Lupin Pharmaceuticals, Inc.

January 2, 2013

2013 JAN -3 A 10:36

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

Citizen Petition

This petition is submitted pursuant to 21 CFR 10.30, and in accordance with the regulations of 21 CFR 314.94 to request the Commissioner of the Food and Drug Administration to amend the "Approved Drug Products with Therapeutic Equivalence Evaluation" list (the "Orange Book"), as outlined below.

A. Action Requested

The petitioner, Lupin Pharmaceuticals, Inc. ("Lupin") requests FDA to amend the "Orange Book" to assign a second reference - listed drug product for Calcium Acetate Capsules.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products, which are eligible for submission as Abbreviated New Drug Applications. That list, referred to as the "Orange Book", contains all the FDA approved drug products.

The current Orange Book does designate PHOSLO® (calcium acetate) Capsules, 667 mg of M/s Fresenium MEDCL (NDA #N021160) as the Reference Listed Drug (RLD). However, it may be noted that to our best of knowledge, the RLD samples are not available in the market since November 2012.

In the current edition of the "Orange Book (relevant pages attached)", there are two other manufacturers listed for Calcium Acetate Capsules namely, M/s Roxane and M/s Paddock LLC. However, out of these two manufacturers only one drug product from manufacturer i.e. M/s Roxane, is currently available in the market.

HARBORPLACE TOWER, 111 SOUTH CALVERT STREET, 21ST FLOOR, BALTIMORE, MD 21202. TEL: 410-576-2000 FAX: 410-576-2221
www.lupinpharmaceuticals.com

FDA-2013-P-0040

2013-70 CP

As the drug product Calcium Acetate Capsules, from M/s Roxane is rated as "AB" in that they are considered to contain effective drug for which "actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence".

The petitioner requests the agency to designate M/s Roxane as the Reference Listed Drug.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis, if requested by the agency.

E. Certification

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

Sincerely,

LESLIE SANDS
Director – Regulatory Affairs (USA)
LUPIN PHARMACEUTICALS, INC.
Harborplace Tower,
111 South Calvert Street, 21st Floor,
Baltimore, Maryland 21202
TEL: 410 576 2000
FAX: 410 576 2221

Enclosures – Relevant Pages of the current edition of the "Orange Book".

Cc: i) Mr. Martin Shimer, Office of Generic Drugs

ii) Mr. William Peter Rickman, Office of Generic Drugs

HARBORPLACE TOWER, 111 SOUTH CALVERT STREET, 21ST FLOOR, BALTIMORE, MD 21202. TEL: 410-576-2000 FAX: 410-576-2221
www.lupinpharmaceuticals.com

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 "calcium acetate."

Appl No	TE Code[4]	RLD[5]	Active Ingredient	Dosage Form; Route	Strength
N018582		No	AMINO ACIDS; CALCIUM ACETATE; GLYCERIN; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE	INJECTABLE; INJECTION	3%;26MG/100ML;3GM/100ML;54MG/100ML;41MG/100ML;1
N021160	AB	Yes	CALCIUM ACETATE	CAPSULE; ORAL	EQ 169MG CALCIUM
A091312	AB	No	CALCIUM ACETATE	CAPSULE; ORAL	EQ 169MG CALCIUM
A077728	AB	No	CALCIUM ACETATE	CAPSULE; ORAL	EQ 169MG CALCIUM
N022581		Yes	CALCIUM ACETATE	SOLUTION; ORAL	EQ 169MG CALCIUM/5ML
A078502	AB	Yes	CALCIUM ACETATE	TABLET; ORAL	EQ 169MG CALCIUM
A091561	AB	No	CALCIUM ACETATE	TABLET; ORAL	EQ 169MG CALCIUM

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 21, 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

Search results from the "OB_Rx" table for query on "021160."

Active Ingredient:	CALCIUM ACETATE
Dosage Form;Route:	CAPSULE; ORAL
Proprietary Name:	PHOSLO GELCAPS
Applicant:	FRESENIUS MEDCL
Strength:	EQ 169MG CALCIUM
Application Number:	N021160
Product Number:	003
Approval Date:	Apr 2, 2001
Reference Listed Drug	Yes
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 21, 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

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

U.S. Food & Drug Administration

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Search results from the "OB_Rx" table for query on "091312."

Active Ingredient:	CALCIUM ACETATE
Dosage Form;Route:	CAPSULE; ORAL
Proprietary Name:	CALCIUM ACETATE
Applicant:	PADDOCK LLC
Strength:	EQ 169MG CALCIUM
Application Number:	A091312
Product Number:	001
Approval Date:	Jun 1, 2012
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

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 21, 2012

Links on this page:

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

U.S. Food & Drug Administration

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

- [1]

FDA[2] Home[3] Drug Databases[4] Orange Book[5]

Search results from the "OB_Rx" table for query on "077728."

Active Ingredient:	CALCIUM ACETATE
Dosage Form;Route:	CAPSULE; ORAL
Proprietary Name:	CALCIUM ACETATE
Applicant:	ROXANE
Strength:	EQ 169MG CALCIUM
Application Number:	A077728
Product Number:	001
Approval Date:	Feb 26, 2008
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 21, 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

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

From: (410) 576-2000
Debashis Mohanty
Lupin Pharmaceuticals, Inc.
111 S. Calvert Street
Suite 2150
Baltimore, MD 21202

Origin ID: ODMA

FedEx Express

J12201209200325

Ship Date: 02JAN13
ActWgt: 0.2 LB
CAD: 1166005/INET3300

Delivery Address Bar Code

SHIP TO: (301) 827-6860 BILL SENDER

Division of Dockets Management
Food and Drug Administration
5630 FISHERS LN RM 1061
DEPT. OF HEALTH AND HUMAN SERVICES
ROCKVILLE, MD 20857

Ref #
Invoice #
PO #
Dept #

TRK# 0201 7944 2836 4602

THU - 03 JAN A2
PRIORITY OVERNIGHT
ASR
20857
MD-US
IAD

19 NSFA