

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
ANDA 074286/S-012 and S-013

Name: Desoximetasone Ointment USP
0.25%

Sponsor: Taro Pharmaceuticals, Inc.

Approval Date: July 25, 2008

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA 074286/S-012 and S-013

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA 074286/S-012 and S-013

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA (See Attached List)

Taro Pharmaceuticals U.S.A., 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 May 7, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug applications for (See Attached List).

Reference is also made to your amendment dated June 5, 2008.

These supplemental applications, submitted as "Supplements - Changes Being Effectuated in 30 Days" provide for the use of (b) (4) and (b) (4) as alternate testing laboratories for testing drug substances, finished products, excipients, and packaging components.

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 application described in 21 CFR 314.80-81.

The material submitted is being retained in our files.

Sincerely yours,

{See appended electronic signature page}

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

Attachment 1: List of supplemental applications

76-587/S001; S002	Alclometasone Dipropionate Cream USP, 0.05%
74-799/S006; S007	Fluocinonide Topical Solution USP, 0.05%
74-935/S008; S009	Fluocinonide Gel USP, 0.05%
75-008/S007; S008	Fluocinonide Ointment USP, 0.05%.
72-494/S009; S010	Fluocinonide Cream USP, 0.05% (Emulsified base)
74-249/S020; S021	Clobetasol Propionate Cream USP, 0.05%
40-040/S008; S009	Triamcinolone Acetonide Ointment USP, 0.025%
73-210/S021; S022	Desoximetasone Cream USP, 0.05%
40-037/S010; S011	Triamcinolone Acetonide Ointment USP, 0.1%
70-730/S017; S018	Triamcinolone Acetonide Dental Paste, USP, 0.1%
40-039/S007; S008	Triamcinolone Acetonide Cream USP, 0.1%
40-038/S007; S008	Triamcinolone Acetonide Cream, USP, 0.025%
77-511/S003; S004	Terbinafine Hydrochloride Cream, 1%
73-193/S028; S029	Desoximetasone Cream USP, 0.25%
63-305/S015; S016	Nystatin and Triamcinolone Acetonide Ointment USP, 100,000 u/g and 1 mg/g
62-364/S018; S019	Nystatin and Triamcinolone Acetonide Cream, USP
73-548/S020; S021	Desonide Cream, 0.05%
76-493/S002; S003	Clotrimazole and Betamethasone Dipropionate Lotion, 1%/0.05% (base)
75-224/S006; S007	Clobetasol Propionate Solution USP, 0.05%
75-279/S007; S008	Clobetasol Propionate Gel USP, 0.05%
74-248/S018; S019	Clobetasol Propionate Ointment USP, 0.05%
64-022/S008; S009	Nystatin Cream, USP 100,000 units/g

72-640/S032; S033	Clotrimazole Cream USP, 1%
19-117/S029; S030	Fluocinonide Cream USP, 0.05%
75-043/S009; S010	Hydrocortisone Valerate Ointment USP, 0.2%
75-042/S009; S010	Hydrocortisone Valerate Cream USP, 0.2%
74-580/S009; S010	Clotrimazole Topical Solution USP, 1%
72-641/S023; S024	Clotrimazole Vaginal Cream USP, 1%
88-759/S025; S026	Hydrocortisone 1% and Acetic Acid 2% Otic Solution USP.
40-247/S006; S007	Hydrocortisone Lotion USP, 2.5%
74-444/S013; S014	Miconazole Nitrate Vaginal Cream 2%
75-633/S004; S005	Clobetasol Propionate Cream USP, 0.05% (Emollient)
86-724/S022; S023	Lidocaine Ointment USP, 5%
77-227/S004; S005	Halobetasol Propionate Cream, 0.05%
76-994/S004; S005	Halobetasol Propionate Ointment, 0.05%
86-155/S046; S047	Hydrocortisone Cream USP, 1%
88-799/S038; S039	Hydrocortisone Cream USP, 2.5%
65-170/S001; S002	Mupirocin Ointment USP, 2%
77-092/S001; S002	Ciclopirox Topical Suspension USP, 0.77% (Lotion)
76-624/S003; S004	Mometasone Furoate Ointment USP, 0.1%.
76-788/S001; S002	Mometasone Furoate Topical Solution USP, 0.1% (Lotion)
76-679/S003; S004	Mometasone Furoate Cream USP, 0.1%
76-773/S002; S003	Miconazole Nitrate Vaginal Cream, 4%
76-790/S001; S002	Ciclopirox Olamine Cream USP, 0.77%
72-041/S016; S017	Betamethasone Valerate Cream USP, 0.1%

76-543/S003; S004	Betamethasone Dipropionate Cream USP, 0.05% (base) (Augmented)
76-508/S003; S004	Betamethasone Dipropionate Gel (Augmented), 0.05% (base)
74-272/S003; S004	Betamethasone Dipropionate Lotion, 0.005%
74-271/S005; S006	Betamethasone Dipropionate Ointment, 0.005%
73-552/S006; S007	Betamethasone Dipropionate Cream, 0.05%
76-216/S002; S003	Ammonium Lactate Lotion, 12% (base)
75-883/S004; S005	Ammonium Lactate Cream, 12% (base)
40-041/S007; S008	Fluocinolone Acetonide Ointment USP, 0.025%
40-042/S003; S004	Fluocinolone Acetonide Cream USP, 0.025%
40-035/S003; S004	Fluocinolone Acetonide Cream USP, 0.01%
75-331/S007; S008	Diflorasone Diacetate Ointment USP, 0.05%
75-508/S005; S006	Diflorasone Diacetate Cream USP, 0.05%
74-254/S005; S006	Desonide Ointment, 0.05%.
74-286/S012; S013	Desoximetasone Ointment USP, 0.25%
74-904/S012; S013	Desoximetasone Gel USP, 0.05%

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Paul Schwartz
7/25/2008 01:00:39 PM
Signed for R. Patel

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA 074286/S-012 and S-013

CHEMISTRY REVIEWS

5-013

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

REVIEW:

1

ANDA

(See Attached List)

SUPPLEMENT

(See Attached List)

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 facilities as alternate testing laboratories for testing of drug substances, excipients, finished products, and packaging components.

(b) (4)

(b) (4)

DATE(S) OF SUBMISSION(S)

Original submission: May 7, 2008

Amendment: June 5, 2008

NONPROPRIETARY NAME

(See Attached List)

DOSAGE FORM

(See Attached List)

POTENCY

(See Attached List)

Rx or OTC

(See Attached List)

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 cGMPs.
- A full description of the testing to be performed by the testing lab.

ESTABLISHMENT INSPECTION

Acceptable on June 10, 2008

REMARKS AND CONCLUSION

The supplements are approvable

PROJECT MANAGER:

Rosalyn Adigun

DATE COMPLETED:

July 18, 2008

Attachment 1: List of supplemental applications

76-587/S001; S002	Alclometasone Dipropionate Cream USP, 0.05%
74-799/S006; S007	Fluocinonide Topical Solution USP, 0.05%
74-935/S008; S009	Fluocinonide Gel USP, 0.05%
75-008/S007; S008	Fluocinonide Ointment USP, 0.05%.
72-494/S009; S010	Fluocinonide Cream USP, 0.05% (Emulsified base)
74-249/S020; S021	Clobetasol Propionate Cream USP, 0.05%
40-040/S008; S009	Triamcinolone Acetonide Ointment USP, 0.025%
73-210/S021; S022	Desoximetasone Cream USP, 0.05%
40-037/S010; S011	Triamcinolone Acetonide Ointment USP, 0.1%
70-730/S017; S018	Triamcinolone Acetonide Dental Paste, USP, 0.1%
40-039/S007; S008	Triamcinolone Acetonide Cream USP, 0.1%
40-038/S007; S008	Triamcinolone Acetonide Cream, USP, 0.025%
77-511/S003; S004	Terbinafine Hydrochloride Cream, 1%
73-193/S028; S029	Desoximetasone Cream USP, 0.25%
63-305/S015; S016	Nystatin and Triamcinolone Acetonide Ointment USP, 100,000 u/g and 1 mg/g
62-364/S018; S019	Nystatin and Triamcinolone Acetonide Cream, USP
73-548/S020; S021	Desonide Cream, 0.05%
76-493/S002; S003	Clotrimazole and Betamethasone Dipropionate Lotion, 1%/0.05% (base)
75-224/S006; S007	Clobetasol Propionate Solution USP, 0.05%
75-279/S007; S008	Clobetasol Propionate Gel USP, 0.05%
74-248/S018; S019	Clobetasol Propionate Ointment USP, 0.05%
64-022/S008; S009	Nystatin Cream, USP 100,000 units/g

72-640/S032; S033	Clotrimazole Cream USP, 1%
19-117/S029; S030	Fluocinonide Cream USP, 0.05%
75-043/S009; S010	Hydrocortisone Valerate Ointment USP, 0.2%
75-042/S009; S010	Hydrocortisone Valerate Cream USP, 0.2%
74-580/S009; S010	Clotrimazole Topical Solution USP, 1%
72-641/S023; S024	Clotrimazole Vaginal Cream USP, 1%
88-759/S025; S026	Hydrocortisone 1% and Acetic Acid 2% Otic Solution USP.
40-247/S006; S007	Hydrocortisone Lotion USP, 2.5%
74-444/S013; S014	Miconazole Nitrate Vaginal Cream 2%
75-633/S004; S005	Clobetasol Propionate Cream USP, 0.05% (Emollient)
86-724/S022; S023	Lidocaine Ointment USP, 5%
77-227/S004; S005	Halobetasol Propionate Cream, 0.05%
76-994/S004; S005	Halobetasol Propionate Ointment, 0.05%
86-155/S046; S047	Hydrocortisone Cream USP, 1%
88-799/S038; S039	Hydrocortisone Cream USP, 2.5%
65-170/S001; S002	Mupirocin Ointment USP, 2%
77-092/S001; S002	Ciclopirox Topical Suspension USP, 0.77% (Lotion)
76-624/S003; S004	Mometasone Furoate Ointment USP, 0.1%.
76-788/S001; S002	Mometasone Furoate Topical Solution USP, 0.1% (Lotion)
76-679/S003; S004	Mometasone Furoate Cream USP, 0.1%
76-773/S002; S003	Miconazole Nitrate Vaginal Cream, 4%
76-790/S001; S002	Ciclopirox Olamine Cream USP, 0.77%
72-041/S016; S017	Betamethasone Valerate Cream USP, 0.1%

76-543/S003; S004	Betamethasone Dipropionate Cream USP, 0.05% (base) (Augmented)
76-508/S003; S004	Betamethasone Dipropionate Gel (Augmented), 0.05% (base)
74-272/S003; S004	Betamethasone Dipropionate Lotion, 0.005%
74-271/S005; S006	Betamethasone Dipropionate Ointment, 0.005%
73-552/S006; S007	Betamethasone Dipropionate Cream, 0.05%
76-216/S002; S003	Ammonium Lactate Lotion, 12% (base)
75-883/S004; S005	Ammonium Lactate Cream, 12% (base)
40-041/S007; S008	Fluocinolone Acetonide Ointment USP, 0.025%
40-042/S003; S004	Fluocinolone Acetonide Cream USP, 0.025%
40-035/S003; S004	Fluocinolone Acetonide Cream USP, 0.01%
75-331/S007; S008	Diflorasone Diacetate Ointment USP, 0.05%
75-508/S005; S006	Diflorasone Diacetate Cream USP, 0.05%
74-254/S005; S006	Desonide Ointment, 0.05%.
74-286/S012; S013	Desoximetasone Ointment USP, 0.25%
74-904/S012; S013	Desoximetasone Gel USP, 0.05%

cc: (See Attached List)
Division File
Field Copy

Endorsements:

HFD-617/PM

HFD-620/TL

V:\Chemistry Division \Team 3\FIRMSNZ\TAROLTRS&RVS\76-587.GSS07MAY08.RV1.DOC

F/T by /RAD

TYPE OF LETTER: APPROVABLE

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Rosalyn Adigun
7/25/2008 01:23:55 PM
CSO

James Fan
7/25/2008 05:49:07 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 074286/S-012 and S-013

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

May 7, 2008

ARCHIVAL COPY

NDA NO. 74286 REF NO. SCB-01241
NDA SUPPL. FOR _____



Taro Pharmaceuticals U.S.A., Inc.

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

NDA NO. 74286 REF NO. SCB-013AT
NDA SUPPL. FOR _____

RE: **CBE-30 - Alternate Testing Sites:**
and _____

(b) (4)

(b) (4)

Alclometasone Dipropionate Cream USP, 0.05%	ANDA 76-587
Ammonium Lactate Cream, 12%	ANDA 75-883
Ammonium Lactate Lotion, 12% (base)	ANDA 76-216
Betamethasone Dipropionate Cream USP, 0.05%	ANDA 73-552
Betamethasone Dipropionate Ointment 0.05%	ANDA 74-271
Betamethasone Dipropionate Lotion USP, 0.05%	ANDA 74-272
Betamethasone Dipropionate Gel, 0.05% (Augmented)	ANDA 76-508
Betamethasone Dipropionate Cream USP, 0.05% (Augmented)	ANDA 76-543
Betamethasone Valerate Cream USP, 0.1%	ANDA 72-041
Ciclopirox Olamine Cream, 0.77%	ANDA 76-790
Ciclopirox Olamine Topical Solution, 0.77%	ANDA 77-092
Clobetasol Propionate Cream USP, 0.05%	ANDA 74-249
Clobetasol Propionate Cream USP, 0.05% (Emmolient)	ANDA 75-633
Clobetasol Priopionate Ointment USP, 0.05%	ANDA 74-248
Clobetasol Propionate Gel USP, 0.05%	ANDA 75-279
Clobetasol Propionate Solution USP, 0.05%	ANDA 75-224
Clotrimazole Cream USP, 1%	ANDA 72-640
Clotrimazole Topical Solution USP, 1%	ANDA 74-580
Clotrimazole Vaginal Cream USP, 1%	ANDA 72-641
Clotrimazole/Betamethasone Dipropionate Lotion, 1%/0.05% (base)	ANDA 76-493
Desonide Cream 0.05%	ANDA 73-548
Desonide Ointment, 0.05%	ANDA 74-254
Desoximetasone Cream USP, 0.05%	ANDA 73-210
Desoximetasone Cream USP, 0.25%	ANDA 73-193
Desoximetasone Ointment USP, 0.25%	ANDA 74-286
Desoximetasone Gel USP, 0.05%	ANDA 74-904
Diflorasone Diacetate Cream USP, 0.05%	ANDA 75-508
Diflorasone Diacetate Ointment USP, 0.05%	ANDA 75-331
Fluocinolone Acetonide Cream USP, 0.01%	ANDA 40-035
Fluocinolone Acetonide Cream USP, 0.025%	ANDA 40-042

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OGD

Fluocinolone Acetonide Ointment USP, 0.025%	ANDA 40-041
Fluocinonide Cream USP, 0.05%	ANDA 19-117
Fluocinonide Cream USP, 0.05% (Emulsified Base)	ANDA 72-494
Fluocinonide Ointment USP, 0.05%	ANDA 75-008
Fluocinonide Gel USP, 0.05%	ANDA 74-935
Fluocinonide Topical Solution USP, 0.05%	ANDA 74-799
Halobetasol Propionate Cream USP, 0.05%	ANDA 77-227
Halobetasol Propionate Ointment USP, 0.05%	ANDA 76-994
Hydrocortisone Cream USP, 1%	ANDA 86-155
Hydrocortisone Cream USP, 2.5%	ANDA 88-799
Hydrocortisone Lotion USP, 2.5%	ANDA 40-247
Hydrocortisone/Acetic Acid Otic Solution USP, 1%/2%	ANDA 88-759
Hydrocortisone Valerate Cream USP, 0.2%	ANDA 75-042
Hydrocortisone Valerate Ointment USP, 0.2%	ANDA 75-043
Lidocaine Ointment USP, 5%	ANDA 86-724
Miconazole Nitrate Vaginal Cream, 2%	ANDA 74-444
Miconazole Nitrate Vaginal Cream, 4%	ANDA 76-773
Mometasone Furoate Cream USP, 0.1%	ANDA 76-679
Mometasone Furoate Ointment USP, 0.1%	ANDA 76-624
Mometasone Furoate Topical Solution USP, 0.1%	ANDA 76-788
Mupirocin Ointment, 2%	ANDA 65-170
Nystatin Cream USP, 100,000 U/g	AADA 64-022
Nystatin/Triamcinolone Acetonide Cream USP, 100,000 U/g/0.1%	AADA 62-364
Nystatin/Triamcinolone Acetonide Ointment USP, 100,000 U/g/0.1%	AADA 63-305
Terbinafine HCl Cream, 1%	ANDA 77-511
Triamcinolone Acetonide Cream USP, 0.1%	ANDA 40-039
Triamcinolone Acetonide Cream USP, 0.025%	ANDA 40-038
Triamcinolone Acetonide Dental Paste USP, 0.1%	ANDA 70-730
Triamcinolone Acetonide Ointment USP, 0.1%	ANDA 40-037
Triamcinolone Acetonide Ointment USP, 0.025%	ANDA 40-040

Dear Sir/Madam,

Reference is made to the approved ANDAs listed above, and to all subsequent supplements and annual reports for these products.

Pursuant to 21CFR 314.70(c) and *Changes to an Approved NDA or ANDA*, Section VI.C.1.d, Taro Pharmaceuticals U.S.A., Inc. is supplementing the above referenced ANDAs to provide for alternate testing sites: (b) (4), (b) (4), and (b) (4).

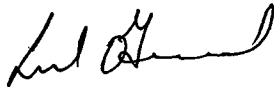
All analytical testing, where possible with respect to availability of equipment, is performed by Taro Pharmaceuticals Inc. (Taro). In the event that Taro would be unable to perform any necessary test, we propose to use the above mentioned contract testing laboratories in addition to the contract laboratories approved in the respective ANDAs.

The proposed site change meets all the criteria established for a CBE-30 submission: (1) the test procedures approved in the application or procedures that have been implemented via an annual report are used, (2) all postapproval commitments made by Taro relating to the test procedures have been fulfilled, and (3) the new testing facilities have the capability to perform the intended testing. The proposed testing facilities have a satisfactory current good manufacturing practice (cGMP) inspection within the past 2 years. (b) (4) was inspected by FDA in (b) (4), and (b) (4) site last FDA audit was in (b) (4).

In support of this supplement, cGMP Certificate and GDEA Certificate from both (b) (4) and (b) (4) are provided.

If there are any questions with regards to this supplement, please do not hesitate to contact the undersigned at (914) 345-9001, ext. 6160.

Sincerely,



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

(b) (6)

cc. FDA, Office of International Programs

May 7, 2008

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



Taro Pharmaceuticals U.S.A., Inc.

Attn: FDA, Office of International Programs

RE: CBE-30 - Alternate Testing Sites:
and

(b) (4)

Alclometasone Dipropionate Cream USP, 0.05%	ANDA 76-587
Ammonium Lactate Cream, 12%	ANDA 75-883
Ammonium Lactate Lotion, 12% (base)	ANDA 76-216
Betamethasone Dipropionate Cream USP, 0.05%	ANDA 73-552
Betamethasone Dipropionate Ointment 0.05%	ANDA 74-271
Betamethasone Dipropionate Lotion USP, 0.05%	ANDA 74-272
Betamethasone Dipropionate Gel, 0.05% (Augmented)	ANDA 76-508
Betamethasone Dipropionate Cream USP, 0.05% (Augmented)	ANDA 76-543
Betamethasone Valerate Cream USP, 0.1%	ANDA 72-041
Ciclopirox Olamine Cream, 0.77%	ANDA 76-790
Ciclopirox Olamine Topical Solution, 0.77%	ANDA 77-092
Clobetasol Propionate Cream USP, 0.05%	ANDA 74-249
Clobetasol Propionate Cream USP, 0.05% (Emmolient)	ANDA 75-633
Clobetasol Priopionate Ointment USP, 0.05%	ANDA 74-248
Clobetasol Propionate Gel USP, 0.05%	ANDA 75-279
Clobetasol Propionate Solution USP, 0.05%	ANDA 75-224
Clotrimazole Cream USP, 1%	ANDA 72-640
Clotrimazole Topical Solution USP, 1%	ANDA 74-580
Clotrimazole Vaginal Cream USP, 1%	ANDA 72-641
Clotrimazole/Betamethasone Dipropionate Lotion, 1%/0.05% (base)	ANDA 76-493
Desonide Cream 0.05%	ANDA 73-548
Desonide Ointment, 0.05%	ANDA 74-254
Desoximetasone Cream USP, 0.05%	ANDA 73-210
Desoximetasone Cream USP, 0.25%	ANDA 73-193
Desoximetasone Ointment USP, 0.25%	ANDA 74-286
Desoximetasone Gel USP, 0.05%	ANDA 74-904
Difflorasone Diacetate Cream USP, 0.05%	ANDA 75-508
Difflorasone Diacetate Ointment USP, 0.05%	ANDA 75-331
Fluocinolone Acetonide Cream USP, 0.01%	ANDA 40-035
Fluocinolone Acetonide Cream USP, 0.025%	ANDA 40-042

Fluocinolone Acetonide Ointment USP, 0.025%	ANDA 40-041
Fluocinonide Cream USP, 0.05%	ANDA 19-117
Fluocinonide Cream USP, 0.05% (Emulsified Base)	ANDA 72-494
Fluocinonide Ointment USP, 0.05%	ANDA 75-008
Fluocinonide Gel USP, 0.05%	ANDA 74-935
Fluocinonide Topical Solution USP, 0.05%	ANDA 74-799
Halobetasol Propionate Cream USP, 0.05%	ANDA 77-227
Halobetasol Propionate Ointment USP, 0.05%	ANDA 76-994
Hydrocortisone Cream USP, 1%	ANDA 86-155
Hydrocortisone Cream USP, 2.5%	ANDA 88-799
Hydrocortisone Lotion USP, 2.5%	ANDA 40-247
Hydrocortisone/Acetic Acid Otic Solution USP, 1%/2%	ANDA 88-759
Hydrocortisone Valerate Cream USP, 0.2%	ANDA 75-042
Hydrocortisone Valerate Ointment USP, 0.2%	ANDA 75-043
Lidocaine Ointment USP, 5%	ANDA 86-724
Miconazole Nitrate Vaginal Cream, 2%	ANDA 74-444
Miconazole Nitrate Vaginal Cream, 4%	ANDA 76-773
Mometasone Furoate Cream USP, 0.1%	ANDA 76-679
Mometasone Furoate Ointment USP, 0.1%	ANDA 76-624
Mometasone Furoate Topical Solution USP, 0.1%	ANDA 76-788
Mupirocin Ointment, 2%	ANDA 65-170
Nystatin Cream USP, 100,000 U/g	AADA 64-022
Nystatin/Triamcinolone Acetonide Cream USP, 100,000 U/g/0.1%	AADA 62-364
Nystatin/Triamcinolone Acetonide Ointment USP, 100,000 U/g/0.1%	AADA 63-305
Terbinafine HCl Cream, 1%	ANDA 77-511
Triamcinolone Acetonide Cream USP, 0.1%	ANDA 40-039
Triamcinolone Acetonide Cream USP, 0.025%	ANDA 40-038
Triamcinolone Acetonide Dental Paste USP, 0.1%	ANDA 70-730
Triamcinolone Acetonide Ointment USP, 0.1%	ANDA 40-037
Triamcinolone Acetonide Ointment USP, 0.025%	ANDA 40-040

Dear Sir/Madam,

The attached document is being submitted as the field copy for the above application.

As required by 21 CFR 314.94(d)(5), Taro Pharmaceuticals U.S.A., Inc. hereby submits and certifies that the enclosed field copy is a true copy of the technical information provided in the above referenced supplement.

If there are any questions, please do not hesitate to contact the undersigned at (914) 345-9001, ext. 6160.

Sincerely,



for

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

June 5, 2008

Rosalyn Adigun, Project Manager
Office of Generic Drugs
Attention: Document Control Room
Metro Park North II, FDA
7500 Standish Place, Room 150
Rockville, Maryland
20855-2773



Taro Pharmaceuticals U.S.A., Inc.

RECEIVED

JUN 06 2008

OGD

RE: Telephone Amendment to CBE-30 Supplement

Alclometasone Dipropionate Cream USP, 0.05%	ANDA 76-587
Ammonium Lactate Cream, 12%	ANDA 75-883
Ammonium Lactate Lotion, 12% (base)	ANDA 76-216
Betamethasone Dipropionate Cream USP, 0.05%	ANDA 73-552
Betamethasone Dipropionate Ointment 0.05%	ANDA 74-271
Betamethasone Dipropionate Lotion USP, 0.05%	ANDA 74-272
Betamethasone Dipropionate Gel, 0.05% (Augmented)	ANDA 76-508
Betamethasone Dipropionate Cream USP, 0.05% (Augmented)	
Betamethasone Valerate Cream USP, 0.1%	ANDA 76-543
Ciclopirox Olamine Cream, 0.77%	ANDA 72-041
Ciclopirox Olamine Topical Solution, 0.77%	ANDA 76-790
Clobetasol Propionate Cream USP, 0.05%	ANDA 77-092
Clobetasol Propionate Cream USP, 0.05% (Emmolient)	ANDA 74-249
Clobetasol Priopionate Ointment USP, 0.05%	ANDA 75-633
Clobetasol Propionate Gel USP, 0.05%	ANDA 74-248
Clobetasol Propionate Solution USP, 0.05%	ANDA 75-279
Clotrimazole Cream USP, 1%	ANDA 75-224
Clotrimazole Topical Solution USP, 1%	ANDA 72-640
Clotrimazole Vaginal Cream USP, 1%	ANDA 74-580
Clotrimazole/Betamethasone Dipropionate Lotion, 1%/0.05% (base)	ANDA 72-641
Desonide Cream 0.05%	
Desonide Ointment, 0.05%	ANDA 76-493
Desoximetasone Cream USP, 0.05%	ANDA 73-548
Desoximetasone Cream USP, 0.25%	ANDA 74-254
✓ Desoximetasone Ointment USP, 0.25%	ANDA 73-210
Desoximetasone Gel USP, 0.05%	ANDA 73-193
Diflorasone Diacetate Cream USP, 0.05%	ANDA 74-286
Diflorasone Diacetate Ointment USP, 0.05%	ANDA 74-904
Fluocinolone Acetonide Cream USP, 0.01%	ANDA 75-508
Fluocinolone Acetonide Cream USP, 0.025%	ANDA 75-331
Fluocinolone Acetonide Ointment USP, 0.025%	ANDA 40-035
Fluocinonide Cream USP, 0.05%	ANDA 40-042
	ANDA 40-041
	ANDA 19-117

Fluocinonide Cream USP, 0.05% (Emulsified Base)	ANDA 72-494
Fluocinonide Ointment USP, 0.05%	ANDA 75-008
Fluocinonide Gel USP, 0.05%	ANDA 74-935
Fluocinonide Topical Solution USP, 0.05%	ANDA 74-799
Halobetasol Propionate Cream USP, 0.05%	ANDA 77-227
Halobetasol Propionate Ointment USP, 0.05%	ANDA 76-994
Hydrocortisone Cream USP, 1%	ANDA 86-155
Hydrocortisone Cream USP, 2.5%	ANDA 88-799
Hydrocortisone Lotion USP, 2.5%	ANDA 40-247
Hydrocortisone/Acetic Acid Otic Solution USP, 1%/2%	ANDA 88-759
Hydrocortisone Valerate Cream USP, 0.2%	ANDA 75-042
Hydrocortisone Valerate Ointment USP, 0.2%	ANDA 75-043
Lidocaine Ointment USP, 5%	ANDA 86-724
Miconazole Nitrate Vaginal Cream, 2%	ANDA 74-444
Miconazole Nitrate Vaginal Cream, 4%	ANDA 76-773
Mometasone Furoate Cream USP, 0.1%	ANDA 76-679
Mometasone Furoate Ointment USP, 0.1%	ANDA 76-624
Mometasone Furoate Topical Solution USP, 0.1%	ANDA 76-788
Mupirocin Ointment, 2%	ANDA 65-170
Nystatin Cream USP, 100,000 U/g	AADA 64-022
Nystatin/Triamcinolone Acetonide Cream USP, 100,000 U/g/0.1%	AADA 62-364
Nystatin/Triamcinolone Acetonide Ointment USP, 100,000 U/g/0.1%	AADA 63-305
Terbinafine HCl Cream, 1%	ANDA 77-511
Triamcinolone Acetonide Cream USP, 0.1%	ANDA 40-039
Triamcinolone Acetonide Cream USP, 0.025%	ANDA 40-038
Triamcinolone Acetonide Dental Paste USP, 0.1%	ANDA 70-730
Triamcinolone Acetonide Ointment USP, 0.1%	ANDA 40-037
Triamcinolone Acetonide Ointment USP, 0.025%	ANDA 40-040

Dear Ms. Adigun,

Taro Pharmaceuticals U.S.A. Inc. hereby submits an Amendment to CBE-30 Supplement:
 Alternate Testing Sites: (b) (4) and (b) (4)
 (b) (4) dated May 7, 2008 in response to Telephone communication on May 16, 2008 and
 June 2, 2008 in which the following comment was communicated:

Comment 1:

Please explicitly state the type of testing performed by the testing laboratories.

Response 1:

Taro proposes to use (b) (4) and (b) (4) for testing of drug substances, excipients, finished products and packaging components, in addition to the contract laboratories approved in the respective ANDAs.

This concludes our Telephone Amendment. If there are any questions with regards to this amendment, please do not hesitate to contact the undersigned at (914) 345-9001, ext. 6160.

Sincerely,



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

(b) (6)

cc. FDA, Office of International Programs

June 5, 2008

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

NDA SUPPL AMENDMENT
508-018-AC
508-013-AC



Taro Pharmaceuticals U.S.A., Inc.

RECEIVED

JUN 06 2008

Attn: FDA, Office of International Programs

RE: Telephone Amendment to CBE-30

OGD

Alclometasone Dipropionate Cream USP, 0.05%	ANDA 76-587
Ammonium Lactate Cream, 12%	ANDA 75-883
Ammonium Lactate Lotion, 12% (base)	ANDA 76-216
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Betamethasone Dipropionate Gel, 0.05% (Augmented)	ANDA 76-508
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Diflorasone Diacetate Ointment USP, 0.05%	ANDA 75-331
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Triamcinolone Acetonide Ointment USP, 0.1%	ANDA 40-037
Triamcinolone Acetonide Ointment USP, 0.025%	ANDA 40-040

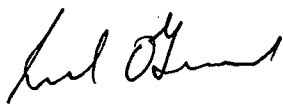
Dear Sir/Madam,

The attached document is being submitted as the field copy for the above application.

As required by 21 CFR 314.94(d)(5), Taro Pharmaceuticals U.S.A., Inc. hereby submits and certifies that the enclosed field copy is a true copy of the technical information provided in the above referenced Telephone Amendment.

If there are any questions, please do not hesitate to contact the undersigned at (914) 345-9001, ext. 6160.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kavita Srivastava', written in a cursive style.

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

CBE Routing Form

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

I. To be completed:

LETTER DATE: May 7, 2008

APPLICATION: (See Attached List) SUPPLEMENT(S): (See Attached List)

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	CBE-30	SELECT CBE TYPE
Endorsement: R.A, June 9, 2008 see below sec. 4 & 5	Endorsement: J.F, June 10, 2008 see below sec. 4 & 5	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:
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:

CTL for testing drug substance and drug product

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: June 10, 2008

Global Supplement By Family

Document: N 076587 SCB 001 07-MAY-08

Global Status/Date: GS 09-JUN-08

Sponsor Applicant: TARO PHARMS (US)

Established Drug Name: ALCLOMETASONE DIPROPIONATE

Dosage: CRM

Strength: 0.05%

Team: 3

Reviewer: RANDOM 3

Member Supplements of Global Supplement Family

<u>Document</u>	<u>Letter Date</u>	<u>Established Drug Name</u>	<u>Strength</u>	<u>Reviewer</u>
N 074799 SCB006	07-MAY-08	FLUOCINONIDE	0.05% TOPICAL	NASHED NASHED
N 074799 SCB007	07-MAY-08	FLUOCINONIDE	0.05% TOPICAL	NASHED NASHED
N 076587 SCB001	07-MAY-08	ALCLOMETASONE DIPROPIONATE	0.05%	RANDOM 3
N 076587 SCB002	07-MAY-08	ALCLOMETASONE DIPROPIONATE	0.05%	RANDOM 3
N 074935 SCB008	07-MAY-08	FLUOCINONIDE	0.05 %	RANDOM 3
N 074935 SCB009	07-MAY-08	FLUOCINONIDE	0.05 %	RANDOM 3
N 075008 SCB007	07-MAY-08	FLUOCINONIDE	0.05%	RANDOM 3
N 075008 SCB008	07-MAY-08	FLUOCINONIDE	0.05%	RANDOM 3
N 072494 SCB009	07-MAY-08	FLUOCINONIDE	0.05%	RANDOM 3
N 072494 SCB010	07-MAY-08	FLUOCINONIDE	0.05%	RANDOM 3
N 074249 SCB020	07-MAY-08	CLOBETASOL PROPIONATE	0.05%	HUANG LIANG LII
N 040040 SCB008	07-MAY-08	TRIAMCINOLONE ACETONIDE	0.025%	NASHED NASHED
N 073210 SCB021	07-MAY-08	DESOXIMETASONE	0.05%	SHARADENDU ANUR
N 040040 SCB009	07-MAY-08	TRIAMCINOLONE ACETONIDE	0.025%	NASHED NASHED
N 040037 SCB011	07-MAY-08	TRIAMCINOLONE ACETONIDE	0.1%	NASHED NASHED
N 070730 SCB017	07-MAY-08	TRIAMCINOLONE ACETONIDE		KANG GIL JONG
N 070730 SCB018	07-MAY-08	TRIAMCINOLONE ACETONIDE		KANG GIL JONG
N 040038 SCB007	07-MAY-08	TRIAMCINOLONE ACETONIDE	0.025%	WETZEL JOSEPH
N 040039 SCB007	07-MAY-08	TRIAMCINOLONE ACETONIDE	0.1%	NASHED NASHED
N 040039 SCB008	07-MAY-08	TRIAMCINOLONE ACETONIDE	0.1%	NASHED NASHED
N 073210 SCB022	07-MAY-08	DESOXIMETASONE	0.05%	SHARADENDU ANUR
N 077511 SCB003	07-MAY-08	TERBINAFINE HYDROCHLORIDE	10 MG/G (1%)	WOODLAND OUTLAW
N 077511 SCB004	07-MAY-08	TERBINAFINE HYDROCHLORIDE	10 MG/G (1%)	WOODLAND OUTLAW
N 073193 SCB028	07-MAY-08	DESOXIMETASONE	0.25%	SHARADENDU ANUR
N 073193 SCB029	07-MAY-08	DESOXIMETASONE	0.25%	SHARADENDU ANUR
N 063305 SCB016	07-MAY-08	NYSTATIN;TRIAMCINOLONE ACETONIDE	100,000 U/G	SHAIKH MUJAHID

Global Supplement By Family

<u>Document</u>	<u>Letter</u>	<u>Date</u>	<u>Established Drug Name</u>	<u>Strength</u>	<u>Reviewer</u>
N 062364	SCB018	07-MAY-08	NYSTATIN;TRIAMCINOLONE ACETONIDE	100,000U/0.1%	SHAIKH MUJAHID
N 062364	SCB019	07-MAY-08	NYSTATIN;TRIAMCINOLONE ACETONIDE	100,000U/0.1%	SHAIKH MUJAHID
N 073548	SCB020	07-MAY-08	DESONIDE	0.05%	HUANG LIANG LIH
N 073548	SCB021	07-MAY-08	DESONIDE	0.05%	HUANG LIANG LIH
N 076493	SCB002	07-MAY-08	CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE	1%/0.05%	NASHED NASHED
N 076493	SCB003	07-MAY-08	CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE	1%/0.05%	NASHED NASHED
N 075224	SCB006	07-MAY-08	CLOBETASOL PROPIONATE	0.05%	SHARADENDU ANUR
N 075224	SCB007	07-MAY-08	CLOBETASOL PROPIONATE	0.05%	SHARADENDU ANUR
N 075279	SCB007	07-MAY-08	CLOBETASOL PROPIONATE	0.05%	HUANG LIANG LIH
N 075279	SCB008	07-MAY-08	CLOBETASOL PROPIONATE	0.05%	HUANG LIANG LIH
N 074248	SCB019	07-MAY-08	CLOBETASOL PROPIONATE	0.05%	RANDOM 3
N 064022	SCB008	07-MAY-08	NYSTATIN	100,000UNITS/G	KIM ERIN
N 072640	SCB032	07-MAY-08	CLOTRIMAZOLE	1%	MURALI RAMAN
N 072640	SCB033	07-MAY-08	CLOTRIMAZOLE	1%	MURALI RAMAN
N 019117	SCB029	07-MAY-08	FLUOCINONIDE	0.05%	WETZEL JOSEPH
N 019117	SCB030	07-MAY-08	FLUOCINONIDE	0.05%	WETZEL JOSEPH
N 075043	SCB009	07-MAY-08	HYDROCORTISONE VALERATE	0.2 %	MURALI RAMAN
N 075042	SCB009	07-MAY-08	HYDROCORTISONE VALERATE	0.2 %	MURALI RAMAN
N 075042	SCB010	07-MAY-08	HYDROCORTISONE VALERATE	0.2 %	MURALI RAMAN
N 074580	SCB009	07-MAY-08	CLOTRIMAZOLE	1% TOPICAL	MURALI RAMAN
N 074580	SCB010	07-MAY-08	CLOTRIMAZOLE	1% TOPICAL	MURALI RAMAN
N 072641	SCB023	07-MAY-08	CLOTRIMAZOLE	1%	MURALI RAMAN
N 072641	SCB024	07-MAY-08	CLOTRIMAZOLE	1%	MURALI RAMAN
N 088759	SCB026	07-MAY-08	HYDROCORTISONE;ACETIC ACID	2%	FARAHANI MAHNAZ
N 040247	SCB006	07-MAY-08	HYDROCORTISONE	2.5%	RANDOM 3
N 040247	SCB007	07-MAY-08	HYDROCORTISONE	2.5%	RANDOM 3
N 074444	SCB013	07-MAY-08	MICONAZOLE NITRATE	2 % VAGINAL	RANDOM 3
N 074444	SCB014	07-MAY-08	MICONAZOLE NITRATE	2 % VAGINAL	RANDOM 3
N 075633	SCB004	07-MAY-08	CLOBETASOL PROPIONATE	0.05% EMOLLIENT	HUANG LIANG LIH
N 086724	SCB022	07-MAY-08	LIDOCAINE	5%	PATANKAR SUHAS
N 086724	SCB023	07-MAY-08	LIDOCAINE	5%	PATANKAR SUHAS
N 075633	SCB005	07-MAY-08	CLOBETASOL PROPIONATE	0.05% EMOLLIENT	HUANG LIANG LIH

Global Supplement By Family

<u>Document</u>	<u>Letter</u>	<u>Date</u>	<u>Established Drug Name</u>	<u>Strength</u>	<u>Reviewer</u>
N 077227	SCB004	07-MAY-08	HALOBETASOL PROPIONATE	0.05%	RANDOM 3
N 077227	SCB005	07-MAY-08	HALOBETASOL PROPIONATE	0.05%	RANDOM 3
N 076994	SCB004	07-MAY-08	HALOBETASOL PROPIONATE	0.05%	RANDOM 3
N 086155	SCB046	07-MAY-08	HYDROCORTISONE	1%	RANDOM 3
N 086155	SCB047	07-MAY-08	HYDROCORTISONE	1%	RANDOM 3
N 088799	SCB038	07-MAY-08	HYDROCORTISONE	2.5%	RANDOM 3
N 088799	SCB039	07-MAY-08	HYDROCORTISONE	2.5%	RANDOM 3
N 065170	SCB001	07-MAY-08	MUPIROCIN	2%	HUSSAIN LATIFF
N 077092	SCB001	07-MAY-08	CICLOPIROX OLAMINE	0.77% (AS CICLOPIROX)	NASHED NASHED
N 065170	SCB002	07-MAY-08	MUPIROCIN	2%	HUSSAIN LATIFF
N 076624	SCB003	07-MAY-08	MOMETASONE FUROATE	0.1%	HUANG LIANG LII
N 077092	SCB002	07-MAY-08	CICLOPIROX OLAMINE	0.77% (AS CICLOPIROX)	NASHED NASHED
N 076788	SCB001	07-MAY-08	MOMETASONE FUROATE	0.1%	HUANG LIANG LII
N 076788	SCB002	07-MAY-08	MOMETASONE FUROATE	0.1%	HUANG LIANG LII
N 076679	SCB003	07-MAY-08	MOMETASONE FUROATE	0.1%	SHARADENDU ANUR
N 076679	SCB004	07-MAY-08	MOMETASONE FUROATE	0.1%	SHARADENDU ANUR
N 076773	SCB003	07-MAY-08	MICONAZOLE NITRATE	4%	RANDOM 3
N 076790	SCB001	07-MAY-08	CICLOPIROX OLAMINE	0.77% (AS CICLOPIROX)	RANDOM 3
N 076790	SCB002	07-MAY-08	CICLOPIROX OLAMINE	0.77% (AS CICLOPIROX)	RANDOM 3
N 072041	SCB016	07-MAY-08	BETAMETHASONE VALERATE	0.1%	RANDOM 3
N 072041	SCB017	07-MAY-08	BETAMETHASONE VALERATE	0.1%	RANDOM 3
N 076543	SCB003	07-MAY-08	BETAMETHASONE DIPROPIONATE	0.05%	SHARADENDU ANUR
N 076543	SCB004	07-MAY-08	BETAMETHASONE DIPROPIONATE	0.05%	SHARADENDU ANUR
N 076508	SCB003	07-MAY-08	BETAMETHASONE DIPROPIONATE	0.05%	NASHED NASHED
N 076508	SCB004	07-MAY-08	BETAMETHASONE DIPROPIONATE	0.05%	NASHED NASHED
N 074272	SCB003	07-MAY-08	BETAMETHASONE DIPROPIONATE	0.05%	HUANG LIANG LII
N 074272	SCB004	07-MAY-08	BETAMETHASONE DIPROPIONATE	0.05%	HUANG LIANG LII
N 074271	SCB005	07-MAY-08	BETAMETHASONE DIPROPIONATE	0.05%	HUANG LIANG LII
N 074271	SCB006	07-MAY-08	BETAMETHASONE DIPROPIONATE	0.05%	HUANG LIANG LII
N 073552	SCB006	07-MAY-08	BETAMETHASONE DIPROPIONATE	0.05%	RANDOM 3

Global Supplement By Family

<u>Document</u>	<u>Letter</u>	<u>Date</u>	<u>Established Drug Name</u>	<u>Strength</u>	<u>Reviewer</u>
N 073552	SCB007	07-MAY-08	BETAMETHASONE DIPROPIONATE	0.05%	RANDOM 3
N 076216	SCB002	07-MAY-08	AMMONIUM LACTATE	12%	NASHED NASHED
N 076216	SCB003	07-MAY-08	AMMONIUM LACTATE	12%	NASHED NASHED
N 075883	SCB004	07-MAY-08	AMMONIUM LACTATE	12%	NASHED NASHED
N 075883	SCB005	07-MAY-08	AMMONIUM LACTATE	12%	NASHED NASHED
N 040041	SCB007	07-MAY-08	FLUOCINOLONE ACETONIDE	0.025%	HUANG LIANG LII
N 040041	SCB008	07-MAY-08	FLUOCINOLONE ACETONIDE	0.025%	HUANG LIANG LII
N 040042	SCB003	07-MAY-08	FLUOCINOLONE ACETONIDE	0.025%	HUANG LIANG LII
N 040042	SCB004	07-MAY-08	FLUOCINOLONE ACETONIDE	0.025%	HUANG LIANG LII
N 040035	SCB003	07-MAY-08	FLUOCINOLONE ACETONIDE	0.01%	HUANG LIANG LII
N 040035	SCB004	07-MAY-08	FLUOCINOLONE ACETONIDE	0.01%	HUANG LIANG LII
N 075331	SCB007	07-MAY-08	DIFLORASONE DIACETATE	0.05%	RANDOM 3
N 075331	SCB008	07-MAY-08	DIFLORASONE DIACETATE	0.05%	RANDOM 3
N 075508	SCB005	07-MAY-08	DIFLORASONE DIACETATE	0.05%	RANDOM 3
N 075508	SCB006	07-MAY-08	DIFLORASONE DIACETATE	0.05%	RANDOM 3
N 074254	SCB005	07-MAY-08	DESONIDE	0.05%	HUANG LIANG LII
N 074254	SCB006	07-MAY-08	DESONIDE	0.05%	HUANG LIANG LII
N 074286	SCB012	07-MAY-08	DESOXIMETASONE	0.25%	HUANG LIANG LII
N 074286	SCB013	07-MAY-08	DESOXIMETASONE	0.25%	HUANG LIANG LII
N 074904	SCB012	07-MAY-08	DESOXIMETASONE	0.05 %	SHARADENDU ANUR
N 074904	SCB013	07-MAY-08	DESOXIMETASONE	0.05 %	SHARADENDU ANUR
N 088759	SCB025	07-MAY-08	HYDROCORTISONE;ACETIC ACID	2%	FARAHANI MAHNAZ
N 075043	SCB010	07-MAY-08	HYDROCORTISONE VALERATE	0.2 %	MURALI RAMAN
N 076773	SCB002	07-MAY-08	MICONAZOLE NITRATE	4%	RANDOM 3
N 076624	SCB004	07-MAY-08	MOMETASONE FUROATE	0.1%	HUANG LIANG LII
N 064022	SCB009	07-MAY-08	NYSTATIN	100,000UNITS/G	KIM ERIN
N 063305	SCB015	07-MAY-08	NYSTATIN;TRIAMCINOLONE ACETONIDE	100,000 U/G	SHAIKH MUJAHID
N 040038	SCB008	07-MAY-08	TRIAMCINOLONE ACETONIDE	0.025%	WETZEL JOSEPH
N 040037	SCB010	07-MAY-08	TRIAMCINOLONE ACETONIDE	0.1%	NASHED NASHED
N 074249	SCB021	07-MAY-08	CLOBETASOL PROPIONATE	0.05%	HUANG LIANG LII
N 074248	SCB018	07-MAY-08	CLOBETASOL PROPIONATE	0.05%	RANDOM 3
N 076994	SCB005	07-MAY-08	HALOBETASOL PROPIONATE	0.05%	RANDOM 3

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/s/

Rosalyn Adigun
7/21/2008 01:50:58 PM