CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

ANDA 074286/S-007 and S-008

Name: Desoximetasone Ointment USP 0.25%

Sponsor: Taro Pharmaceuticals, Inc.

Approval Date: April 26, 2004

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-007 &S-008

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Reviews / Information Included in this Review	
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Labeling Review(s)	X
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Bioequivalence Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
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APPLICATION NUMBER:

ANDA 074286/S-007 and S-008

APPROVAL LETTER

ANDA 74-286/S-007 and S-008

Taro Pharmaceuticals USA Inc.
Attention: Vesna Lucic
5 Skyline Drive
Hawthorne, NY 10532

APR 26 2004

Dear Madam:

This refers to your supplemental new drug applications dated October 09, 2003, submitted pursuant to 21 CFR 314.70, for Desoximetasone Ointment USP, 0.25%.

The supplemental applications submitted as "Supplement- Changes Being Effected in 30 Days", provide for:

S-007 The addition of a new pack size, 5-gram aluminum tubes, for physician's samples.

S-008 Labeling revision

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,

RMPatel 4/22/04

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

cc: ANDA #74286/S-007 and S-008
Division File
Field Copy
HFD-92

Endorsements:

HFD-627/Liang-Lii Huang, Ph.D./4/15/04 for, CK 4/20/04
HFD-627/James Fan, Team Leader/4/15/04 for, L Huang 4/20/04
HFD-617/Ann Vu, PM/ 4/15/04 4/22/04
HFD-615/B. Weitzman 4/4/04
HFD-615/J. Grace 4/21/04

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April 15, 2004

F/T by:

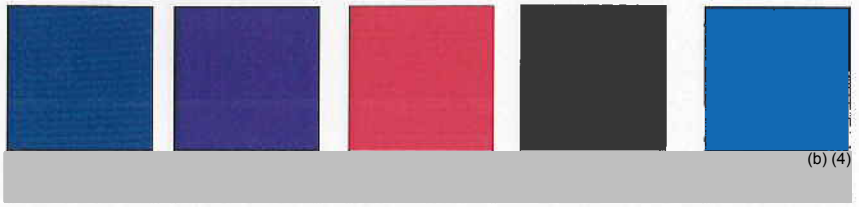
CENTER FOR DRUG EVALUATION AND RESEARCH

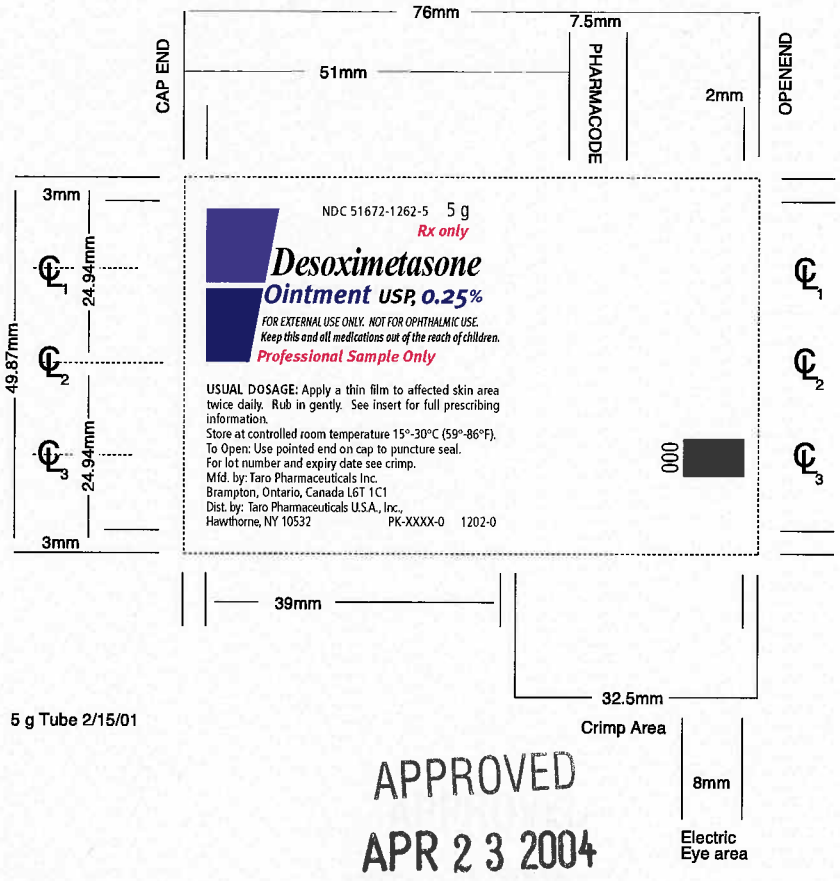
APPLICATION NUMBER:

ANDA 074286/S-007 & S-008

LABELING

ORIG





5 g Tube 2/15/01

APPROVED
APR 2 3 2004

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-007 and S-008

LABELING REVIEWS

REVIEW OF PROFESSIONAL LABELING

SUPPLEMENT

Final Printed Labeling

DATE OF REVIEW: April 19, 2004

ANDA #: 74-286/S-008 combined with chemistry supplement 007

NAME OF FIRM: Taro Pharmaceuticals

NAME OF DRUG: Desoximetasone Ointment USP, 0.25%

PROPRIETARY NAME: Topicort Ointment USP, 0.25%

DATE OF SUBMISSION: October 9, 2003

COMMENTS:

1) CONTAINER (5 g professional sample) - Satisfactory in FPL as of October 9, 2003 submission.

RECOMMENDATIONS:

Approve the supplement

NOTE TO CHEMIST: None

FOR THE RECORD:

1. This supplement provides for a new container size (5 g), and is combined with chemistry supplement SCA 007.

cc: ANDA 74-286/S-008
Division File
HFD-613/BWeitzman/JGrace (no cc:) BWW 4-19-2004
V:\FIRMSNZ\Taro\LTRS&REV\74-286s008.apl 4/19/04
Review

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-007 and S-008

CHEMISTRY REVIEWS

1. CHEMISTRY REVIEW NO. # 1

2. ANDA # 74-286/S-007, s-008

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

4. LEGAL BASIS OF SUBMISSION:
N/A

5. Supplements:
74-286/S-007 (0.25%)packaging addition
74-286/s-008 (0.25%)labeling revisions

6. PROPRIETARY NAME: None

7. NONPROPRIETARY NAME:
Desoximetasone Ointment USP, 0.25%

8. SUPPLEMENT(s) PROVIDE (s) FOR:
CBE-30

The use of an additional pack size 5-gram aluminum tubes to be used for physician samples (s-007) and labeling revisions (s-008)

Labeling Revisions for the 5 gram tube size

9. AMENDMENTS AND OTHER DATES:
October 09, 2003 Supplement submitted.

10. PHARMACOLOGICAL CATEGORY:
Synthetic topical corticosteroid

11. Rx or OTC: Rx

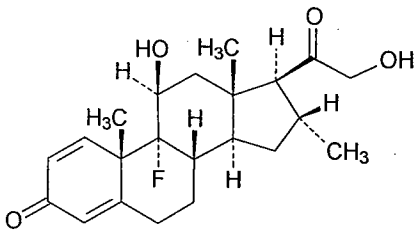
12. RELATED IND/NDA/DMF(s):
DMF (b)(4), DMF (b)(4), DMF (b)(4), DMF (b)(4), and DMF (b)(4).

13. DOSAGE FORM: Ointment

14. STRENGTH: 0.25%

15. CHEMICAL NAME AND STRUCTURE:
Desoximetasone. Pregna-1,4-diene-3,20-dione, 9-fluoro-11,21-

dihydroxy-16-methyl-,(11β, 16α)-.$C_{22}H_{29}FO_4$. 376.46. 382-67-2.
Anti-inflammatory.



16. RECORDS AND REPORTS: N/A

17. COMMENTS:
The supplemental application is approvable.

18. CONCLUSIONS AND RECOMMENDATIONS:
The supplemental application is approvable.

19. REVIEWER: DATE COMPLETED:
Liang-Lii Huang, Ph.D. 4/9/04
Endorsed by J. Fan, Team Leader/ 4/15/04

Following this page, 2 pages withheld in full (b)(4)-CCI/TS

(b) (4)

[redacted]

30. CONTROL NUMBERS: N/A

31. SAMPLES AND RESULTS: N/A

32. LABELING:

74-286/S-008: Acceptable
FPL is evaluated to be acceptable (4/19/04 B. Weitzman).

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 XX
No _____

If no, explain reason(s) below:

This page appears blank in original application

37. **DMF CHECKLIST FOR ANDA #74-286/S-007 REVIEW # 1**

DMF #	DMF TYPE/SUBJECT/HOLDER	ACTION CODE	RESULT OF REVIEW	DATE REVIEW COMPLETED
(b) (4)	III/ (b) (4) / (b) (4)	4		

Comments:

(b) (4)	III/ (b) (4) / (b) (4)	4		

Comments:

(b) (4)	III/ (b) (4) / (b) (4)	4		

Comments:

(b) (4)	III/ (b) (4) / (b) (4)	4		

Comments:

(b) (4)	IV/ (b) (4) / (b) (4)	7		

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-Li Huang 4/20/04
Reviewer Signature Date

cc: ANDA #74286/S-007
Division File
Field Copy

Endorsements:

HFD-627/Liang-Lii Huang, Ph.D./4/15/04
HFD-627/James M Fan, Team Leader/4/15/04

Fan GK 4/20/04
for, L Huang 4/20/04

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April 15, 2004

CMC - Approvable

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-007 and S-008

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

ARCHIVAL COPY

Taro Pharmaceuticals U.S.A., Inc.

October 9, 2003

Office of Generic Drugs
Center for Drug Evaluation and Research
Attention: Document Control Room
Metro Park North II, FDA
7500 Standish Place, Room 150
Rockville, Maryland
20855-2773

NDA NO. 74286 REF NO. SLA 008/AT
NDA SUPPL FOR Packaging Add

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

NDA NO. 74286 REF NO. SL-008
NDA SUPPL FOR Labeling Rev
AT

Addition of a new pack size (5-gram aluminum tube)

Dear Sir/Madam:

Reference is made to our approved ANDA for Desoximetasone Ointment USP, 0.25%. At this time Taro wishes to supplement the ANDA to provide for the use of an additional pack size, 5-gram aluminum tubes to be used for physician's samples.

This supplement is submitted in accordance with Section IX.C. Guidance for Industry "Changes to an Approved NDA or ANDA", dated November 1999.

The 5-g metal tubes proposed in this supplement are manufactured by (b) (4) (b) (4) (aluminum tubes manufacturer approved in the ANDA). In addition, the tube components are supplied from the same manufacturers as approved in the ANDA.

In support of the above change, we have included the following documentation:

1. Container –closure information:

   1.1. Taro's specifications and test results for the 5-gram aluminum tubes used to package the finished product in this application – Desoximetasone Ointment USP, 0.25% (L) 2I084. (Supplementary pages 3 – 10).

   1.2. Information from (b) (4) (Supplementary pages 11 – 15).

   - Description of the aluminum tube components.
   - Specification including technical drawing for the 5-gram tube from (b) (4).

RECEIVED
OCT 10 2003

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

- Certificate of Conformance of the 5-gram tube used to package Desoximetasone Ointment USP, 0.25% (L) 2I084.

2. Stability data – three (3) months at accelerated and 9 months at room temperature for a production batch of Desoximetasone Ointment USP, 0.25% (L) 2I084 in 5-gram aluminum tubes. (Supplementary pages 16 – 20).

Based on the available data, Taro Pharmaceuticals Inc. proposes 24-months expiration dating for the product packaged in 5-gram tubes.

3. Twelve (12) copies of final printed labels for the 5-gram tube and side-by-side labeling comparison with the current reference listed drug. (Supplementary pages 21 – 34).

This concludes the supplement to this application. If there are any questions, or if you require additional information, please do not hesitate to contact us at:

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

Sincerely,

V. Lucic

Vesna Lucic
Director, Regulatory Affairs

\ml

cc: FDA Office of International Programs

CKD to VUA (Ann Vu)

CBE- THIRTY (30) DAY SUPPLEMENT ROUTING FORM

This form is to accompany all CBE-30 Day supplements. Upon completion, return to the OGD Document Room

I. To be completed by the OGD Document Room using information from the applicant Cover letter:

DATE PROCESSED: 10.10-03
APPLICATION # : 74-286. SUPPLEMENT # : SCA-007/MT SL-008 AE

II: To be determined by Chemistry Division Staff.

Date and initial appropriate category.

Thirty (30) Day CBEs:

Chemistry Div. Staff	Qualifies as CBE-30 (GR)	Does Not Qualify. This is a CBE-0. (DC)	Does not Qualify. This is an Annual Report (DA)	Does not Qualify. This is a Prior Approval Supp. (DN)
Chemistry/Micro Project Manager(s)	D 10/17/03	SPECIAL		
Micro and/or Labeling Team Leader (as needed)				
Chemistry Team Leader	10/15/03			
Chemistry Div. Dir. Or Deputy* Dir.				

*Div/Deputy Director signature needed only when: 1) CBE elevated to PAS or 2) PM/TM recommend different actions,

COMMENTS: IX.C.

III. To 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 when CBE qualifies for submssion as an Annual Report DATE _____

IV. To Document Room

Record appropriate CBE Code GR
[illegible] final submission

Previous Jacket checked out