceuticals, Inc.

Approval Date: November 23, 2004

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-009

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Reviews / Information Included in this Review	
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Microbiology Review(s)	
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-009

APPROVAL LETTER

ANDA 73-193/S-022 (Desoximetasone Cream USP, 0.25%)
73-210/S-017 (Desoximetasone Cream USP, 0.05%)
74-904/S-008 (Desoximetasone Gel USP, 0.05%)
74-286/S-009 (Desoximetasone Ointment USP, 0.25%)

Taro Pharmaceuticals, Inc.
Attention: Kalpano Rao
5 Skyline Drive
Halthorne, NY 10532

NOV 23 2004

Dear Madam:

This is in reference to your supplemental new drug applications dated October 21, 2004 submitted pursuant to 21 CFR 314.70 (c) (Special Supplement - Changes Being Effected) regarding your abbreviated new drug applications for desoximetasone cream USP, desoximetasone cream USP, desoximetasone gel USP and desoximetasone ointment USP.

These supplemental applications provide for proposed secondary packaging (cartons for 10 physician sample tubes) for the 5 g sample tubes.

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

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the guidance for industry regarding electronic submissions (Providing Regulatory Submissions in Electronic Format - ANDAs, issued 6/2002) available at the following website:

http://www.fda.gov/cder/guidance/5004fnl.htm.

Although the guidance specifies labeling to be submitted in PDF format, we request that labeling also be submitted in MS Word format to assist our review."

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.

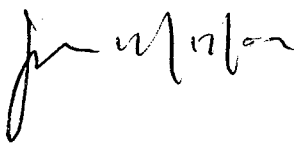
Sincerely yours,

Wm. Peter Rickman
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

cc:ANDA 73-193/S-022 (Desoximetasone Cream USP, 0.25%)
73-210/S-017 (Desoximetasone Cream USP, 0.05%)
74-904/S-008 (Desoximetasone Gel USP, 0.05%)
74-286/S-009 (Desoximetasone Ointment USP, 0.25%)
Division File
HFD-600/Reading File
Field Copy
V:\FIRMSNZ\TARO\LTRS&REV\74286s9.apletter.doc

APPROVABLE LETTER - MULTIPLE SUPPLEMENTS

Endorsements:
HFD-613/JBarlowforBeverlyWeitzman

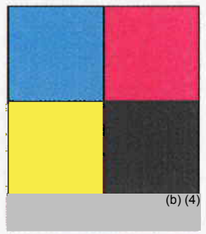


CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-009

LABELING



NDC 51672-5203-5 5 g

Topicort®

Rx only

Desoximetasone Ointment USP, 0.25%

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Keep this and all medications out of the reach of children.

Professional Sample Only

TaroPharma™

Directions for puncturing tube seal: Remove cap. Turn cap upside down and place puncture tip onto tube. Push cap until tube end is punctured. Screw cap back on to reseal tube.

EACH GRAM CONTAINS: 2.5 mg desoximetasone in an ointment base consisting of white petrolatum and fractionated coconut oil.

USUAL DOSAGE: Apply a thin film to affected skin area twice daily. Rub in gently. See insert for full prescribing information.

Store at controlled room temperature 15°-30°C (59°-86°F).

For lot number and expiry date see back of carton or crimp of tube.

PK-4886-0 0904-0

Mfd. by: Taro Pharmaceuticals Inc.
Brampton, Ontario, Canada L6T 1C1
Dist. by: TaroPharma
a division of Taro Pharmaceuticals U.S.A., Inc.
Hawthorne, NY 10532
Topicort® and TaroPharma™ are trademarks of Taro Pharmaceuticals U.S.A., Inc. and/or its affiliates.

N 3 51672 52035 9

NDC 51672-5203-5 5 g

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TaroPharma™

NDC 51672-5203-5 5 g

Topicort®

Rx only

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FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Keep this and all medications out of the reach of children.

Professional Sample Only

TaroPharma™

T-152

APPROVED
NOV 23 2004

PANEL = NO VARNISH FOR LOT AND EXP. CODING

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-009

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

October 21, 2004

Taro Pharmaceuticals U.S.A., Inc.

Office of Generic Drugs
Document Control Room
CDER, FDA, MPN II
7500 Standish Place, Room 150
Rockville, MD 20855

NDA NO. 74-286 REF. NO. SL-009-AIC
NDA SUPPL FOR labeling Rev.

RECEIVED
OCT 2 2 2004
OGD / CDER

Re: **ANDA's:**
Desoximetasone Cream USP, 0.25% (73-193)
Desoximetasone Cream USP, 0.05% (73-210)
Desoximetasone Gel USP, 0.05% (74-904)
Desoximetasone Ointment USP, 0.25% (74-286)

Supplement - Changes Being Effected **(CBE-0)- new secondary packaging for physician size tubes.**

Dear Sir/Madam:

Reference is made to Taro Pharmaceuticals Inc.'s Abbreviated New Drug Application (ANDA), approved on November 30, 1990, under Section 505(j) of the Federal Food, Drug and Cosmetic Act for Desoximetasone Cream USP, 0.25% (73-193), Desoximetasone Cream USP, 0.05% (73-210), Desoximetasone Gel USP, 0.05% (74-904), Desoximetasone Ointment USP, 0.25% (74-286). Also, reference is made to supplements 73-210/S-020, 73-193/S-015, 74-904/S-007, 74-286/S-006 approved December 19, 2003 for the use of the proprietary name "Topicort" on our labeling.

Taro wishes at this time to supplement its ANDA with a new secondary packaging for its physician size samples. We currently possess an approval for the primary packaging of the 5g tubes, and both primary and secondary packaging for our 15g, and 60g sizes. The new secondary packaging (carton for 10 physician sample tubes) includes all the same approved text that currently exists on our other sized approved secondary packaging.

Enclosed you will find:
12 – Final Printed 5 g cartons (10 units per box) for Desoximetasone Cream USP, 0.25% (73-193)
12 – Final Printed 5 g cartons (10 units per box) for Desoximetasone Cream USP, 0.05% (73-210)
12 – Final Printed 5 g cartons (10 units per box) for Desoximetasone Gel USP, 0.05% (74-904)
12 – Final Printed 5 g cartons (10 units per box) for Desoximetasone Ointment USP, 0.25% (74-286)

Five Skyline Drive, Hawthorne, NY 10532 Tel: 914-345-9001 1-888-TARO-USA Fax: 914-345-8728 www.taro.com

Please be advised that it is our intention to implement this change immediately as provided for in the "Guidance for Industry – Changes to an Approved NDA or ANDA".
Please feel free to contact the undersigned should you have any questions, at 914-345-9001, ext. 6298.

Sincerely,

10/21/09

Kalpana Rao (U.S. Agent)
Vice President, Regulatory Affairs

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: 10/21/04

APPLICATION: 74-286 SUPPLEMENT(S): SL-009-AR

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. *

* 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: Y Denied: _____

Team Leader Signature: _____ Decision Date: 10/25/04

IV. Basis for Decision/Comments:

V. Project Manager Chemistry 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: _____

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: 10/26/04

CBE Zero____ CBE 30____ Prior Approval____ Annual Report____