FDA MARCS Recalls 4.3.1

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FDA/ORA General Recall General Recall Specific

Home **Event ID:** 51476 **Status:** Ongoing **Updated:** 06/19/2009 **Role:** District Recall Coordinator

Recall Details

Event Information

Recall Event Id 51476
District Detroit
Firm Awareness Date 03/23/2009
Center (Int) Center for Drug Evaluation and Research
Recalling Firm FEI 1833173
Manufacturer FEI 1833173
Responsible Firm FEI 1833173
Public Reason for Recall Some of the tablets are oversized or undersized, which will result in the patient not receiving the expected dose.
Edit Mode Viewable
Voluntary/Mandated (Int) FDA Initiated
Firm Recommended Recall Depth Consumers/User
Recall Initiation Date (Int) 03/31/2009
Classification Date 06/19/2009
FDA Sample Number None.

Coordinator Sandra L. Williams
District Awareness Date 03/25/2009
Coordinator Catherine Ann Gould
Name (Int) Caraco Pharmaceutical Laboratories, Ltd.
Name (Int) Caraco Pharmaceutical Laboratories, Ltd.
Name Caraco Pharmaceutical Laboratories, Ltd.
Recall Status (Int) Ongoing
Date (Int) 03/31/2009
Date Distribution Chain Notified 03/31/2009
Firm Initial Notification Letter

Complete Reason for Recall The firm decided to recall after FDA initiated an inspection in March 2009. The firm had received a complaint of tablets being of different thicknesses in Dec 2008 relating to 0.125 mg; lot (b) (4) The firm states that, during packaging of 0.125 mg; lot (b) (4) the operator noted size variation. Caraco investigated this lot and concluded that (b) (4) (b) (4) (b) (4) . After discussions with CDER and DET-DO, the firm conducted a more thorough investigation and expanded their recall to 0.25 mg tablets and to additional lots.

Root Cause Other
Root Cause Narrative Lack of adequate production and lot release controls.
Center Comments An HHE from the Division of Cardiovascular and Renal Products (DCRP) stated that excessive dosing "(b) (7)(E) . Based on the HHE from DCRP, CDER finds a class I recall is warranted.
Type Of Injury None known.
Quantity Manufactured bottles
Quantity Distributed (Int) bottles

Number of Domestic Consignees (b) (4)
Number of Foreign Consignees
Distributed From 10/18/2006 To 03/26/2009
Distribution Pattern (Int) Nationwide.
Manufactured From 01/30/2006 To 10/30/2008
Public Summary of Recall Strategy (Int) The firm issued a press release on 3/31/09. Direct consignees were notified by telephone on or about 3/31/09 and by letter dated 3/31/09. A follow-up letter dated 4/7/09 was also sent to each consignee.
Recall Strategy The firm issued a press release on 3/31/09. Direct consignees were notified by telephone on or about 3/31/09 and by letter dated 3/31/09. A follow-up letter dated 4/7/09 was also sent to each consignee.
Audit/Effectiveness Check Modification CDER suggests audit checks as follows: A(100%) to direct accounts (b) (4) consignees) and C (10%) to subaccounts, not to exceed (b) (4) per wholesale audit
Effectiveness Check Level A Percent 100
Audit Check Level C Percent 10
What Consumers Should Do (Int)
Expanded Comments for What Consumers Should Do (Int)
Firm Press Issued (Int) 2009-03-31
URL (Int) http://www.fda.gov/oc/po/firmrecalls/caraco03_09.html
State Press Issued (Int)
URL (Int)
FDA Press Issued (Int)
URL (Int)
Additional Medical Product Information (Int)
URL (Int)

Consignee Details

List of Domestic and/or Foreign Consignees, Distribution addresses or comments Consignees all appear to be distributors or store chain headquarters.

Consignees	Approx. Number	Consignees	Approx. Number
Distributors	[redacted]	Repacker/Relabeler	(b) (4)
Retail		Direct Accounts	
Institutions		Veterans Administration	
Medical Facility		Department of Defense	
Internet Sales		Manufacturer	
Physicians		USDA	
Consumer/Patient		Other	

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Summary/Termination Information

Quantity Recovered/Number of Units Corrected
Product Disposition
Number of Consignees Responding to Notification
Effectiveness Check Information
Audit Check Information
Section of Law Violated

Preventive Action Taken by Firm	
District Follow-Up	
District Review	
Legal Action	
Class I Termination Recommendation	
Recommended/Prepared By	
District Management Approval	Date
Center Concurrence	
Recall Completed Date	
Termination Letter Date	

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CDER Center Information

Docs Rcvd at Ctr Date	04/22/2009
HHE Sent	
HHE Signed	
HHE Preceden	(b) (7)(E)
NDA Field Alert	Y
Alert Number	

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Product Information

Product : 1

Industry-Product Code	63-FCA6
Precedent Recall	(b) (7)(E)
Precedent Policy	
Precedent Policy Comment	
Product Description (Int) (Label/Packaging)	Digoxin Tablets, USP, 0.125 mg, Rx only, Manufactured by: Caraco Pharmaceutical Laboratories, Inc, Detroit, MI; 100 tablets, NDC 57664-437-88 and 1000 tablets, NDC 57664-437-18.
Trade Name (Int)	
Generic Name (Int)	Digoxin Tablets, USP
Product Usage	For the treatment of mild to moderate heart failure and for the control of ventricular response rate in patients with chronic atrial fibrillation.
Product Quantity Distributed (Int)	[redacted] bottles
Recall Number (Int)	D-1213-2009
Product Public Reason for Recall (Int)	Some of the tablets are oversized, and some undersized, which will result in the patient not receiving the expected dose.
Field Recommended Classification	Class I
Center Classification (Int)	Class I
Center Recommended Depth	Consumers/User
Product Effectiveness Check Level	A Percent 100
Product Audit Check Level	C Percent 10
Code Information (Int)	All lot numbers beginning with 61 through 82; expiry 9/30/09-9/30/11
Expected Life	9/2011
Shelf Life	9/2011
Dosage Form	Oral Tablet
NDC Number	57664-437-18
NDA/ANDA Number	76-363
Drug Type	Rx
Number of Lots	46

Container Size TABLETS
Container Type BOTTLE

Deaths		**Injuries**	
Sold/Labeled Sterile	N	**Sterile**	N
		Deficiency	
Software Controlled	N	**Packaging**	N
CDER Reason	Tablet Thickness		

Product : 2

Industry-Product Code 63-FCA6
Precedent Recall (b) (7)(E)
Precedent Policy
Precedent Policy Comment
Product Description (Label/Packaging) (Int) Digoxin Tablets, USP, 0.25 mg, Rx only, Manufactured by: Caraco Pharmaceutical Laboratories, Inc, Detroit, MI; 100 tablets, NDC 57664-441-88 and 1000 tablets, NDC 57664-441-18 .
Trade Name (Int)
Generic Name (Int) Digoxin Tablets, USP
Product Usage For the treatment of mild to moderate heart failure and for the control of ventricular response rate in patients with chronic atrial fibrillation.
Product Quantity Distributed (Int) (b) (4) bottles
Recall Number (Int) D-1214-2009
Product Public Reason for Recall (Int) Some of the tablets are oversized, and some undersized, which will result in the patient not receiving the expected dose.
Field Recommended Classification Class I
Center Classification (Int) Class I
Center Recommended Depth Consumers/User
Product Effectiveness Check Level A Percent 100
Product Audit Check Level C Percent 10
Code Information (Int) All lot numbers beginning with 61 through 82; expiry 9/30/09-9/30/11
Expected Life 9/2011
Shelf Life 9/2011
Dosage Form Oral Tablet
NDC Number 57664-441-18
NDA/ANDA Number 76-363
Drug Type Rx
Number of Lots [redacted]
Container Size TABLETS
Container Type BOTTLE

Deaths		**Injuries**	
Sold/Labeled Sterile	N	**Sterile**	N
		Deficiency	
Software Controlled	N	**Packaging**	N
CDER Reason	Tablet Thickness		

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Recalling Firm Information

FEI 1833173
Firm Name (Int) Caraco Pharmaceutical Laboratories, Ltd.
Address (Int) 1150 Elijah Mccoy Dr
City (Int) Detroit
State/Province (Int) Michigan
Country (Int) United States
Postal Code (Int) 48202-3344
Telephone - Ext Country Code

Comment

Most Responsible Individual

Official's Name Daniel H. Movens
Title Chief Executive Officer
Firm Name (Int) Caraco Pharmaceutical Laboratories, Ltd.
Address (Int) 1150 Elijah Mccoy Dr
City (Int) Detroit
State/Province (Int) Michigan
Country (Int) United States
Postal Code (Int) 48202-3344
Telephone 313-871-8400 **Ext Country Code**
Facsimile - **Ext Country Code**
E-mail Address
Comment

Manufacturer Information

FEI 1833173
Firm Name (Int) Caraco Pharmaceutical Laboratories, Ltd.
Address (Int) 1150 Elijah Mccoy Dr
City (Int) Detroit
State/Province (Int) Michigan
Country (Int) United States
Postal Code (Int) 48202-3344
Telephone - **Ext Country Code**
Comment

Responsible Firm Information

FEI 1833173
Firm Type Unknown/unavailable
Firm Name (Int) Caraco Pharmaceutical Laboratories, Ltd.
Address (Int) 1150 Elijah Mccoy Dr
City (Int) Detroit
State/Province (Int) Michigan
Country (Int) United States
Postal Code (Int) 48202-3344
Telephone - **Ext Country Code**
Comment

Recall Contact

Official's Name [redacted]
Title
Firm Name (Int) Caraco Pharmaceutical Laboratories, Ltd.
Address (Int) 1150 Elijah Mccoy Dr
City (Int) Detroit
State/Province (Int) Michigan
Country (Int) United States
Postal Code (Int) 48202-3344
Telephone [redacted] **Ext Country Code**
Facsimile - **Ext Country Code**
E-mail Address
Comment [redacted]

Public Contact

Official's Name (b) (6)
Title
Firm Name (Int) Caraco Pharmaceutical Laboratories, Ltd.
Address (Int) 1150 Elijah Mccoy Dr
City (Int) Detroit
State/Province (Int) Michigan
Country (Int) United States
Postal Code (Int) 48202-3344
Telephone (b) (6) **Ext Country Code**
Facsimile - **Ext Country Code**
E-mail Address
Comment

Summary Cancel Help

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Printed by: Sandra L. Williams