

Date Assigned: 06/05/2009	Inspection Start Date: 04/09/2009	Inspection End Date: 04/09/2009
Firm Name & Address: Caraco Pharmaceutical Laboratories, LTD. , 31060 Oak Creek Wixom, MI 48393 US		
Firm Mailing Address:		
FEI: 3007621109	JD/TA: 12	County: OAKLAND
Phone:	District: DET-DO	Est Size: (b) (4)
Conveyance Type:	% Interstate:	Inspectional Responsibility:
Profiled: No		

Endorsement

Purpose:
 This was a warehouse inspection conducted concurrently with FACTS assignment 1007751(Compliance follow-up Number 42518) performed 3/11/2009 -5/12/2009. This is Caraco Pharmaceuticals Laboratories Ltd., main warehouse.

History:
 This was the first inspection of this facility.

Current Findings:
 Inspection revealed no objectionable conditions or practices regarding finished product product storage (see Inspection Summary).

Action: Classify: NAI.

Distribution:
 O+IRRS: DET-DO Files (EF)
 FMD-145 Form: FMD 145 Monitor (HFR-CE740)

Endorsement Location:

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Patsy J Domingo	06/05/2009 04:16 PM ET	Art O Czabaniuk	06/05/2009 04:59 PM ET
Patsy J Domingo	06/05/2009 04:11 PM ET		ET
Patsy J Domingo	06/05/2009 04:06 PM ET		ET

Food and Drug Administration Establishment Inspection Report

FEI:3007621109

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Firm Name & Address: Caraco Pharmaceutical Laboratories, LTD. , 31060 Oak Creek Wixom, MI 48393 US

Related Firm FEI:

Name & Address of Related Firm:

1833173

Caraco Pharmaceutical Laboratories, Ltd. , 1150 Elijah Mccoy Dr Detroit,MI 48202-3344 US

Registration Type

Registration Dates

There are no Registration Types

Establishment Type

Industry Code

WA	Warehouse-Ambient Storage	60	Human and Animal Drugs
WA	Warehouse-Ambient Storage	61	Human and Animal Drugs
WA	Warehouse-Ambient Storage	62	Human and Animal Drugs
WA	Warehouse-Ambient Storage	63	Human and Animal Drugs
WA	Warehouse-Ambient Storage	64	Human and Animal Drugs
WA	Warehouse-Ambient Storage	65	Human and Animal Drugs
WR	Warehouse-Refrigerated Storage	60	Human and Animal Drugs

District Use Code:

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Inspection Basis: Surveillance

Inspected Processes & District Decisions

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
56R800	Warehouse-Ambient Storage	62 O C A				No Action Indicated (NAI)

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
Y	06/05/2009	No Action Indicated (NAI)	Czabaniuk, Art O	DET-GRP2

Remarks:

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
56R800	Warehouse-Ambient Storage	63 F C A				No Action Indicated (NAI)

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
Y	06/05/2009	No Action Indicated (NAI)	Czabaniuk, Art O	DET-GRP2

Remarks:

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Products Covered

Product Code	Est Type	Description	Additional Product Description
62 O C A 44	Warehouse-Ambient Storage	Metoprolol Tartrate (Anti-Hypertensive - Part II); Human - Rx/Single Ingredient; Prompt Release Tabl	
63 F C A 06	Warehouse-Ambient Storage	Digoxin (Cardiotonic); Human - Rx/Single Ingredient; Prompt Release Tablets	

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
Le, Caroline H	INV	DET-DO	56R800	Warehouse-Ambient Stora	62 O C A	2
Domingo, Patsy J	INV	DET-DO	56R800	Warehouse-Ambient Stora	62 O C A	3
Domingo, Patsy J	INV	DET-DO	56R800	Warehouse-Ambient Stora	63 F C A	3
Le, Caroline H	INV	DET-DO	56R800	Warehouse-Ambient Stora	63 F C A	2
Total Hours:						10

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Inspection Result

EIR Location

Trips Num

Inspection Summary

This was the initial inspection of a 140,000 square foot warehouse which is the final product storage and distribution point for Rx drugs manufactured by Caraco Pharmaceutical Laboratories, Ltd, Detroit, MI as well as for (b) (4). In addition to finished product storage, (b) (4) stability samples and retain samples for all of Caraco's products are stored at this facility.

Credentials were shown and FDA-482, Notice of Inspection, was issued to Akin-Remi Ajac-Ayodele, Director Quality. Robert Leahey, Sr. Distribution Manager is the most responsible individual on a day to day basis for this facility.

This inspection was conducted concurrent with the 3/11-5/12/09 inspection of Caraco's Detroit, MI facilities.

We observed finished product storage (racks) which included both released and quarantined product. We also observed controlled substance storage cage area and the returned product storage cage area. No objectionable conditions were noted. This warehouse also had a large roped floor area designated for rejected product, both Caraco and (b) (4) products, which were awaiting destruction. Reportedly, a truck is ordered once every (b) (4) to remove the rejected products.

We observed portions of (b) (4) Digoxin lots in the Returned cage area, both recalled lots and lots that had not been released (b) (4) for example.

The refrigerated storage area was built to store product manufactured by (b) (4). This area was currently not stocked but was maintained at refrigerated temperature.

IB Suggested Actions

Action	Remarks
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Referrals

Org Name	Mail Code	Remarks
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Refusals

Inspection Refusals:

Samples Collected

Sample Number	Recall Numbers	Related Complaints
	Recall Number	Consumer Complaint Number

FDA 483 Responses

Date: 06/29/2009

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483 Issued?:

483 Location:

Response Type	Response Mode	Response Date	Response Summary
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