

Food and Drug Administration Office of Regulatory Affairs**Collection Report****For Sample Number: 713432**

This is an accurate reproduction of the original electronic record as of 10/18/2011

Flag		Flag Remarks			
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Environ-Survl	Investigational	11188563	Completed
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3008442043	09/10/2011	52YYY99	Grower	03R266	26
Compliance Num	Country of Origin				
67413	United States				
Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
713431	INV	DEN-DO			Refrigerated
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
No				N/A	

Product Description

Environmental Swabs

Product Label

N/A

Reason for Collection

Analyze for listeria. Collected to investigate on-going listeria outbreak in melons per SCSO Bryan Love's guidance.

MFG Codes**Expiration Date****Firm Legal Name**

Jensen Farms

Jensen Farms

Address

310 N Cline Granada, CO 81041 US

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Type of Firm

Dealer

Grower

Firm FEI

3008442043

3008442043

FCE**Size of Lot**

N/A

Est. Value**Rcpt Type**

FDA484

Carrier Name**Date Shipped****Description of Sample**

39 environmental swabs and 2 control subs collected as part of investigation for ongoing listeria outbreak investigation at a melon producer.

Method of Collection

See continuation.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"713432 9/10/11 KMM sub 1-39/a-b"

Collector's Identification on Seal

"713432 9/10/11 Kathryn M. Mogen"

Sample Delivered To

DEN-LAB on-call staff

Date Delivered

09/11/2011

Orig C/R & Records To

DEN-DO

Lab w/Split Sample

0

Lab

DEN-LAB

Document Number	Document Date	Document Type	Document Remarks
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Remarks

See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	Yes	No	Kathryn M Mogen

Date: 10/18/2011

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Name of Signer	Date & Time of Signature			Meaning
Kathryn M Mogen	10/05/2011	11:29 AM	ET	Collector
Kathryn M Mogen	10/05/2011	10:59 AM	ET	Collector
Kathryn M Mogen	09/28/2011	04:06 PM	ET	Collector
Kathryn M Mogen	09/14/2011	10:35 AM	ET	Collector

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Continuation:

Method of Collection

2 control subs (subs A [sterile gloves, size 7 with lot no. 54123RU10K7001 dated 8/2010] and B [sponge swab with lot no. 2012-05-BE and expiration 2012-05-28]) and 39 environmental pre-moistened sponge swabs (Subs 1-39) were collected aseptically during EI of the grower. CSO Dion collected all samples with assistance by Clark Wilson, Environmental Protection Specialist of the Colorado Department of Public Health and Environment. All documentation and maps were collected by CSO Mogen. All photographs were taken by Jeff McCollum, Epidemiologist for State of Colorado Department of Public Health. All sponges were sealed in the original whirlpack bags. All samples were collected from the cantaloupe processing line and cooler. Production was occurring during sample collection.

How Prepared

All sponge swabs (subs 1-39) were placed in original whirlpack bags and whirled closed. All bags were labeled as below in black ink on white labels. All subs were then double bagged in secondary whirlpack bags and whirled closed. All subs and controls were placed in one large clear plastic bag and taped closed. Official FDA sealed and FDA 525 attached. Placed in cooler for transport.

Remarks

Send 704(d) sample results to Ryan D. Jensen, Owner at Jensen Farms 31 Cline St. Granada, CO 81041. Samples were stored overnight under FDA seal in locked sample prep room refrigerator. Samples were hand delivered to the lab by DIB Paul Teitell on 9/11/11. Sub 28 was collected out of order (between subs 20-21) due to a labeling error. Notes on collection form and map used to document sub locations were changed to reflect this error. Attached to this CR are a map of swab locations (3 pgs.) and photos/descriptions of each sub location (13 pgs.). FDA 484 and FDA 463a are attached to sample 713431. Although this sample is investigational, the samples were not labeled with the letters "INV".