

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Application : ANDA 77511/000

Sponsor: TARO PHARMS (US)

Org Code : 600

5 SKYLINE DR

Priority :

HAWTHORNE, NY 10532

Stamp Date : 03-JAN-2005

Brand Name :

PDUFA Date :  
ORIDE

Estab. Name: TERBINAFINE HYDROCHL

Action Goal :

Generic Name:

District Goal: 03-DEC-2005

Dosage Form: (CREAM)

Strength : 10 MG/G (1%)

FDA Contacts: B. DANSO  
1-827-5849

Project Manager (HFD-617) 30

S. LIU  
1-827-9275

Team Leader (HFD-623) 30

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--Overall Recommendation: -----  
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Establishment : CFN :

FEI :

(b) (4)

DMF No: (b) (4)

AADA:

Responsibilities: DRUG SUBSTANCE MANUFACTURER

Profile : CSN OAI Status: NONE

Last Milestone: SUBMITTED TO OC

Milestone Date: 25-FEB-05

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

(b) (4)

DMF No:

AADA:

Responsibilities: FINISHED DOSAGE OTHER TESTER

Profile : CTL OAI Status: NONE

Last Milestone: SUBMITTED TO OC

Milestone Date: 25-FEB-05

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

(b) (4)

DMF No:

AADA:

Responsibilities:

FINISHED DOSAGE OTHER TESTER

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Profile : CTL OAI Status: NONE  
Last Milestone: SUBMITTED TO OC  
Milestone Date: 25-FEB-05  
:  
:

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Establishment : CFN : 9614240 FEI : 3002808384  
TARO PHARMACEUTICALS INC  
130 EAST DRIVE  
BRAMPTON, ONTARIO, CA

DMF No: AADA:

Responsibilities: FINISHED DOSAGE MANUFACTURER

Profile : OIN OAI Status: NONE  
Last Milestone: SUBMITTED TO OC  
Milestone Date: 25-FEB-05  
:  
:

17511  
TARD

Terbinafine ~~Tablets~~  
Cream

20 JAN 06

Orig strength: 1% (OTC)

Brands (R.D.): Lamisil 20-980

patent/cnts: PIII → '534 exp 12/30/2006

NO unexpired exclusivity

AKK for filing 1/3/2005 (L.O dated 2/25/05)

Labatory Review complete 5/11/05

7/15/05

Strength (Label claim):		(1%) 10 mg/g
Component and Quality Standard	Quantity per unit (mg/g)	%
Terbinafine hydrochloride	10	1.00
Purified water, USP	(b) (4)	(b) (4)
Polysorbate 60, NF		
Cetyl alcohol, NF		
Stearyl alcohol, NF		
Cetyl palmitate, NF		
Isopropyl myristate, NF		
Sorbitan monostearate, NF		
Sodium hydroxide, NF		
Benzyl alcohol, NF		
Total Weight / Volume	1000 mg	100.00

ii) Functions of components:

Component	Intended Functions
Purified water, USP	(b) (4)
Polysorbate 60, NF	(b) (4)
Cetyl alcohol, NF	
Stearyl alcohol, NF	
Cetyl palmitate, NF	
Isopropyl myristate, NF	
Sorbitan monostearate, NF	
Sodium hydroxide, NF	
Benzyl alcohol, NF	

c) Description of accompanying reconstitution diluent(s), if applicable:

Not applicable

d) Type of container closure system used for the dosage form and accompanying reconstitution diluent, if applicable:

The container-closure system is manufactured using commercially available materials, suitable for use in the packaging of semi solid dosage form pharmaceuticals.

## **Inactive Ingredients for ANDA 77-511**

POLYSORBATE 60 (b) (4)

CETYL ALCOHOL (b) (4)

STEARYL  
ALCOHOL (b) (4)

CETYL  
PALMITATE (b) (4)

ISOPROPYL  
MYRISTATE (b) (4)

SORBITAN  
MONOSTEARATE (b) (4)

SODIUM  
HYDROXIDE (b) (4)

BENZYL ALCOHOL (b) (4)

Excipients are acceptable per IIG



Taro Pharmaceuticals U.S.A., Inc.

October 4, 2006

Center for Drug Evaluation and Research  
Central Document Room  
12420 Parklawn Drive  
Room 2-14  
Rockville, Maryland  
U.S.A. 20852

Attention: FDA, Office of International Programs

Ref: **ANDA 77-511**  
**Terbinafine Hydrochloride Cream, 1%**  
**Minor Amendment – Final Approval Requested**

Dear Sir/Madam:

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 Minor Amendment – Final Approval Requested.

If there are any questions in regards to this documentation, please do not hesitate to contact the undersigned at 914-345-9001, Ext. 6298.

Sincerely,

*for* A handwritten signature in cursive script, appearing to read "Kalpana Rao".

Kalpana Rao  
GVP, Regulatory Affairs (Global)  
Taro Pharmaceuticals U.S.A., Inc.

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0338  
Expiration Date: August 31, 2005  
See OMB Statement on page 2.

**APPLICATION TO MARKET A NEW DRUG, BIOLOGIC,  
OR AN ANTIBIOTIC DRUG FOR HUMAN USE**

(Title 21, Code of Federal Regulations, Parts 314 & 601)

FOR FDA USE ONLY

APPLICATION NUMBER

**APPLICANT INFORMATION**

NAME OF APPLICANT Taro Pharmaceuticals U.S.A. Inc.	DATE OF SUBMISSION October 4, 2006
TELEPHONE NO. (Include Area Code) 914-345-9001	FACSIMILE (FAX) Number (Include Area Code) 914-593-0078
APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued): 3 Skyline Drive Hawthorne, N.Y., 10532 USA	AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE N/A

**PRODUCT DESCRIPTION**

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) 77-511		
ESTABLISHED NAME (e.g., Proper name, USP/USAN name) Terbinafine Hydrochloride Cream, 1%		PROPRIETARY NAME (trade name) IF ANY N/A
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If any) (E)-N-(6,6-dimethyl-2-hepten-4-ynyl)-N-methyl-1-naphthalene methanamine hydrochloride		CODE NAME (If any)
DOSAGE FORM: Cream	STRENGTHS: 1% (10 mg/g)	ROUTE OF ADMINISTRATION: Topical
(PROPOSED) INDICATION(S) FOR USE: Treatment of athlete's foot.		

**APPLICATION INFORMATION**

APPLICATION TYPE (check one)			
<input type="checkbox"/> NEW DRUG APPLICATION (21 CFR 314.50)		<input checked="" type="checkbox"/> ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)	
<input type="checkbox"/> BIOLOGICS LICENSE APPLICATION (21 CFR Part 601)			
IF AN NDA, IDENTIFY THE APPROPRIATE TYPE <input type="checkbox"/> 505 (b)(1) <input type="checkbox"/> 505 (b)(2)			
IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION			
Name of Drug <u>Lamisil</u>		Holder of Approved Application <u>Novartis Consumer Health Inc.</u>	
TYPE OF SUBMISSION (check one)			
<input type="checkbox"/> ORIGINAL APPLICATION		<input checked="" type="checkbox"/> AMENDMENT TO PENDING APPLICATION	
<input type="checkbox"/> PRESUBMISSION	<input type="checkbox"/> ANNUAL REPORT	<input type="checkbox"/> ESTABLISHMENT DESCRIPTION SUPPLEMENT	<input type="checkbox"/> EFFICACY SUPPLEMENT
<input type="checkbox"/> LABELING SUPPLEMENT	<input type="checkbox"/> CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT	<input type="checkbox"/> OTHER	
IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: <u>N/A</u>			
IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY <input type="checkbox"/> CBE <input type="checkbox"/> CBE-30 <input type="checkbox"/> Prior Approval (PA)			
REASON FOR SUBMISSION Minor Amendment – Request for Final Approval.			
PROPOSED MARKETING STATUS (check one)			
<input type="checkbox"/> PRESCRIPTION PRODUCT (Rx)		<input checked="" type="checkbox"/> OVER THE COUNTER PRODUCT (OTC)	
NUMBER OF VOLUMES SUBMITTED <u>1</u> THIS APPLICATION IS <input checked="" type="checkbox"/> PAPER <input type="checkbox"/> PAPER AND ELECTRONIC <input type="checkbox"/> ELECTRONIC			

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Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

**Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)**

RECEIVED

OCT 05 2006

OGD / CDER

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<input type="checkbox"/>	8. Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
<input type="checkbox"/>	9. Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
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<input type="checkbox"/>	12. Case report forms (e.g., 21 CFR 314.50 (f)(2); 21 CFR 601.2)
<input type="checkbox"/>	13. Patent information on any patent which claims the drug (21 U.S.C. 355(b) or (c))
<input type="checkbox"/>	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
<input type="checkbox"/>	15. Establishment description (21 CFR Part 600, if applicable)
<input type="checkbox"/>	16. Debarment certification (FD&C Act 306 (k)(1))
<input checked="" type="checkbox"/>	17. Field copy certification (21 CFR 314.50 (l)(3))
<input type="checkbox"/>	18. User Fee Cover Sheet (Form FDA 3397)
<input type="checkbox"/>	19. Financial Information (21 CFR Part 54)
<input checked="" type="checkbox"/>	20. OTHER (Specify) Request for final approval and a revised analytical method.

#### CERTIFICATION

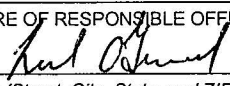
I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act Section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

**Warning:** A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT 	TYPED NAME AND TITLE for Kalpana Rao, G.V.P. Regulatory Affairs (Global)	DATE: Oct 4, 2006
ADDRESS (Street, City, State, and ZIP Code) 3 Skyline Dr. Hawthorne, NY 10532		Telephone Number ( 914 ) 345-9001

**Public reporting burden for this collection of information** is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration  
CDER, HFD-99  
1401 Rockville Pike  
Rockville, MD 20852-1448

Food and Drug Administration  
CDER (HFD-94)  
12229 Wilkins Avenue  
Rockville, MD 20852

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

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APR 02 2007  
U.S. FOOD & DRUG ADMINISTRATION

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CDER, HFD-99  
1401 Rockville Pike  
Rockville, MD 20852-1448

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NUMBER OF VOLUMES SUBMITTED	THIS APPLICATION IS	
1	<input checked="" type="checkbox"/> PAPER <input type="checkbox"/> PAPER AND ELECTRONIC <input type="checkbox"/> ELECTRONIC	
ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.) Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.		

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

RECEIVED

OCT 05 2006

OGD / CDER

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<input type="checkbox"/>	1. Index
<input type="checkbox"/>	2. Labeling (check one) <input type="checkbox"/> Draft Labeling <input type="checkbox"/> Final Printed Labeling
<input type="checkbox"/>	3. Summary (21 CFR 314.50 (c))
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<input type="checkbox"/>	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
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<input type="checkbox"/>	18. User Fee Cover Sheet (Form FDA 3397)
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<input checked="" type="checkbox"/>	20. OTHER (Specify) Request for final approval and a revised analytical method.

#### CERTIFICATION


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SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT 	TYPED NAME AND TITLE for Kalpana Rao, G.V.P. Regulatory Affairs (Global)	DATE: Oct 4, 2006
ADDRESS (Street, City, State, and ZIP Code) 3 Skyline Dr. Hawthorne, NY 10532		Telephone Number ( 914 ) 345-9001

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Department of Health and Human Services  
Food and Drug Administration  
CDER, HFD-99  
1401 Rockville Pike  
Rockville, MD 20852-1448

Food and Drug Administration  
CDER (HFD-94)  
12229 Wilkins Avenue  
Rockville, MD 20852

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

**APPLICATION TO MARKET A NEW DRUG, BIOLOGIC,  
OR AN ANTIBIOTIC DRUG FOR HUMAN USE**

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338  
Expiration Date: August 31, 2005  
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

**APPLICANT INFORMATION**

NAME OF APPLICANT Taro Pharmaceuticals U.S.A. Inc.	DATE OF SUBMISSION August 23, 2005
TELEPHONE NO. (Include Area Code) 914-345-9001	FACSIMILE (FAX) Number (Include Area Code) 914-593-0078
APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued): 3 Skyline Drive Hawthorne, N.Y., 10532 USA	AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE N/A

**PRODUCT DESCRIPTION**

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) 77-511		
ESTABLISHED NAME (e.g., Proper name, USP/USAN name) Terbinafine Hydrochloride Cream, 1%	PROPRIETARY NAME (trade name) IF ANY N/A	
CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If any) (E)-N-(6,6-dimethyl-2-hepten-4-ynyl)-N-methyl-1-naphthalene methanamine hydrochloride	CODE NAME (If any)	
DOSAGE FORM: Cream	STRENGTHS: 10 mg/g (1%)	ROUTE OF ADMINISTRATION: Topical
(PROPOSED) INDICATION(S) FOR USE: Treatment of athlete's foot.		

**APPLICATION INFORMATION**

APPLICATION TYPE (check one)		
<input type="checkbox"/> NEW DRUG APPLICATION (21 CFR 314.50) <input checked="" type="checkbox"/> ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94) <input type="checkbox"/> BIOLOGICS LICENSE APPLICATION (21 CFR Part 601)		
IF AN NDA, IDENTIFY THE APPROPRIATE TYPE <input type="checkbox"/> 505 (b)(1) <input type="checkbox"/> 505 (b)(2)		
IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION		
Name of Drug	Holder of Approved Application	
Lamisil	Novartis Consumer Health Inc.	
TYPE OF SUBMISSION (check one)		
<input type="checkbox"/> ORIGINAL APPLICATION <input checked="" type="checkbox"/> AMENDMENT TO PENDING APPLICATION <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> PRESUBMISSION <input type="checkbox"/> ANNUAL REPORT <input type="checkbox"/> ESTABLISHMENT DESCRIPTION SUPPLEMENT <input type="checkbox"/> EFFICACY SUPPLEMENT <input type="checkbox"/> LABELING SUPPLEMENT <input type="checkbox"/> CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT <input type="checkbox"/> OTHER		
IF A SUBMISSION OF PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION: N/A		
IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY <input type="checkbox"/> CBE <input type="checkbox"/> CBE-30 <input type="checkbox"/> Prior Approval (PA)		
REASON FOR SUBMISSION Response to Minor Amendment dated June 30, 2005		
PROPOSED MARKETING STATUS (check one) <input type="checkbox"/> PRESCRIPTION PRODUCT (Rx) <input checked="" type="checkbox"/> OVER THE COUNTER PRODUCT (OTC)		
NUMBER OF VOLUMES SUBMITTED	THIS APPLICATION IS	
1	<input checked="" type="checkbox"/> PAPER <input type="checkbox"/> PAPER AND ELECTRONIC <input type="checkbox"/> ELECTRONIC	
ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.) Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.		
Man/Pack/Controls: Taro Pharmaceuticals Inc., 130 East Dr., Brampton, ON, Canada (Establishment No. FCCA133); Controls:		
(b) (4)		
Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)		
(b) (4)		

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AUG 24 2005

OGD/CDER

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<input type="checkbox"/>	19. Financial Information (21 CFR Part 54)
<input type="checkbox"/>	20. OTHER (Specify)

#### CERTIFICATION

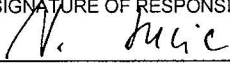
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SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT 	TYPED NAME AND TITLE for Kalpana Rao, V.P. Regulatory Affairs (Global)	DATE: Aug. 23, 2005
ADDRESS (Street, City, State, and ZIP Code) 3 Skyline Dr. Hawthorne, NY 10532		Telephone Number ( 914 ) 345-9001

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1401 Rockville Pike  
Rockville, MD 20852-1448

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FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0338  
Expiration Date: August 31, 2005  
See OMB Statement on page 2.

**APPLICATION TO MARKET A NEW DRUG, BIOLOGIC,  
OR AN ANTIBIOTIC DRUG FOR HUMAN USE**  
(Title 21, Code of Federal Regulations, Parts 314 & 601)

FOR FDA USE ONLY

APPLICATION NUMBER

**APPLICANT INFORMATION**

NAME OF APPLICANT Taro Pharmaceuticals U.S.A., Inc.	DATE OF SUBMISSION May 25, 2005
TELEPHONE NO. (Include Area Code) (914) 345-9001	FACSIMILE (FAX) Number (Include Area Code) (914) 593-0078
APPLICANT ADDRESS (Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued): Taro Pharmaceuticals U.S.A., Inc. 3 Skyline Drive, Hawthorne, NY 10532 (914) 345-9001 phone (914) 593-0078	AUTHORIZED U.S. AGENT NAME & ADDRESS (Number, Street, City, State, ZIP Code, telephone & FAX number) IF APPLICABLE N/A

**PRODUCT DESCRIPTION**

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CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (If any) (E)-N-(6,6-dimethyl-2-hepten-4-ynyl)-N-methyl-1-naphthalene methanamine hydrochloride	CODE NAME (If any) 51672-2080	
DOSAGE FORM: Cream	STRENGTHS: 1%	ROUTE OF ADMINISTRATION: Topical

(PROPOSED) INDICATION(S) FOR USE: Cures most athlete's foot (tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis). Relieves itching, burning, cracking and scaling which accompany these conditions.

**APPLICATION INFORMATION**

APPLICATION TYPE (check one) <input type="checkbox"/> NEW DRUG APPLICATION (21 CFR 314.50) <input checked="" type="checkbox"/> ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94) <input type="checkbox"/> BIOLOGICS LICENSE APPLICATION (21 CFR Part 601)			
IF AN NDA, IDENTIFY THE APPROPRIATE TYPE <input type="checkbox"/> 505 (b)(1) <input type="checkbox"/> 505 (b)(2)			
IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION			
Name of Drug <u>Lamisil® Cream</u>		Holder of Approved Application <u>Novartis</u>	
TYPE OF SUBMISSION (check one) <input type="checkbox"/> PRESUBMISSION <input type="checkbox"/> ANNUAL REPORT <input checked="" type="checkbox"/> AMENDMENT TO APENDING APPLICATION <input type="checkbox"/> RESUBMISSION <input type="checkbox"/> LABELING SUPPLEMENT <input type="checkbox"/> CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT <input type="checkbox"/> EFFICACY SUPPLEMENT <input type="checkbox"/> OTHER			
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REASON FOR SUBMISSION <u>Labeling Response</u>			
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SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT 	TYPED NAME AND TITLE FOR <b>Kalpana Rao</b> Vice President, Regulatory Affairs (Global)	DATE: 05/25/05
ADDRESS (Street, City, State, and ZIP Code) 3 Skyline Drive, Hawthorne, NY 10532		Telephone Number (914) 345-9001

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