

**Establishment Inspection Report**

Blue Bell Creameries, L.P.  
Brenham, TX 77833-4413

FEI: 1682009  
EI Start: 02/28/2012  
EI End: 02/29/2012

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**SUMMARY**

This GMP inspection of a food manufacturer was conducted per FACTS assignment #1356103 and DAL-DO FY 2012 FSMA HR Food Inspection Program in accordance with CP 7303.803 & CP 7321.005 and covered PAC's 03803 and 21005.

The previous inspection conducted on 5/11-12/2010 by FDA was classified as NAI.

On 2/28/12, FDA credentials were shown and a FDA 482 was issued to Greg A. Bridges, V.P. Operations. The current inspection found the firm continuing to operate as a manufacturer of various ice creams and ice cream novelties. During the inspection, Cake and Ice Cream was manufactured and covered and operations of the bakery were inspected. A field exam was conducted on Cake and Ice Cream and reported separately into FACTS without deviations. A copy of the FDA document entitled "Information Sheet - Assessment of Reinspection and Recall User Fees FY 2012 by the FDA" was provided to Greg A. Bridges, V.P. Operations. At the conclusion of

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the inspection, there were no observations noted and a FDA 483 was not issued. There were no refusals. No samples were collected during this inspection. FDA correspondence should be addressed to Paul W. Kruse, CEO, at the mailing address below.

**ADMINISTRATIVE DATA**

Inspected firm: Blue Bell Creameries, L.P.  
Location: 1101 S Blue Bell Rd  
Brenham, TX 77833-4413  
Phone: 979-836-7977  
FAX: 979-830-2111  
Mailing address: P.O. Box 1807  
Brenham, TX 77834-1807  
  
Dates of inspection: 2/28/2012, 2/29/2012  
Days in the facility: 2  
Participants: Robert T. Lorenz, Investigator

On 2/28/12, FDA credentials were shown and a FDA 482 was issued to Greg A. Bridges, V.P. Operations. A RFR Brochure had previously been issued to the firm. On 2/28/12 I provided Greg A. Bridges, V.P. Operations with a copy of the FDA document entitled "Information Sheet - Assessment of Reinspection and Recall User Fees for FY 2012 by the FDA" which provides the statutory authority granted to FDA to collect user fees for re-inspections by FSMA, who will be assessed user fees, and the rates.

**HISTORY**

The firm has been in business since 1907 as a family business and started as a private corporation. The inspected facility was first constructed at this site in 1972. The company was reorganized in 2008 and is currently Blue Bell Creameries, L.P., a Limited Partnership #74-2983269 organized in the State of Texas.

Operating hours are generally (b) (4) There are about (b) (4) production employees and (b) (4) office employees at this location. Sales are (b) (4)% wholesale and annual volume is about (b) (4) gallons at this plant and (b) (4) at all plants combined. Total sales are about \$(b) (4) annually.

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Two other associated Blue Bell ice cream plants are located in Broken Arrow, OK and Sylacauga, AL. A smaller plant associated with this firm is located nearby and manufactures primarily ice cream novelties on sticks (802 Creamery St., Brenham, TX 77833). The firm has a webpage at [www.bluebell.com](http://www.bluebell.com).

The previous inspection was conducted on 5/11-12/2010 by FDA and was classified as NAI.

### INTERSTATE COMMERCE

Milk comprises about (b) (4)% of most ice creams and is primarily purchased from (b) (4) (b) (4) within a (b) (4) mile radius of the facility. Other ingredients such as sugar, corn syrup, cocoa, colors, & flavors originate from interstate commerce. About (b) (4)% of the finished product ice creams and novelties are shipped to distribution centers in (b) (4) surrounding states from this plant.

Shipping documents and a certificate of analysis for (b) (4) high fructose corn sugar shipped by rail from (b) (4) in (b) (4) to the firm were collected as **Exhibit 1**. Documentation for finished ice cream shipping from the firm to a frozen warehouse distribution center in (b) (4) was collected as **Exhibit 3**.

### JURISDICTION

The firm operates as a food manufacturer where ingredients are from interstate commerce and finished products are shipped into interstate commerce. The firm is thereby subject to 21 CFR Part 110 as well as other applicable regulations.

### INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

On 2/28/12, FDA credentials were shown and a FDA-482 was issued to Greg A. Bridges, V.P. Operations (**Attachments 1**). A RFR Brochure had previously been distributed to the firm.

Mr. Bridges identified himself as the most responsible person at the time. Mr. Bridges reports to Mr. Paul W. Kruse, CEO.

Mr. Kruse was not present during the inspection but is normally present on a day-to-day basis, oversees all management aspects of production, manufacturing, and quality control unit and has overall authority to detect, prevent and correct problems at the facility. Mr. Kruse has been CEO for about 7 years and reports to the Board of Directors.

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Present at the discussions, and accompanying me during the inspections and at the closing meeting were Andrew (Andy) F. Kollman, Quality Control Manager and [REDACTED] (b) (6) [REDACTED], Quality Control. Mr. Kollman has been at his present position for 6 years and with the company for 14 years. Mr. Paul Prazak, Manager of Plant Operations was also present briefly at the opening meeting. Mr. Prazak has responsibility for all plant operations on a day-to-day basis.

### FIRM'S TRAINING PROGRAM

All new employees undergo initial training in GMP, hand washing and sanitation, and food handling via classroom instruction and videos. New refresher videos and coursework are provided on a periodic, at least (b) (4) basis. Training is documented and updated (b) (4).

The firm also provides employees with (b) (4) training, internal training for each department, Good Manufacturing Procedures (GMPs) training, Hazard Analysis & Critical Control Points (HACCP) training, food safety training, and food defense training. Employees receive training on allergens and each department receives specialized training for their specific job duties.

Mr. Supak, Mr. Kollman, and Mrs. Thiel train employees in a variety of areas, but specifically will train on procedures. The lab technicians are trained by Mr. Kollman and Mrs. Thiel. The firm also receives training from (b) (4) on food protection.

### MANUFACTURING OPERATIONS

The firm is located on approximately (b) (4) acres with several buildings. The firm has one primary production building of about (b) (4) sq ft used for the manufacturing of all ice cream products, ice cream and ice water novelties, cold storage as well as the corporate office space, tour center, and small retail area. The warehouse building of about (b) (4) sq ft consists of storage area on the first floor and the bakery area on the second and third floors. The bakery products are used as ice cream flavor ingredients such as cookies and ice cream sandwich wafers. The firm also has a small retail shop for tour groups to purchase products.

The firm has a milk truck receiving bay with (b) (4) building and (b) (4) silos. The firm has one cream bay with (b) (4) cream silos. There is also a fleet maintenance building for truck repairs and a rail car spur for receiving rail shipments such as corn syrup. The firm maintains their own fleet of trucks to deliver products directly to distribution centers and stores. The firm uses the (b) (4) (b) (4) system for maintenance and temperature checks on trucks (b) (4).

The firm operates as a manufacturer of numerous ice cream flavors as well as ice cream novelties such as ice cream cones, ice cream sandwiches, and popsicles. This site is also the corporate headquarters for Blue Bell Creameries, Inc. which includes two other manufacturing facilities in

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facilities in Broken Arrow, OK and Sylacauga, AL. and numerous frozen warehouse distribution center throughout (b) (4) states. This facility manufactures about (b) (4) gallons annually. The other two Blue Bell facilities located in Broken Arrow, OK and Sylacauga, AL produce about (b) (4) gallons. The firm's top Customers include; (b) (4) and (b) (4).

A list of all products currently manufactured at this facility was collected as **Exhibit 4**. Production schedules for 2/28-29/2012 were collected as **Exhibit 7**. The three largest volume ice creams are (b) (4), and (b) (4). Popsicles are also manufactured on separate dedicated lines.

During the inspection on 2/28/12 and 2/29/12, the firm was observed manufacturing ice cream sandwiches, pints of Rocky Road, 3 oz. cups of Cookies and Cream Sundae, pints of Great Divide, ½ gallons of Home Made Vanilla, ½ gallons of Dutch Chocolate, 3 gallons of Buttered Pecan, 3 gallons of Cookies N Cream, ½ gallons of Moo-Lineum Crunch, ½ gallons of Country Vanilla, ½ gallons of Strawberry & Homemade Vanilla, ½ gallons of Cake & Ice Cream, ½ gallons of Cookies N Cream, 3 oz cups of Homemade Vanilla. Pints of Chocolate Chip Cookie Dough, Pints of Buttered Pecan, Pints of Cotton Candy, and 3 gallons of Cake Batter.

Ingredient suppliers are required to complete a "Supplier Ingredient Information" sheet which is a declaration of all ingredients. An example for (b) (4) Chocolate Chip Cookie (b) (4) was collected as **Exhibit 9**. The general recipe for Cake & Ice Cream was collected as **Exhibit 10**. A field exam was conducted on Cake and Ice Cream and reported separately into FACTS without deviations.

Milk comprises about (b) (4)% of most ice cream products. Milk is purchased by contract from (b) (4) dairies located within a (b) (4) mile radius of the firm. Milk is delivered from (b) (4). Tankers arrive at the firm scale station weighed, and samples are taken and tested for (b) (4) (b) (4) and (b) (4). Texas DSHS oversees antibiotic testing at the firm at least annually.

After testing acceptance, tankers are unloaded into one of (b) (4) gallon refrigerated silos dedicated for milk storage. Total milk storage capacity is about (b) (4) gallons. Milk tankers are dedicated and washed out at the firm after unloading.

The general process for manufacturing of ice creams is as follows:

(b) (4)

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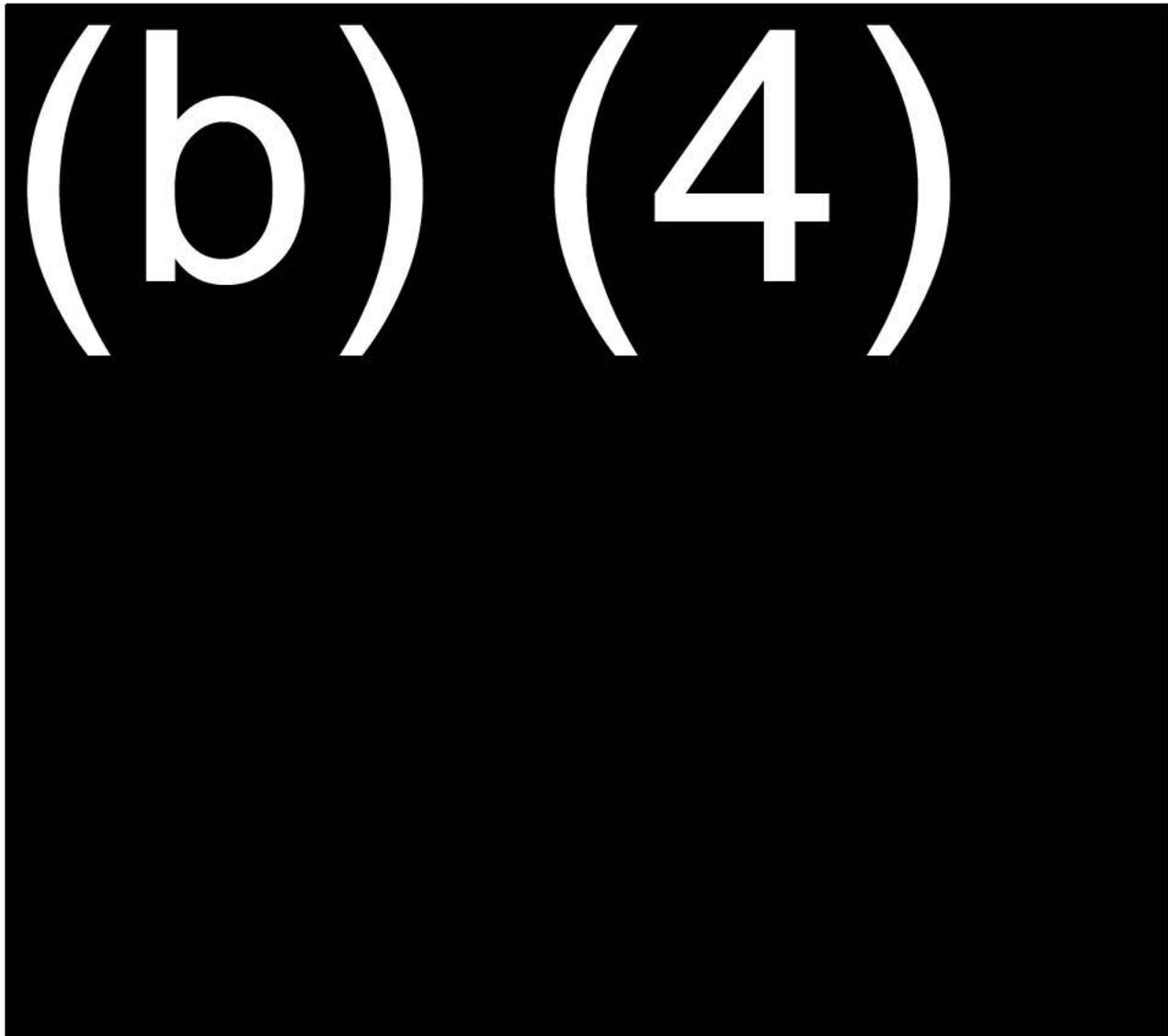
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After the (b) (4) mixture is pumped to (b) (4) gallon hold tanks for chilling it is then drawn into (b) (4) gallon (b) (4) vats where (b) (4). The flavored mixture is then pumped to freezer units in the production room and chilled to (b) (4)F and (b) (4).

The final mixture is then (b) (4) with (b) (4) just prior to filling various size packages. The firm has (b) (4) fill lines that consist of 3 gallon, ½ gallon, pints, 3 oz cups, sandwiches, and other frozen novelties. Finished products are tested for weight, fill height, correct lot codes, and taste.

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All (b) (4) products are made (b) (4), followed by a (b) (4) then a (b) (4). The firm uses (b) (4) if line is used for allergen, with allergens (b) (4) followed by (b) (4). The firm also has an allergen (b) (4). Egg yolks are ingredients for French Vanilla ice cream and Chocolate Moo-Ilenium Crunch. Nuts used in ice creams include; pecans, almonds, walnuts, peanuts and macadamia nuts. Nuts are received from (b) (4) (b) (4) and (b) (4). Certificates of Analysis are required for nut acceptance with tests conducted for (b) (4). All ingredients are inventoried and used on a (b) (4)

The firm utilizes HACCP concepts with CCP's at (b) (4) (b) (4). The two CCP's have monitoring, verification/validation and recordkeeping associated with them.

**Warehouse:**

This Warehouse/Bakery is about (b) (4) SF in a separate building from the main production area located on the northeast corner of the property. This warehouse on the first floor primarily stores raw ingredients and packaging for products.

When a shipment is received, the seals on the truck are checked and the incoming items are inspected and scanned into system. The firm uses (b) (4) and (b) (4) computer systems to enter and then assign a warehouse storage slot. This system assists in allocating products (b) (4)

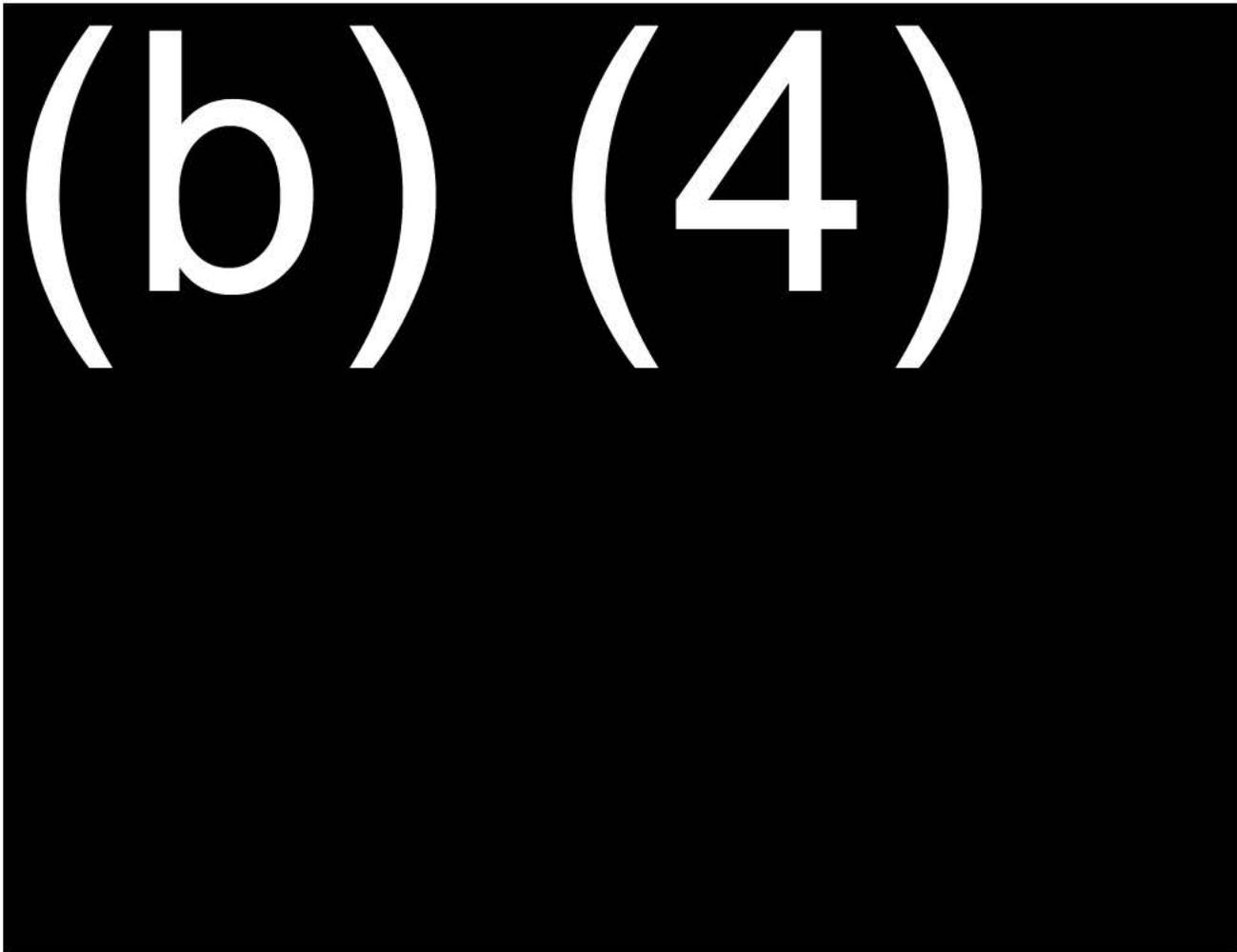
Tin cats were observed around the interior perimeter of the warehouse area. There were no observations noted for the warehouse.

**Bakery:**

The firm's Bakery is located on the second and third floor of the warehouse building. The bakery produces ingredients for the ice creams such as cookies used in Cookies n Cream Ice Cream and chocolate wafers used in ice cream sandwiches, cones, and cake pieces.

The general process for the production of cream filled cookies is as follows:

(b) (4)



There are (b) (4) employees in Quality Control who oversee testing, certificates of analysis and incoming product evaluations. Milk is tested for (b) (4) (b) (4) and (b) (4). Samples are taken at (b) (4) and tested for (b) (4), using the (b) (4). About (b) (4) tests are conducted (b) (4). Environmental swabs are taken with (b) (4) on a (b) (4) basis in (b) (4) random areas of the production plant.

**SANITATION**

Sanitation chemicals and training for their use is supplied by (b) (4). The firm has a sanitation manual with SOP's for clean in place (CIP) and clean out of place (COP) operations of the various equipment. Chemicals include; (b) (4) cleaner for manual cleaning, (b) (4), used for the HTST (b) (4) in CIP, (b) (4) sanitizer for COP, (b) (4) cleaner for CIP and COP, (b) (4) detergent (b) (4) for exteriors, (b) (4) detergent (b) (4) for exteriors, (b) (4) detergent for manual

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(b) (4) for painted surfaces, (b) (4) for CIP, (b) (4) and environmental sanitizer, (b) (4) sanitizer for floors and doorways, (b) (4), a sanitizer for fruit buckets, (b) (4) sanitizer for pre-op CIP systems, freezer circuits, and draw lines. A list of sanitation chemicals was collected as Exhibit 8.

CIP cleaning is generally conducted (b) (4)

cleaning is generally conducted with (b) (4)

COP cleaning was observed during the inspection. There were no observations noted for cleaning and sanitation.

**Silo Sanitation:**

The firm washes silos every (b) (4) using the following CIP system:

(b) (4)

Floors are concrete with drains within the manufacturing areas. A floor plan of the facility has been collected during previous inspections. Employees were observed wearing hairnets or hats, gloves, uniform shirts and aprons where appropriate. Hand wash stations in production rooms as well as employee rest rooms were inspected and had adequate hot water, soap and towels. The firm utilizes (b) (4). (b) (4) are tested (b) (4) and used only for outdoor cleaning and milk truck washouts.

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Pest control is contracted to (b) (4) and administered (b) (4) for the interior and (b) (4) for the exterior. Pest control records were reviewed for the previous 6 months. (b) (4)

were observed in various areas of the plant and perimeter of the building. There were no observations noted for pests.

**MANUFACTURING CODES**

Manufacturing codes are ink printed or heat branded onto the bottom of containers. The lot codes are changed on a (b) (4) basis by the floor Production Manager and are verified by Quality Control personnel.

On 2/28/12, the lot code of a half gallon container of ice cream was '022814A' where '02' designates February, '28' designates the 28<sup>th</sup> day of the month, '14' designates the year 2014 plus two years (expiration date), and 'A' designates that the ice cream (b) (4) (b) (4). This plant uses (b) (4) for various package sizes.

The Broken Arrow, OK plant uses letters (b) (4) exclusively as the last digit of the lot code. The Sylacauga, AL plant uses letters (b) (4) exclusively as the last digit of the lot code. A more detailed explanation of the lot coding system was collected as **Exhibit 6**.

**COMPLAINTS**

The firm has a procedure for documenting and investigating complaints. All complaints received by the firm are handled by (b) (6) and documented. The most common complaints include nut shell pieces in walnut or pecan ice cream, stems in strawberry ice cream or peach and cherry pits in ice creams.

Complaint #117716 was listed in FACTS to follow-up. The complaint concerning a foreign object found in Blue Bell milk chocolate on 11/12/2010 was covered and reported into FACTS. The complaint was cross correlated with the firm's as "Record ID #15324".

The complainant contacted the firm on 11/5/2010 about a 'hard, white object' in a ½ gallon container of Milk Chocolate ice cream, lot code '100812R'. The lot code indicated that it was manufactured at the Broken Arrow, OK plant. (b) (6) sent the complainant a self-addressed padded envelope and letter from the CEO, Paul W. Kruse, so the object could be sent back to the firm for analysis. The complainant did not send the object back and the complaint was eventually closed on 12/13/2010. Documents concerning the complaint were collected as **Exhibit 5**.

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**RECALL PROCEDURES**

The firm conducts mock recalls (b) (4) . (b) (4) for concerning a raw ingredient and (b) (4) finished product. A general procedure was collected as **Exhibit 2**.

**OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**

There were no significant objectionable conditions and a FDA 483 was not issued.

**REFUSALS/SAMPLES**

There were no refusals. No samples were collected during this inspection.

**ADDITIONAL INFORMATION**

(b) (3) (A)

**VOLUNTARY CORRECTIONS**

No voluntary corrections were implemented during the inspection.

**EXHIBITS COLLECTED**

1. Corn sugar interstate shipping documents (4 pages).
2. Recall procedure (2 ages).
3. Shipping document to (b) (4) (2 pages).
4. List of products manufactured (10 pages).
5. Complaint 117716 documents (3 pages).
6. Lot coding information (3 pages).
7. Production schedules (2 pages).
8. List of chemicals (1 page).
9. Supplier Ingredient Information (10 pages).
10. Recipe for Cake & Ice Cream (1 page).

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**ATTACHMENTS**

1. FDA 482 issued to Greg A. Bridges, V.P. Operations on 2/28/12.
2. FACTS assignment sheets.



Robert T. Lorenz, Investigator