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January 21, 2013

Food and Drug Administration
Division of Dockets Management (HFA-305)
Department of Health and Human Services
5360 Fishers Lane,
Room 1061
Rockville, MD 20852

**AMENDMENT TO CITIZEN PETITION FDA-2013-P-0028/CP1
FOR CLOTRIMAZOLE TROCHE/LOZENGE**

Dear Sir or Madam,

We are hereby submitting replacement attachment for the attachments previously submitted with the original Citizen's Petition for Clotrimazole Troche/Lozenge submitted on December 28, 2012 and filed on December 31, 2012. We request that you replace these attachments with those previously submitted.

If you have any questions, please do not hesitate to contact me at the information in the signature line below.

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

FDA Home³

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; 10MG ORAL		MYCELEX	BAYER HLTHCARE
A076763 AB	No	CLOTRIMAZOLE	TROCHE/LOZENGE; 10MG ORAL		CLOTRIMAZOLE	PADDOCK LLC
A076387 AB	No	CLOTRIMAZOLE	TROCHE/LOZENGE; 10MG ORAL		CLOTRIMAZOLE	ROXANE

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Division of Labeling and Program Support

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Orange Book Data Updated Through November, 2012

Patent and Generic Drug Product Data Last Updated: December 27, 2012

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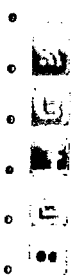
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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

[FDA Home](#)³ [Drug Databases](#)⁴ [Orange Book](#)⁵

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

Active Ingredient:	CLOTTRIMAZOLE
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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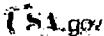
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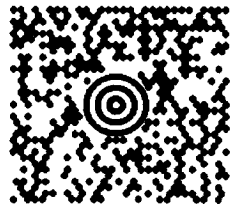
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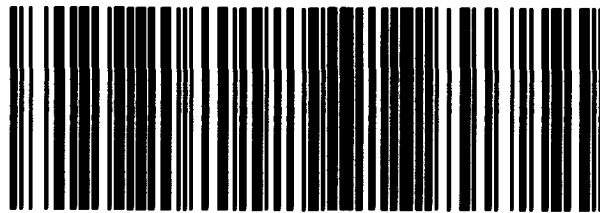
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