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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 Impax Pharmaceutical's Midodrine Hydrochloride Tablets, ANDA 076449, as the reference listed drug ('RLD"). Prior to its discontinuation, Proamatine was designated as the RLD for Midodrine Hydrochloride Tablets; 5 mg as NDA 19815 held by Shire LLC. However as noted in the attached Orange Book Reference as Attachment A, Proamatine has been discontinued

A. Action Requested

The undersigned requests that the Commissioner of Food and Drugs designate Impax Pharmaceutical's Midodrine Hydrochloride Tablets, ANDA 076449, as the RLD for the purposes of submitting an ANDA for a generic version of Midodrine Hydrochloride Tablets

B. State of Grounds

Proamatine 5 mg was assigned as the RLD and has since been discontinued. There is a sound basis for designating a new RLD. The orange book currently lists five approved suppliers of Midodrine Hydrochloride Tablets as documented in Attachment B. However, only Sandoz's and Impax's products are currently available in the US. Of the two available suppliers, Impax was the first approved ANDA and therefore we request it be listed as the RLD.

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Without such a designation, the product will be shielded from generic competition. Therefore, the Petitioner is hereby requesting that the Impax product be designated as the RLD to permit the filing of ANDAs for Midodrine Hydrochloride Tablets.

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
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Fax: (760) 301-0048
E-mail: fdefesche@custopharm.com

Attachments

U.S. Food & Drug Administration

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

[1]

FDA Home[2][3]

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

Appl No	TE Code[4]	RLD[5]	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
A076002	AB	No	BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE	CREAM; TOPICAL	EQ 0.05% BASE;1%	CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE	ACTAVIS MID ATLANTIC
A075502	AB	No	BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE	CREAM; TOPICAL	EQ 0.05% BASE;1%	CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE	FOUGERA PHARMS
N018827	AB	Yes	BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE	CREAM; TOPICAL	EQ 0.05% BASE;1%	LOTRISONE	MERCK SHARP DOHME
A075673	AB	No	BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE	CREAM; TOPICAL	EQ 0.05% BASE;1%	CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE	TARO
A076516	AB	No	BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE	LOTION; TOPICAL	EQ 0.05% BASE;1%	CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE	FOUGERA PHARMS
N020010	AB	Yes	BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE	LOTION; TOPICAL	EQ 0.05% BASE;1%	LOTRISONE	SCHERING CORP
A076493	AB	No	BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE	LOTION; TOPICAL	EQ 0.05% BASE;1%	CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE	TARO
A078338	AB	No	CLOTRIMAZOLE	CREAM; TOPICAL	1%	CLOTRIMAZOLE	FOUGERA PHARMS
A090219	AB	No	CLOTRIMAZOLE	CREAM; TOPICAL	1%	CLOTRIMAZOLE	GLENMARK PHARMS
A072640	AB	Yes	CLOTRIMAZOLE	CREAM; TOPICAL	1%	CLOTRIMAZOLE	TARO
N018181	AT	Yes	CLOTRIMAZOLE	SOLUTION; TOPICAL	1%	MYCELEX	BAYER HLTHCARE
A074580	AT	No	CLOTRIMAZOLE	SOLUTION; TOPICAL	1%	CLOTRIMAZOLE	TARO
A073306	AT	No	CLOTRIMAZOLE	SOLUTION; TOPICAL	1%	CLOTRIMAZOLE	TEVA
N018713	AB	Yes	CLOTRIMAZOLE	TROCHE/LOZENGE; ORAL	10MG	MYCELEX	BAYER HLTHCARE
A076763	AB	No	CLOTRIMAZOLE	TROCHE/LOZENGE; ORAL	10MG	CLOTRIMAZOLE	PADDOCK LLC
A076387	AB	No	CLOTRIMAZOLE	TROCHE/LOZENGE; ORAL	10MG	CLOTRIMAZOLE	ROXANE

ATTACHMENT A

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

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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
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U.S Department of **Health & Human Services**

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U.S. Food & Drug Administration

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

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

Search results from the "OB_Rx" table for query on "018713."

Active Ingredient:	CLOTRIMAZOLE
Dosage Form;Route:	TROCHE/LOZENGE; ORAL
Proprietary Name:	MYCELEX
Applicant:	BAYER HLTHCARE
Strength:	10MG
Application Number:	N018713
Product Number:	001
Approval Date:	Jun 17, 1983
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

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Search results from the "OB_Rx" table for query on "076387."

Active Ingredient:	CLOTRIMAZOLE
Dosage Form;Route:	TROCHE/LOZENGE; ORAL
Proprietary Name:	CLOTRIMAZOLE
Applicant:	ROXANE
Strength:	10MG
Application Number:	A076387
Product Number:	001
Approval Date:	Jul 29, 2004
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

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Search results from the "OB_Rx" table for query on "076763."

Active Ingredient:	CLOTRIMAZOLE
Dosage Form;Route:	TROCHE/LOZENGE; ORAL
Proprietary Name:	CLOTRIMAZOLE
Applicant:	PADDOCK LLC
Strength:	10MG
Application Number:	A076763
Product Number:	001
Approval Date:	Oct 28, 2005
Reference Listed Drug	No
RX/OTC/DISCN:	RX
TE Code:	**AB**
Patent and Exclusivity Info for this product:	View

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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.

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   Your driver will pickup your shipment(s) as usual.

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