CUSTOpharm, Inc.
Custom Solutions for the Pharmaceutical World

December 28, 2012

Food and Drug Administration
Division of Dockets Management (HFA-305)
Department of Health and Human Services
5630 Fishers Lane,
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam,

The undersigned submits this Citizen Petition pursuant to the Federal Food, Drug and Cosmetic Act ("FD&C Act") and the Food and Drug Administration's ("FDA's") regulations at 21 CFR §§ 10.20, 10.30, and 314.93 to request that FDA amend the Approved Drug Products with Therapeutic Equivalence Evaluations (referred to as the "FDA's Orange Book") to designate generic Clotrimazole Troche/Lozenge, ANDA 076387, held by Roxane as a second reference listed drug ('RLD'). Currently, Mycelex NDA 018713, of Bayer Healthcare is designated as the RLD for Clotrimazole Troche/Lozenge; 10 mg.

A. Action Requested

The undersigned requests that the Commissioner of Food and Drugs designate Roxane's Clotrimazole Troche, ANDA #76387, as a second RLD for the purposes of submitting an ANDA for a generic version of Clotrimazole Troche.

B. State of Grounds

Mycelex Troche/Lozenge 10 mg is assigned as the RLD. There is a sound basis for designating a second RLD. Bayer's Mycelex Troche/Lozenge 10 mg has been unavailable in the US for many months. The orange book currently lists two generic suppliers of Clotrimazole Troche/Lozenge; Paddock and Roxane as demonstrated in Attachment A. Therefore we are requesting that the first approved generic, Roxane's Clotrimazole Troche/Lozenge, be listed as a second RLD.

2325 Camino Vida Roble, Suite A • Carlsbad, CA 92011• tel 760-683.0901 • fax 760-301-0048 • www.custopharm.com

CUSTOpharm, Inc.
Custom Solutions for the Pharmaceutical World

Without such a designation, the product may be shielded from generic competition. Therefore, the Petitioner is hereby requesting that the Roxane product be designated as a second RLD to permit the filing of ANDAs for Clotrimazole Troche/Lozenge.

C. Environmental Impact

The Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 CFR § 25 .31.

D. Economic Impact

Pursuant to 21 CFR § 10.30(b), the Petitioner will, upon request by the Commissioner, submit economic impact information.

E. Certification

The undersigned certifies that to the best of its knowledge, this petition includes all information on which the Petition relies, and that it includes representative data and information known to the Petitioner, that are unfavorable to the Petition.

Respectfully submitted,

Frederik Defesche
President
Tel: (760) 683-0901
Fax: (760) 301-0048
E-mail: fdefesche@custopharm.com

Attachment: FDA's Orange Book for Clotrimazole Troche

ATTACHMENT A

U.S. Food & Drug Administration

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

[1]

FDA Home[2]

Active Ingredient Search Results from "OB_Disc" table for query on "midodrine."

Appl No	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
N019815	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	10MG	PROAMATINE	SHIRE LLC
N019815	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	2.5MG	PROAMATINE	SHIRE LLC
N019815	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	5MG	PROAMATINE	SHIRE LLC

Return to Electronic Orange Book Home Page [4]

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through November, 2012
Patent and Generic Drug Product Data Last Updated: December 27, 2012

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. ../default.cfm

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

- Accessibility
- Contact FDA
- Careers
- FDA Basics
- FOIA
- No Fear Act
- Site Map
- Transparency
- Website Policies

U.S. Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

- [illegible].gov
- [illegible]
- [illegible]
- [illegible]
- [illegible]
- [illegible]
- [illegible]
- For Government
- For Press
- Combination Products
- Advisory Committees
- Science & Research
- Regulatory Information
- Safety
- Emergency Preparedness
- International Programs
- News & Events
- Training and Continuing Education
- Inspections/Compliance
- State & Local Officials
- Consumers
- Industry
- Health Professionals

U.S. Department of Health & Human Services

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. ../default.cfm

U.S. Food & Drug Administration

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

[1]

FDA Home[2] Drug Databases[3] Orange Book[4]

Search results from the "OB_Disc" table for query on "019815."

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	PROAMATINE
Applicant:	SHIRE LLC
Strength:	2.5MG
Application Number:	N019815
Product Number:	001
Approval Date:	Sep 6, 1996
RX/OTC/DISCN:	DISCN
Patent and Exclusivity Info for this product:	View

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	PROAMATINE
Applicant:	SHIRE LLC
Strength:	5MG
Application Number:	N019815
Product Number:	002
Approval Date:	Sep 6, 1996
RX/OTC/DISCN:	DISCN
Patent and Exclusivity Info for this product:	View

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	PROAMATINE
Applicant:	SHIRE LLC
Strength:	10MG
Application Number:	N019815
Product Number:	003
Approval Date:	Mar 20, 2002
RX/OTC/DISCN:	DISCN
Patent and Exclusivity Info for this product:	View

Return to Electronic Orange Book Home Page [6]

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
- Orange Book Data - **Monthly**
- Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through November, 2012
Patent and Generic Drug Product Data Last Updated: December 27, 2012

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
5. ../default.cfm
6. ../default.cfm

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

- Accessibility
- Contact FDA
- Careers
- FDA Basics
- FOIA
- No Fear Act
- Site Map
- Transparency
- Website Policies

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

- USA.gov
-
-
-
-
-
-
- For Government
- For Press
- Combination Products
- Advisory Committees
- Science & Research
- Regulatory Information
- Safety
- Emergency Preparedness
- International Programs
- News & Events
- Training and Continuing Education
- Inspections/Compliance
- State & Local Officials

- Industry
- Health Professionals

U.S. Department of Health & Human Services

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
5. ../default.cfm
6. ../default.cfm

ATTACHMENT B

U.S. Food & Drug Administration

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

[1]

FDA Home[2]

Active Ingredient Search Results from "OB_Rx" table for query on "MIDODRINE HYDROCHLORIDE."

Appl No	TE Code[4]	RLD[5]	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
A077746	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	10MG	MIDODRINE HYDROCHLORIDE	APOTEX INC
A077746	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	2.5MG	MIDODRINE HYDROCHLORIDE	APOTEX INC
A077746	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	5MG	MIDODRINE HYDROCHLORIDE	APOTEX INC
A076449	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	10MG	MIDODRINE HYDROCHLORIDE	IMPAX PHARMS
A076449	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	2.5MG	MIDODRINE HYDROCHLORIDE	IMPAX PHARMS
A076449	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	5MG	MIDODRINE HYDROCHLORIDE	IMPAX PHARMS
A076577	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	10MG	MIDODRINE HYDROCHLORIDE	MYLAN
A076577	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	2.5MG	MIDODRINE HYDROCHLORIDE	MYLAN
A076577	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	5MG	MIDODRINE HYDROCHLORIDE	MYLAN
A076514	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	10MG	MIDODRINE HYDROCHLORIDE	SANDOZ
A076514	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	2.5MG	MIDODRINE HYDROCHLORIDE	SANDOZ
A076514	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	5MG	MIDODRINE HYDROCHLORIDE	SANDOZ
A076725	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	10MG	ORVATEN	UPSHER SMITH
A076725	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	2.5MG	ORVATEN	UPSHER SMITH
A076725	AB	No	MIDODRINE HYDROCHLORIDE	TABLET; ORAL	5MG	ORVATEN	UPSHER SMITH

Return to Electronic Orange Book Home Page [6]

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through November, 2012
Patent and Generic Drug Product Data Last Updated: December 27, 2012

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#Therapeutic Equivalence-Related Terms
5. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#Reference Listed Drug
6. ../default.cfm

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

- Accessibility
- Contact FDA
- Careers
- FDA Basics
- FOIA
- No Fear Act
- Site Map
- Transparency
- Website Policies

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

- USA.gov
-
-
-
-
-
-
- For Government
- For Press
- Combination Products
- Advisory Committees
- Science & Research
- Regulatory Information
- Safety
- Emergency Preparedness

- International Programs
- News & Events
- Training and Continuing Education
- Inspections/Compliance
- State & Local Officials
- Consumers
- Industry
- Health Professionals

U.S. Department of Health & Human Services

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#Therapeutic Equivalence-Related Terms
5. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm#Reference Listed Drug
6. ../default.cfm

U.S. Food & Drug Administration

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

FDA Home[2] Drug Databases[4] Orange Book[5]

Search results from the "OB_Rx" table for query on "076514."

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	MIDODRINE HYDROCHLORIDE
Applicant:	SANDOZ
Strength:	2.5MG
Application Number:	A076514
Product Number:	001
Approval Date:	Sep 11, 2003
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	MIDODRINE HYDROCHLORIDE
Applicant:	SANDOZ
Strength:	5MG
Application Number:	A076514
Product Number:	002
Approval Date:	Sep 11, 2003
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	MIDODRINE HYDROCHLORIDE
Applicant:	SANDOZ
Strength:	10MG
Application Number:	A076514
Product Number:	003
Approval Date:	Jul 2, 2004
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

Return to Electronic Orange Book Home Page [6]

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support

Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through November, 2012
Patent and Generic Drug Product Data Last Updated: December 27, 2012

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
5. ../default.cfm
6. ../default.cfm

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

- Accessibility
- Contact FDA
- Careers
- FDA Basics
- FOIA
- No Fear Act
- Site Map
- Transparency
- Website Policies

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

- USA.gov
-
-
-
-
-
-
- For Government
- For Press

- Combination Products
- Advisory Committees
- Science & Research
- Regulatory Information
- Safety
- Emergency Preparedness

- International Programs
- News & Events
- Training and Continuing Education
- Inspections/Compliance
- State & Local Officials
- Consumers
- Industry
- Health Professionals

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
5. ../default.cfm
6. ../default.cfm

U.S. Food & Drug Administration

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

[1]

FDA Home[2] Drug Databases[3] Orange Book[4]

Search results from the "OB_Rx" table for query on "076449."

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	MIDODRINE HYDROCHLORIDE
Applicant:	IMPAX PHARMS
Strength:	2.5MG
Application Number:	A076449
Product Number:	001
Approval Date:	May 27, 2004
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	MIDODRINE HYDROCHLORIDE
Applicant:	IMPAX PHARMS
Strength:	5MG
Application Number:	A076449
Product Number:	002
Approval Date:	May 27, 2004
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

Active Ingredient:	MIDODRINE HYDROCHLORIDE
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	MIDODRINE HYDROCHLORIDE
Applicant:	IMPAX PHARMS
Strength:	10MG
Application Number:	A076449
Product Number:	003
Approval Date:	Dec 16, 2005
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

Return to Electronic Orange Book Home Page [5]

FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support

Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through November, 2012
Patent and Generic Drug Product Data Last Updated: December 27, 2012

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
5. ../default.cfm
6. ../default.cfm

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

- Accessibility
- Contact FDA
- Careers
- FDA Basics
- FOIA
- No Fear Act
- Site Map
- Transparency
- Website Policies

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

- USA.gov
-
-
-
-
-
-
-
- For Government
- For Press
- Combination Products
- Advisory Committees
- Science & Research
- Regulatory Information
- Safety
- Emergency Preparedness

- News & Events
- Training and Continuing Education
- Inspections/Compliance
- State & Local Officials
- Consumers
- Industry
- Health Professionals

U.S. Department of Health & Human Services

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
5. ../default.cfm
6. ../default.cfm

UPS Internet Shipping: View/Print Label

1. **Ensure there are no other shipping or tracking labels attached to your package.** Select the Print button on the print dialog box that appears. Note: If your browser does not support this function select Print from the File menu to print the label.

2. **Fold the printed sheet containing the label at the line so that the entire shipping label is visible. Place the label on a single side of the package and cover it completely with clear plastic shipping tape. Do not cover any seams or closures on the package with the label.** Place the label in a UPS Shipping Pouch. If you do not have a pouch, affix the folded label using clear plastic shipping tape over the entire label.

3. **GETTING YOUR SHIPMENT TO UPS**
   UPS locations include the UPS Store®, UPS drop boxes, UPS customer centers, authorized retail outlets and UPS drivers.
   Find your closest UPS location at: www.ups.com/dropoff
   Take your package to any location of The UPS Store®, UPS Drop Box, UPS Customer Center, UPS Alliances (Office Depot® or Staples®) or Authorized Shipping Outlet near you. Items sent via UPS Return Services(SM) (including via Ground) are also accepted at Drop Boxes. To find the location nearest you, please visit the 'Find Locations' Quick link at ups.com.

   Customers with a Daily Pickup
   Your driver will pickup your shipment(s) as usual.

FOLD HERE