

**Establishment Inspection Report**

Bidart Bros.  
Shafter, CA 93263

FEI: 3010540230  
EI Start: 12/23/2014  
EI End: 01/06/2015

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**SUMMARY**

This comprehensive inspection of an apple cooler/packing facility was directed by Coordinated Outbreak Response and Evaluation Network (CORE) as part of a traceback investigation, incident name "*Listeria monocytogenes*/Caramel Apples (suspect)/ML/Nov 2014" under FACTS assignment number 11504350.

This was the initial inspection of this facility. During the inspection we covered the apple packaging process and reviewed records relating to receiving, sanitation, employee training, consumer complaints, recall procedures, and pest monitoring. At the close out of the inspection, we issued a Form FDA 483, Inspectional Observations for:

- 1) Seven environmental swabs that were confirmed positive for *Listeria monocytogenes*
- 2) Direct food contact areas of packaging equipment used during the 2014 apple season, constructed and/or maintained in a manner so that they cannot be properly cleaned and sanitized.

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We informed management that conditions observed may, after further review by the Agency, be considered to be violations of the Food, Drug, and Cosmetic Act or other statutes and legal sanctions available to the FDA may include seizure, injunction, civil money penalties, and prosecution.

The firm's president promised to make immediate corrective actions to the items listed on Form FDA 483.

One sample, INV 870215, was collected on 12/23/2014. It consisted of 110 environmental swab samples collected from food and non-food contact surfaces in the packaging area, common cold storage south, and bins stored outside, which were analyzed for *Listeria monocytogenes*. Seven sub samples were confirmed positive for *Listeria monocytogenes*.

We did not encounter refusals; the firm's management was very cooperative.

**ADMINISTRATIVE DATA**

Inspected firm: Bidart Bros.  
Location: 5055 E Lerdo Hwy  
Shafter, CA 93263  
Phone: 661-410-1400  
FAX: 661-410-1401  
Mailing address: 4813 Calloway Drive  
Bakersfield, CA 93312

Dates of inspection: 12/23/2014, 12/24/2014, 12/29/2014, 1/6/2015  
Days in the facility: 4  
Participants: Estefania Fernandez, Investigator (Lead)  
Steven M. Galvez, Investigator (present 12/23/2014)  
Joanne M. Fukuda, Investigator (present 12/23/14 & 01/06/15)  
Duy Truong, CDPH-FDB Investigator (present 12/23 & 24/2014)

This was a joint team inspection with California Department of Public Health- Food and Drug Branch (CDPH-FDB) and the Food and Drug Administration (FDA). Investigator Duy Truong was the California Department of Health- Food and Drug Branch representative. I was the lead investigator and wrote this report in its entirety.

On 12/23/2014, FDA Investigators Joanne M. Fukuda, Steven M. Galvez, and I displayed our FDA Official Credentials and issued Form FDA 482, Notice of Inspection to Leonard A. Bidart, President, who identified himself as the most responsible person (Attachment 1)\*. A copy of the "Information

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Sheet—Assessment of Reinspection and Recall Fees by the FDA” was also provided to Mr. Bidart. Mr. Bidart introduced us to the following Bidart Bros. representatives:

Jake Burns, Packing Manager  
Leo Chavez, Cold Storage Manager  
Timothy P. Sullivan, General Manager  
Jim Blair, Field Manager/Sales  
Jay Reyna, Safety Director

(b) (4), (b) (6)

All of the Bidart Bros. representatives accompanied us during our walk through of the facility. During our record review Bob Sullivan, Vice President/Secretary and John Bidart, Vice President made a brief appearance and introduced themselves to CPDH-FBD Investigator Truong and me.

On 01/06/2015, Investigator Fukuda and I issued a second Form FDA 482, Notice of Inspection to Leonard A. Bidart, President (Attachment 2).

A Form FDA 483, Inspectional Observations (Attachment 3), and Form FDA 484, Receipt for Samples (Attachment 4), were also issued to Leonard A. Bidart, President on 01/06/14.

\*On 12/23/14, Leonard A. Bidart stated the address at this facility was “5501 Lerdo Hwy,” which is the address included on the FDA 482 issued on 12/23/14. On 01/06/2015, Investigator Fukuda and I noticed a sign at the entrance of the facility that had the number “5055.” We asked Mr. Bidart to verify the address of this location. He made a call to the main office (in Bakersfield, CA) to have someone verify the exact address to which Mr. Bidart stated the address as 5055 East Lerdo Hwy.

**HISTORY**

Bidart Bros. was incorporated in 1983 in California. Equal ownership of Bidart Bros. is shared between five siblings: Leonard A. Bidart, John Bidart, Betsy Bidart, Patricia Bidart, and Marianne Bidart. (b) (4)

The three members of Bidart Bros. board of directors are: Leonard A. Bidart (President), John Bidart (Vice President), and Bob Sullivan, (Vice President /Secretary). Mr. Bidart explained that Mr. Sullivan is his brother-in-law, husband of Betsy Bidart, and he represents her

Bidart Bros. is a grower of apples, potatoes, oranges, lemons, table grapes, and almonds. The firm also owns two calf operations. Bidart Bros. has its main office at 4813 Calloway Drive, Bakersfield, CA 93312 and a potato shed located at 34702 7<sup>th</sup> Standard Road, Bakersfield, CA 93314.

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(b) (4)

This apple cooler/packing facility operates seasonally. Apples are harvested and received from July to October. The packaging facility starts receiving fruit and operating in July, and will typically stop packaging (b) (4) weeks after the firm stops receiving fruit for the season. During the peak season there are approximately (b) (4) employees and (b) (4) employees doing maintenance on equipment during the off-season.

The apple cooler/packing facility operates all year round (b) (4)  
from (b) (4) Apple cooler/packing office hours are 5:30 am to 3:30 pm.

(b) (3) (A)

All FDA correspondence should be addressed to:

Mr. Leonard A. Bidart, President

Bidart Bros.

4813 Calloway Drive

Bakersfield, CA 93312

**INTERSTATE COMMERCE**

All apples are grown by Bidart Bros. within a (b) (4) of the cooler/packing facility.

Three of the firm's major interstate customers are:

(b) (4)

(b) (4)

(b) (4)

(b) (4)

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(b) (4)

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The firm's apple customer list is included as Exhibit 1.

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**JURISDICTION**

Bidart Bros. owns a total of (b) (4) acres of apple orchards. (b) (4) acres are Granny Smith variety apples (b) (4) acres are Gala variety apples, and (b) (4) acres are non-producing,

Gala and Granny Smith apples harvested from Bidart Bros. apple orchards are brought to the apple packing facility for cold storage and packaging. Apples are distributed to the fresh market, processors, and juice manufacturers. In 2014, (b) (4) bins of Granny Smith variety apples and (b) (4) bins of Gala variety apples were received at Bidart Bros. (each receiving bin is approximately (b) (4) lbs.).

Apples destined for the fresh market are packed in 3-5 lb. poly bags, 3 lb. mesh bags (poly and mesh bags are placed in cases) or 40-42 lb. cases under Granny's Best brand label or Big B brand label. **Exhibit 2** includes photographs of the Granny's Best and Big B brand labels.

Apples sold to processors (peelers and candy/caramel) are packed in plain 700 lb. triwall bins with only a pallet tag affixed. **Exhibit 3** is an example of the pallet tag affixed to the triwall bins. Apples for juice manufactures are shipped in the customer's bins or in Bidart Bros. wooden bins.

**INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED**

Leonard A. Bidart, President is the most responsible individual at Bidart Bros. He has been in his current position since 1989. He stated that as the President of Bidart Bros. he is responsible for the overall operations of Bidart Bros., including apple packaging. Jake Burns (Packing Manager), Leo Chavez (Cold Storage Manager), and Timothy P. Sullivan (General Manager), report to Mr. Bidart. Mr. Bidart stated he approves all expenses over (b) (4) at the cold storage and apple packing facility. Mr. Bidart accompanied us during the inspectional walk through of the facility and met with us during the close out meeting. He provided information pertaining to apple growing/harvesting, individual responsibilities, the firm's history, and planned corrective actions.

Jake Burns, Packaging Manager is the most responsible individual at the apple cooler/packing facility. He is responsible and oversees all packing operations, including sanitation. He has been in his current position for approximately two years. He reports directly to Tim Sullivan, General Manager and Leonard Bidart, President. He stated the (b) (4) apple packing supervisors report directly to him. Mr. Burns stated that maintenance expenses less than (b) (4) are typically discussed, and approved by Tim Sullivan, General Manager. Mr. Burns accompanied me on all days of the inspection and provided most of the documentation and information included in this report.

Mr. Bidart stated Timothy P. Sullivan, General Manager is the son of Bob Sullivan, Vice President/Secretary, and oversees the entire apple production, including harvesting of the crop. Mr. Sullivan accompanied us during the inspectional walk through of the facility and during the environmental sampling. During the environmental sampling, he provided the descriptions of the sites that were sampled.

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Leo Chavez, Cold Storage Manager accompanied us during the inspectional walk through of the facility and during the environmental sampling. He provided information about their receiving procedures. He also provided copies of the receiving logs for 2014 crop production.

Jim Blair, Field Manager/Sales was present on the first day of the inspection. He stated he is an apple farmer and is responsible for overseeing the crop prior to harvest. He provided general information about the growing and harvesting of apples.

Jay Reyna, Safety Director accompanied us on the first day of the inspection. He provided information about employee training. He is responsible for conducting food safety training for all employees at the beginning of the season.

(b) (4), (b) (6) was present on the first day of the inspection. He accompanied us on the first day of the inspection during the walk through and briefly during the documentation review portion of our inspection.

**FIRM'S TRAINING PROGRAM**

Jay Reyna, Safety Director, stated he provides employee health and hygiene training to all employees. He is bilingual and provides the training in Spanish and English. The training is conducted in August at the beginning of the season. On 12/23/14, CDPH- FDB Investigator Truong and I reviewed training records. 2014 pre-season training topics included: proper personal hygiene, food handling practices, MSDS, emergency procedures, forklift safety, and evacuation procedures. Mr. Reyna explained that employees are gathered in the breakroom area and he presents the information orally.

Jake Burns, Packing Manager, stated he provides sanitation training to the (b) (4) employees responsible for sanitization. Mr. Burns stated he demonstrates how the cleaning and sanitation is to be conducted. On 12/23/14, I asked to review sanitation training records; Mr. Burns stated sanitation training was not documented.

**MANUFACTURING/DESIGN OPERATIONS**

Bidart Bros. apple cooler/packing facility has been at this location and started packing apples in 1987. Prior to 1987 Bidart Bros. apples were sold to a packer. The entire facility is approximately (b) (4) square feet; it includes common cold storage north, common cold storage south, (b) (4) controlled atmosphere storage rooms, apple packing facility, grape fumigation room, and grape cold storage. The apple production area is approximately (b) (4) square feet; see Attachment 6 for a diagram of the facility.

Gala and Granny Smith variety apples are packaged using the same process and using the same equipment. On 12/23/14, Jake Burns, Packing Manager stated the only difference in the processing

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of the two varieties is: (b) (4) Gala variety apples, since they are not held in controlled atmosphere storage due to their shorter self-life.

The firm was not in operation during the time of the inspection. The last day the packaging equipment was in operation was on 10/31/14. On 12/23/14, Leo Chavez (Cold Storage Manager) and Jake Burns (Packing Manager) described the apple packing process from receiving to shipping of packaged product.

**Receiving**

Mr. Chavez explained that apples are harvested by hand into a canvas picking bag. When the bag becomes full, it is dumped into a wooden bin. Once the bins are full, they are transported at ambient temperature to the apple cooler/packing facility using straddle lift trucks. Mr. Chavez explained that the straddle lift trucks transport the bins by picking them up; they are not loaded onto a truck or trailer. At the cooler/packing facility, the straddle lift trucks place the apple filled wooden bins under the (b) (4). At the (b) (4)

(b) (4) is poured over the bins of apples for (b) (4) minutes. The concentrations of (b) (4) are tested up to (b) (4) per day. I reviewed (b) (4) and (b) (4) monitoring records for 2014; I didn't note levels under (b) (4)

(b) (4) while in storage. (b) (4) is only used on Granny Smith variety apples to control scalding while in cold and controlled atmosphere storage. (b) (4) The decision whether to use (b) (4) is based on the fruits' condition in the field, and risk of (b) (4) while in long term storage.

The water in the (b) (4) is sourced from a (b) (4) and is (b) (4) during the day. The water is filtered by (b) (4) stages; the final stage uses a (b) (4). The water storage pit used for (b) (4) water is cleaned and sanitized with (b) (4) prior to the start of the season. At the end of each day, water is pumped out of the water storage pit and transferred to a holding tank. The solids accumulated at the bottom of the water storage pit are removed, and the pit is rinsed with fresh water. The next day, the water from the holding tank is pumped into the water storage pit, fresh water is added to fill the water storage pit, chemicals are added, and product is (b) (4)

The bins are picked up from under the (b) (4) and transported to the common cold storage north or any of the controlled atmosphere (CA) storage rooms. Mr. Burns stated there are (b) (4) CA storage rooms, but only (b) (4) are in operation.

Controlled atmosphere (CA) storage rooms are filled with up to (b) (4) and product. The common cold storage area has (b) (4) and also serves (b) (4)

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**Packaging**

The following process was described by Mr. Burns on 12/23/2014: Bins are removed from common cold storage or CA storage and taken to the packing facility. Mr. Burns stated they typically allow the product to temper for (b) (4) before it is introduced into the dump tank. Bins (stacked bins high) are placed on the (b) (4) and submerged in the water dump tank. When the bin is submerged, the apples float out; a water flume (using the same dump tank water) guides the apples onto the wash lines. The empty bins are conveyed up and out of the dump tank.

The water in the dump tank is sourced from the (b) (4) and is (b) (4) using (b) (4). A (b) (4) solution is used to (b) (4) as needed. The system is controlled by an (b) (4) with a target of (b) (4). The water in the dump tank or bin immersion tank is replaced after every (b) (4) bins or approximately (b) (4) days.

Mr. Burns stated this was the first year they used water sourced from the (b) (4) in the packing facility for processing and sanitation. He explained this was because the (b) (4) of their (b) (4) and not able to pump enough water for the (b) (4) and packing facility.

The dump tank water temperature and product pulp temperature is taken and recorded approximately every (b) (4) hours. (b) (4) are recorded on the Bidart Bros. Immersion Wash Monitoring Log. I reviewed Immersion Wash Monitor Logs for the 2014 crop production, and noted the dump tank water is approximately (b) (4) F and the pulp temperature ranges from (b) (4) F.

After the dump tank, product is split into the (b) (4) Wash Line. (b) (4) wash lines follow the same steps). Apples are conveyed out of the dump tank on (b) (4) rollers. Once apples are on the (b) (4) rollers and out of the dump tank, water from the dump tank is (b) (4) on the apples. The apples are then transferred to green roller brushes and (b) (4) is sprayed on with (b) (4) F water. The water used at this step is fresh water, and not reused from the dump tank. The apples are conveyed via the green roller brushes and (b) (4) F fresh water is sprayed on the apples once again. The combination of the cleaner, hot water, and agitation from the bristles aid in cleaning the surface of the apples. The apples are then conveyed on the red drying brushes and then onto the black polishing roller brushes. Fans are located above the red drying and black polishing brushes to blow off excess water. Apples are then hand graded, they continue on the main processing line to be waxed or the Granny's Best Line.

At the Granny's Best Line it can be packed for juice, peelers, candy/caramel, or Granny's Best brand label carton. Approximately (b) (4) % of the firm's total production volume is packed at the Granny's Best Line. The Granny's Best Line process flow is included as Attachment 7, page 2.

Apples that are not diverted to the Granny's Best Line continue onto the main processing line and are waxed. (b) (4) onto the apples while rolling on the black waxing brushes made of a (b) (4) mix of (b) (4). The apples then



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enter a dryer on painted metal rollers for (b) (4) minutes at (b) (4) F. After the dryer, the apples go through another hand grading station, and a manual color sorting station. Apples that are not selected for fresh pack are diverted to be packed for candy/caramel at (b) (4). Apples selected for fresh pack continue on the main processing line, auto singulator, a PLU sticker applied, and sized by weight. Sized apples can be manually packed into poly bags (1 table), automatically packed into trays (lines), or automatically packed into poly or mesh bags (b) (4). Poly bags, mesh bags, or trays are placed into cartons. Cartons are sealed, lot code is ink printed, and closed cartons are conveyed to the refrigerated apple shipping area. In the apple shipping area, cartons are separated by size and grade, and palletized. Once they are palletized, product can be shipped out immediately or taken to Common Cold Storage South.

Attachment 7 is a process flow diagram I created to summarize the process.

**Cleaning and Sanitation**

Mr. Burns oversees sanitation procedures and provided the information under this subsection.

**Daily:**

All equipment before the dryer is rinsed with water prior to applying sanitizing solution. Compressed air may be used prior to applying the sanitizer, if there is a lot of accumulation on the brushes. Sanitizing solution used on this equipment is (b) (4). The equipment includes (b) (4) rollers, green washing brushes, red drying brushes, black polishing brushes, and black waxing brushes.

On 12/29/14, Mr. Burns stated they started using (b) (4) on 09/16/14. Prior to this date, they were using a (b) (4) solution. The change was prompted due to elevated counts of mold from swabs collected on 08/12/14, see Exhibit 4.

The rest of the equipment is wiped with a towel and (b) (4) solution: grading table/rollers, the rollers in dryer, sorting tables/rollers, cups for packing into trays, packing belts (used for trays), manual packing table, and automatic bag packing machine.

Mr. Burns stated he is responsible for conducting visual pre-operations sanitation checks daily. He also stated there is a time separation between lots but no cleaning and sanitation is conducted between packaging of lots.

**End of season:**

This procedure is followed once all the apple packaging is done for the season and the initiation of equipment maintenance. Equipment is rinsed with water → degreaser (b) (4) is applied → (b) (4) soap is applied → equipment is scrubbed using brushes → rinsed with water → (b) (4) solution is sprayed and allowed to air dry. Mr. Burns stated that conveyor belts and the roller brushes are removed and stored on pallets, so they are able to make repairs on the frame of the

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equipment. When all repairs are done, the parts are installed back on the equipment, and prior to the start of the season, the daily sanitation procedure is done.

Water used for cleaning is sourced from the (b) (7) (C) (b) (7) (D)

#### **MANUFACTURING CODES**

Jake Burns, Packing Manager stated all fresh pack cartons are identified with lot/field number and the pack date. Apples sold in triwall bins are identified only with a bin pallet tag. Exhibit 3 is an example of a triwall bin pallet tag, which also includes the pack date and lot number (under block #).

#### **COMPLAINTS**

Jake Burns, Packing Manager stated consumer complaints are typically received by the salesperson and then directed to him. He is responsible for the investigation of the nature of the complaint and providing a corrective action.

Mr. Burns stated no injury or health related complaints have been received. There were no consumer complaints reported in FACTS.

#### **RECALL PROCEDURES**

Bidart Bros. uses a computerized inventory system (b) (4) for tracing back product. Bins are received with bin tags, which include the date harvested and lot number. When the bins are introduced to the packaging line, the bin dump operator removes and retains all the bin tags processed. The finished product cases (identified with the lot number and pack date) are then identified to the bin tag retained. The pack date and lot number is used to trace back the product to the field from which it was harvested.

The firm performs annual mock recalls. The last mock recall exercise was done on 08/05/2014.

#### **GENERAL DISCUSSION WITH MANAGEMENT / OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**

The close out meeting was held on 01/06/2015 with Leonard A. Bidart, President and Jake Burns, Packing Manager. Prior to issuing the FDA 483, I read the opening paragraph and informed them that they can verbally respond to each observation and/or respond in writing within 15 days of the closeout of the inspection. I also informed Mr. Bidart that conditions observed may, after further review by the Agency, be considered to be violations of the Food, Drug, and Cosmetic Act or other statutes and legal sanctions available to the FDA may include seizure, injunction, civil money penalties, and prosecution.

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Observations listed on the FDA 483

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Observation 1

Food that has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

Specifically:

1) On 12/23/14, we collected sample INV 870215, consisting of 110 environmental swabs collected from food and non-food contact surfaces in the packaging area, common cold storage South, and bins stored outside. The following seven subs were confirmed positive for *Listeria monocytogenes*:

Sub 3, Black polishing brush

Sub 39, 41, 44, Red drying brushes

Sub 63, Auto line (b) (4) Lan (b) (4)

Sub 100, Main packing line drain between the north and south flumes

Sub 106, Inside area of non-painted Bidart wooden bin

Six of these sites (Sub 3, 39, 41, 44, 63, and 106) are direct food contact surfaces.

2) On 12/23/14, we observed direct food contact areas of packaging equipment, used during the 2014 apple season, constructed and/or maintained in a manner so that they cannot be properly cleaned and sanitized:

A) Damaged conveyor belt and chipping/peeling paint on the (b) (4) transfer chute on the Granny's Best packaging line.

B) Frayed edges and exposed foam-like material on the green vinyl coated padding, lining the transfer chute to the peeler on the Granny's Best packaging line.

C) Green vinyl coating is separating away from the padding, exposing foam-like material on the entrance to packaging (b) (4) Candy Apple (b) (4)

D) Torn and cracked padded flap located on the end of packaging (b) (4) Candy Apple (b) (4)

E) Cracked vinyl coating and exposed foam-like material on bump pad at the end of Lane (b) (4) leading to packaging on (b) (4) Candy Apple (b) (4)

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F) Bucket conveyer on (b) (4) Candy Apple (b) (4) made of canvas material has frayed edges and metal staples. The padded flap on the end of packaging (b) (4) Candy Apple (b) (4) was torn and cracked.

**Supporting Evidence and Relevance:**

- 1) On 01/02/2015, seven of the 110 environmental samples collected on 12/23/14 were confirmed positive for *Listeria monocytogenes*. Five of the seven positive swabs (Subs 3, 39, 41, 44, and 63) were collected from direct food contact surfaces inside the packaging facility. One of the positive swabs (Sub 106) was collected from the inside of a wooden bin; the wooden bins are used to hold apples during storage, which is a direct food contact surface. The final positive swab (Sub 100) was collected from the drain area inside the apple packaging facility.

Subs 3, 39, 41, 44, and 63 were collected from direct food contact surfaces on equipment that was cleaned and sanitized after production on 10/31/14. This equipment was last used to package Granny Smith variety apples on 10/31/14.

On 12/23/14 and 01/06/15, Jake Burns, Packing Manager stated the last day the firm operated the equipment was on 10/31/2014. He also stated the equipment was cleaned and sanitized using their end of season cleaning and sanitizing procedures which, involves using degreaser, detergent, and sanitizer before repairs started, see the "Cleaning and Sanitation" subsection under **Manufacturing/Design Operations**.

Wooden bins are used to hold apples from the time they are harvested until they are introduced into the packaging process. On 12/23/14, Leo Chavez, Cold Storage Manager stated the wooden bins are stored outside during the off season. He also stated the wooden bins are only cleaned and sanitized if there is evidence of rodent or bird droppings; otherwise the bins are only swept prior to being used. Wooden bins are (b) (4) (b) (4) which Mr. Bidart stated represents (b) (4) Some of the bins we observed being stored outside had (b) (4) on the bin, representing that these bins have been in use (b) (4)

These wooden bins are taken out to the field and harvested apples are placed in them. Apples are drenched with water while in the wooden bins, and apples are stored under cold storage in the wooden bins. When the apples are to be packaged, the wooden bins filled with apples are removed from cold storage, and introduced into the packaging process by submerging the wooden bins into water. The inside of the wooden bins are a direct food contact surface, which cannot be adequately cleaned and sanitized.

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Sub 100, was collected from the main drain inside the packaging facility. Timothy P. Sullivan, General Manager stated water from the north and south wash lines drain into this main drain. The area around the drain was observed to be wet during the time of the sample collection, although the last time the facility processed apples was on 10/31/2014. Leo Chavez, Cold Storage Manager stated it was probably water that spilled during the maintenance of water valves. The drain was sampled as suggested by Attachment 3 of Field Bulletin #30 (October 2014).

- 2A) **Exhibit 5** is a photograph of the damaged conveyor belt and chipping/peeling paint on the (b) (4) transfer chute on the Granny's Best packaging line. All apples diverted from the main production line at the hand grading step to the Granny's Best packaging line pass through this area. The apples are in direct contact with this portion of the equipment after they have been washed, dried, and polished.
- 2B) **Exhibit 6** is a photograph showing frayed edges and exposed foam-like material on the green vinyl coated padding, lining the transfer chute to the peeler on the Granny's Best packaging line. Apples are exposed to this area after the hand grading step, after they are washed, dried, and polished.
- 2C) **Exhibit 7** is a photograph showing the green vinyl coating is separating away from the padding, exposing foam-like material on the entrance to packaging (b) (4) Candy Apple (b) (4). All candy/caramel apples being packaged into triwall bins at this drop point (Candy Apple (b) (4)) are exposed to this area. This is after the apples are washed, dried, and polished, just prior to being packaged into triwall bins.
- 2D) **Exhibit 8** is a photograph showing the torn and cracked padded flap located on the end of packaging (b) (4) Candy Apple (b) (4). Apples being packaged into triwall bins at this drop area come in direct contact with this padded flap. It is also possible for the padded flap to come in contact with the inside of the triwall bins in which the apples are being packaged.
- Mr. Jake Burns, Packaging Manager explained the end of the (b) (4) Candy Apple packaging machine is lowered into the bin so the apples do not drop far to prevent bruising.
- 2E) **Exhibit 9** is a photograph showing the cracked vinyl coating and exposed foam-like material on the bump pad at the end of Lane (b) (4) leading to packaging on (b) (4) Candy Apple (b) (4). Apples may come in contact with this area after they have been washed, dried, polished, and waxed.
- 2F) **Exhibit 10** is a photograph showing the bucket conveyer on (b) (4) Candy Apple (b) (4) which is made of canvas material, and has frayed edges and metal staples. The padded flap on the

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end of packaging (b) (4) Candy Apple (b) (4) was torn and cracked. This is a direct food contact area to which apples are exposed after they have been washed, dried, polished, and waxed. Also, the end of this padded flap remains directly above the exposed apples during packaging and may come in contact with the inside of the triwall bin as it is being filled.

All the aforementioned areas (2A- 2F) are direct food contact surfaces that are not maintained in a way to protect food from being contaminated by any source. These surfaces are not constructed or maintained so they can adequately be cleaned and sanitized to minimize the accumulation of food particles, dirt, and organic matter, and thus minimize the opportunity for growth of microorganisms.

#### Discussion with Management:

Mr. Bidart stated he was informed of the finding of *Listeria monocytogenes* in his facility by the FDA. He stated that as a result of the finding, they contacted their chemical supplier (b) (4). They have scheduled a meeting with the (b) (4) representative for the following week (week of (b) (4)). He stated they will consult with (b) (4) to find a cleaner and sanitizer that will be more effective for their intended use.

In regards to the direct food contact surfaces that were not maintained in a way to protect food from being contaminated, Mr. Bidart stated he understood the importance of maintaining the equipment in a manner that can be adequately cleaned and sanitized. He stated they were only replacing the padding or foam if it was worn and causing bruising, but now they will replace the padding anytime the vinyl coating becomes worn so that it can be properly cleaned.

Jake Burns, Packing Manager stated they are consulting with (b) (4) to replace the foam-like material at the entrance to packaging (b) (4) Candy Apple (b) (4) Observation 1 2C).

#### REFUSALS

We did not encounter refusals; management was very cooperative.

#### ADDITIONAL INFORMATION

The "Packing and/or Cooling Operations" and "Transportation – Packing Operations" sections (Page 13-17) of the From FDA 3623, Farm Investigation Questionnaire were completed and included as Attachment 5.

The Pulsed-field gel electrophoresis (PFGE) patterns of the seven positive *Listeria monocytogenes* environmental swabs matched the PFGE patterns from outbreak patient isolates, see Attachment 8.

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**SAMPLES COLLECTED**

On 12/23/14, one sample, INV 870215, was collected. It consisted of 110 environmental swabs and controls. Environmental swabs were collected from food and non-food contact in common storage cooler south, packing area, and wooden bins stored outside. Seven of the environmental swabs were confirmed positive for *Listeria monocytogenes*, see the **Observation 1 and Supporting Evidence and Relevance** subsection for more information.

**VOLUNTARY CORRECTIONS**

After being notified of the positive *Listeria monocytogenes* environmental swabs on 01/09/2015, Bidart Bros. worked with San Francisco District Recall Coordinator, Marjorie Schultz to recall all Gala and Granny Smith apples packaged by Bidart Bros. during the 2014 season.

**EXHIBITS COLLECTED**

1. Apple customer list (3 pages)
2. Photographs of the Granny's Best and Big B brand labels ( 2 pages)
3. Copy of triwall pallet tag (1 page)
4. Mold swab results (1 page)
5. Copy of photograph of the damaged conveyor belt and chipping/peeling paint on the (b) (4) transfer chute (1 page)
6. Copy of photograph showing frayed edges and exposed foam-like material on the green vinyl coated padding (1 page)
7. Copy of photograph showing the green vinyl coating is separating from the padding (1 page)
8. Copy of photograph showing the torn and cracked padded flap (1 page)
9. Copy of photograph showing the cracked vinyl coating and exposed foam-like material on the bump pad (1 page)
10. Copy of photograph showing the bucket conveyor on (b) (4) Candy Apple (b) (4) 1 page)
11. CD-Rs containing original copies of photographs taken during EI (2 pages)

**ATTACHMENTS**

1. Form FDA 482, Notice of Inspection dated 12/23/14
2. Form FDA 482, Notice of Inspection dated 01/06/15
3. Form FDA 483, Inspectional Observations
4. Form FDA 484, Receipt for Sample
5. Form FDA 3623, Farm Investigation Questionnaire (only Page 13-17)
6. Diagram of Facility (1 page)
7. Gala and Granny Smith Apple Process Flow (2 pages)
8. Copy of e-mail Subject: FW: PFGE for 870215: *Listeria monocytogenes*/Caramel Apples(suspect)/ML/Nov 2014 (4 pages)

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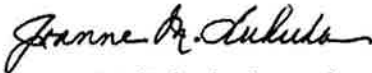
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