7770711

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 643701

This is an accurate reproduction of the original electronic record as of 09/20/2011

Flag

Flag Remarks

Other-Survln

Episode Number

Origin Domestic Basis

Sample Type Investigational FIS Smpl Num

Status Completed

FEI

Date Collected

Product Code

Responsible Firm

PAC

Hours

3008442043

09/09/2011

221FB01

Grower

03803D

11188542

7

Compliance Num

Country of Origin

United States

Related Smpl Num Position Class

Sampling District

NDC Number

Permit Number

Storage Rormnt.

Refrigerated

Dealer is Consumer Crx/DEA Schedule Recall Num

DEN-DO

Consumer Compl. Num Brand Name

Frontera Produce Rocky Ford

Cantaloupes

Type of Firm

Ingredient

Supplier

Grower

Dealer

Product Description Cantaloupes raw and whole

Product Label

See continuation.

Reason for Collection

Collected in response to a Listeria monocytogenes outbreak and

per CP7303.803, Domestic Food Program. Analyze for Listeria monocytogenes.

MFG Codes

N/A

Expiration Date

FCE

N/A

Firm Legal Name

(b) (4)

Jensen Farms

(b)(4)Size of Lot

(b) (4) whole, raw cantaloupes

Address

310 N Cline Granada, CO 81041 US

(b) (4)

Est. Value (b) (4)

FDA484

Carrier Name Rcpt Type

Date Shipped

3008442043

Description of Sample

Samples consists of 10 sub samples, each sub sample consists of one raw, whole cantaloupe

Method of Collection

See continuation.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

see Remarks

Sample Delivered To

DEN-DO Sample Custodian

Collector's Identification on Seal

"INV643701 9/9/11 Jennifer A. Baker"

Date Delivered

Orig C/R & Records To

09/09/2011

DEN-DO

Lab w/Split Sample

Lab

DEN-LAB

Document Number

Document Date

09/09/2011

Document Type

Document Remarks

Copy of Form FDA-482, Notice of Inspection, issued

t. Store Manager of (b) (4)

Date: 09/20/2011

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Other

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	09/09/2011	Other	Copy of to and sig	Form FDA-484 aned by (b) (4	A, Receipt for Sample, issued Store Manager
	09/09/2011	Affidavit			Ba, Affidavit, issued to and Store Manager of
1	09/08/0111	Invoice	Invoice (09/08/11	uanitity Shipp	ed with Delivery Date of 9CT CANTALOUPES, 5
2	09/09/2011	Invoice			cantaloupe and case, 2 pages
3	09/09/2011	Other	_	Digital image files contained in a CDR taken during sampling, 1 page	
Remarks See continuation.					
Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's N	ame
\$0.00	No Charge	No	No	Jennifer A Ba	ker
Name of Signer Jennifer A Baker Jennifer A Baker Jennifer A Baker		Date & 09/20/ 09/20/ 09/12/	2011 05:44 PM	ET ET	Meaning Collector Collector Collector

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Continuation:

Product Label

End panels of cases containing cantaloupes read in part: "***FONTERA PRODUCE***ROCKY FORD CANTALOUPES***Shipped By: FRONTERA PRODUCE LTD. EDINBURG, TEXAS 78541 www.fronteraproduce.com***Grown and Packed By: JENSEN FARMS GRANADA, CO 81041 www.jensenfarms.com***"

Method of Collection

9 whole, raw cantaloupes were randomly selected from (b) (4) cases of cantaloupes received on 9/8/11, which were stored in ambient storage. A 10th cantaloupe was selected randomly from the collected using aseptic technique and placed in sterile stomacher bags. Subs 1-5 were placed into one cooler with frozen ice packs. Subs 6-10 were placed into a second cooler with frozen ice packs.

How Prepared

The two cooler's containing the subs and ice packs were placed into a GOV car and driven back to the DEN-DO office. Once at DEN-DO, tape was wrapped around each cooler. Each cooler was then sealed with "INV643701 9/9/11 Jennifer A. Baker". Form FDA-525's were attached to each cooler. The coolers were hand walked to the DEN-DO Sample Custodian.

Remarks

The Ingredient Supplier was th(b) (4)

were collected had no documentation showing the delivery of product to the firm. The firm's Store Manager.(b) (4)

(b) (4)

stated that the documentation is kept at the(b) (4)

had closed for the business day by the time I began my sample collection.

Al ases delivered to the firm on 9/8/11 were present in storage and unopened.

Open and closed controls were included with the cooler containing subs 1-5.

Collector's Identification on Package and/or Label:

"INV643701 Sub# (1-10) JB 9/9/11" was written on each sub containing whirl-pack. After returning to the ofice, I realized that I should have identified the subs as "INV643701 9/9/11 JB Sub (1-10)".

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