

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 Project Manager (HFD-617) 30
1-827-5849
S. LIU Team Leader (HFD-623) 30
1-827-9275

--Overall Recommendation: -----

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

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

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

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
:
:

17-511
TADE

Terbutamine ~~TADE~~
cream

120 Jan 06

Drug strength: 1% (OTC)

Basis (Ref): Latisil 20-980

Patents/refs: PIII → 1534 exp 12/30/2006
No unexpired exclusions

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

Marketing 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 (b) (4)
Purified water, USP		
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	
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,

Kalpana Rao
for *Kalpana Rao*

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

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 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	
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	Lamisil	Holder of Approved Application	
Novartis Consumer Health Inc.			
TYPE OF SUBMISSION (check one)	<input type="checkbox"/> ORIGINAL APPLICATION	<input checked="" type="checkbox"/> AMENDMENT TO APENDING 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 CBE CBE-30 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	1	THIS APPLICATION IS
		<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"/>	2. Labeling (check one) <input type="checkbox"/> Draft Labeling <input type="checkbox"/> Final Printed Labeling
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<input type="checkbox"/>	4. Chemistry section
<input type="checkbox"/>	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
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<input type="checkbox"/>	10. Statistical section (e.g., 21 CFR 314.50(d)(6); 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

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
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DOSAGE FORM: Cream	STRENGTHS: 1% (10 mg/g)	ROUTE OF ADMINISTRATION: Topical

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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.			
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<i>APP 02 2007</i> <i>READY/ORDER</i>			
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CERTIFICATION

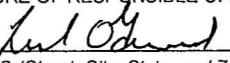
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<input type="checkbox"/>	2. Labeling (check one) <input type="checkbox"/> Draft Labeling <input type="checkbox"/> Final Printed Labeling
<input type="checkbox"/>	3. Summary (21 CFR 314.50 (c))
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<input type="checkbox"/>	A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
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<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

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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	Lamisil	Holder of Approved Application	Novartis Consumer Health Inc.
TYPE OF SUBMISSION (check one)	<input type="checkbox"/> ORIGINAL APPLICATION	<input checked="" type="checkbox"/> AMENDMENT TO APENDING 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 CBE CBE-30 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	1	THIS APPLICATION IS <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"/>	20. OTHER (Specify)

CERTIFICATION

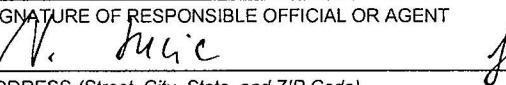
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SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT 	TYPED NAME AND TITLE Kalpana Rao, V.P. Regulatory Affairs (Global)	DATE: Aug. 23, 2005
ADDRESS (Street, City, State, and ZIP Code) 3 Skyline Dr. Hawthorne, NY 10532	Telephone Number (914) 345-9001	

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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 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

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) 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	Lamisil® Cream	Holder of Approved Application	Novartis
TYPE OF SUBMISSION (check one)	<input type="checkbox"/> ORIGINAL APPLICATION	<input checked="" type="checkbox"/> AMENDMENT TO APENDING 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
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IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY			
REASON FOR SUBMISSION	<input type="checkbox"/> CBE	<input type="checkbox"/> CBE-30	<input type="checkbox"/> Prior Approval (PA)
Labeling Response			
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SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT 	TYPED NAME AND TITLE Kalpana Rao 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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