

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: **1682009**

EI Start: 05/11/2010

EI End: 05/12/2010

TABLE OF CONTENTS

Summary..... 1
Administrative Data..... 3
History 4
Interstate Commerce..... 4
Jurisdiction..... 6
Individual Responsibility and Persons Interviewed 6
Firm's Training Program..... 7
Manufacturing/Design Operations 7
Manufacturing Codes 20
Complaints..... 20
Recall Procedures 20
Objectionable Conditions and Management's Response 21
Refusals 21
General Discussion with Management 21
Additional Information 22
Samples Collected 23
Voluntary Corrections 23
Exhibits Collected..... 23
Attachments 23

SUMMARY

This comprehensive inspection of food manufacturer was conducted in accordance with Compliance Program Guidance Manuals (CPGM) 7303.803: Domestic Food Safety Program, the Code of Federal Regulations 21, Parts 110: Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. This assignment was conducted per DAL-DO's FY 2010 work plan under FACTS assignment Number 1101846.

The previous inspection on 7/23/09-7/24/09 found the firm operating as a manufacturer of various ice creams and ice cream novelties. A 1-item FDA 483 was issued concerning condensation from an overhead caramel pipe dripping into 3 gallon tubs prior to filling and filler heads dripping

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009
EI Start: 05/11/2010
EI End: 05/12/2010

condensate onto wafers for ice cream sandwiches prior to filling. Some corrections were made and verified. The inspection was classified as VAI and is subject to routine follow-up.

The firm manufactures a variety of ice cream flavors and novelty frozen products. The current inspection covered the firm's receiving, warehouse storage, manufacturing, packaging, and exterior. The pest control, complaint and recall procedures were reviewed. The products covered during the inspection of ice cream and frozen novelties included: Homemade Vanilla Ice Cream, Banana Split Ice Cream, Buttered Pecan Ice Cream, Mini Cones, Dutch Chocolate Ice Cream, Ultimate Neapolitan Ice Cream, Ice Cream Sandwiches, Fudge Bomb, Rainbow Bar, Strawberry Fruit Bar, Cookies n Cream Ice Cream and Strawberry Ice Cream. The products covered during the inspection of baked goods that were then incorporated with frozen products were Cookies for Cookies n Cream Ice Cream and Mini Sugar Crisp cones for Mini Cones. A reconciliation exam was conducted on (b) (4) Cocoa, all bags were accounted for when matched with the Bill of Lading and no unexplainable discrepancies were noted.

No FDA-483 was issued, however the following items were discussed with management:

1. There was a small drip of condensation around one of the Ice Cream Sandwich lines. The firm corrected this during the inspection by making a bigger drip catch plate. I verified that this correction was done.
2. I observed a wire hanging over the fruit bar line and pointed this out to Mr. Prazak.
3. In filling areas I observed employees rotating to different areas from loading lids, loading containers, filling. The employees were not consistently using gloves and were moving from different tasks without changing gloves, adding gloves or washing hands. I discussed this with firm management and they said they would work on this through training employees.
4. I observed that the lid was missing at the beginning of the fruit bar line where strawberry puree is added. Mr. Prazak immediately instructed employee to replace lid and the lid was put in place to cover the open fruit puree port.
5. I observed boxes of sugar cone boxes on the floor in warehouse area.
6. I discussed with the firm that a bag of brown sugar had a hole in it. The issue was corrected by taping the bag closed.
7. I discussed with firm that, in the staging area, items were packed in tightly and not easily inspected. Mr. Kollman said they would correct this by re-organizing areas so these areas would not be so cluttered.

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009
EI Start: 05/11/2010
EI End: 05/12/2010

8. I observed a ripped open bag of sugar. Mr. Supak instructed employee to get tape and close up the bag.

9. I observed and discussed the following items found in warehouse: spider webs and spider near confectioner's sugar, leaning boxes against bags of sweet (b) (4) buttermilk, and bags of citric acid which caused there to be no space to walk around. Mr. Kollman said that he would take care of cleaning the warehouse and re-organize to reduce clutter.

10. I observed and discussed with the firm that the fans used to cool the cookies needed to be cleaned. Mr. Kollman said that he would put the fans on the cleaning schedule.

No samples were collected or refusals encountered during the current inspection.

(b) (3) (A) For additional information the ALERT card and Reportable Food Registry (RFR) at a Glance was given to the firm.

ADMINISTRATIVE DATA

Inspected firm: Blue Bell Creameries Inc
Location: 1101 S Blue Bell Rd
Brenham, TX 77833-4413
Phone: 979-836-7977
FAX: 979-421-2595
Mailing address: 1101 S Blue Bell Rd
Brenham, TX 77833-4413

Dates of inspection: 5/11/2010, 5/12/2010
Days in the facility: 2
Participants: Lorie S Hannappel, Investigator

On 5/11/2010, I, Consumer Safety Officer Lorie S. Hannappel arrived at the firm, displayed credentials, and issued the FDA 482- Notice of Inspection to Mr. Paul W. Kruse, President of Blue Bell Creameries, LP who identified himself as the most responsible person at the firm.

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009
EI Start: 05/11/2010
EI End: 05/12/2010

HISTORY

The firm was started in 1907 as LP (Limited Partnership) and has always been in Brenham, Tx. This location is the headquarters. The firm has another facility located in Brenham at 802 Creamery St, which they call the Snack Plant. The Snack Plant has (b) (4) lines where water based products are made and then brought to the cold storage at this location. The firm has two other facilities located outside of Brenham; Broken Arrow, Oklahoma and Sylacauga, Alabama. The firm has been at this location since 1972 and about every (b) (4) years they (b) (4).

The firm has (b) (4) sq ft of production and cold storage space and (b) (4) sq ft of warehouse space. There are several buildings on this facility. There are two buildings used for production of products. The main building is used for production of ice cream, ice cream novelties and cold storage. The other building functions mainly as a warehouse, with Bakery located on second floor of warehouse building. The Bakery products are used in ice cream and ice cream novelties.

The firm has (b) (4) full time employees divided into approximately (b) (4) office employees and (b) (4) employees throughout the rest of the firm. The firm's estimated gross annual sales are approximately \$(b) (4).

The firm's office hours are 8:00am-5:00pm Monday through Friday and manufacturing hours are (b) (4).

The previous inspection on 7/23/09-7/24/09 found the firm operating as a manufacturer of various ice creams and ice cream novelties. A 1-item FDA 483 was issued concerning condensation from an overhead caramel pipe dripping into 3 gallon tubs prior to filling and filler heads dripping condensate onto wafers for ice cream sandwiches prior to filling. Some corrections were made and verified. The inspection was classified as VAI and is subject to routine follow-up.

All FMD-145 and post-inspectional FDA correspondence should be directed to:

Mr. Paul W. Kruse, President
1101 S. Horton, P.O. Box 1807
Brenham, TX 77834

INTERSTATE COMMERCE

The firm has (b) (4)% interstate commerce. The firm sells (b) (4)% wholesale. The firm has a small shop for tours to purchase products.

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009
EI Start: 05/11/2010
EI End: 05/12/2010

The firm's top Customers out of State are:

(b) (4)

I received a copy of an Invoice showing product to be delivered to Walmart, 2008 W. Grant, Pauls Valley, OK 73075 from Blue Bell Creameries, Brenham, Tx (**Exhibit #1**).

The firm's top Suppliers out of State and one of the raw products they supply are listed below:

(b) (4)

I received a copy of the Straight Bill of Lading from (b) (4) showing interstate commerce of raw ingredients from shipping point (b) (4) (b) (4) (**Exhibit #2**). This Bill of Lading was used in the Reconciliation Exam.

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009

EI Start: 05/11/2010

EI End: 05/12/2010

JURISDICTION

The firm manufactures a variety of ice cream flavors and novelty frozen products. The products covered during the inspection of ice cream and frozen novelties included: Homemade Vanilla Ice Cream, Banana Split Ice Cream, Buttered Pecan Ice Cream, Mini Country Cones, Dutch Chocolate Ice Cream, Ultimate Neapolitan Ice Cream, Ice Cream Sandwiches, Fudge Bomb, Rainbow Bar, Strawberry Fruit Bar, Cookies n Cream Ice Cream and Strawberry Ice Cream. See **Exhibit #3** for labels of Strawberry Ice Cream. The products covered during the inspection of baked goods that were then incorporated with frozen products were Cookies for Cookies and Cream Ice Cream and Mini Sugar Crisp cones for Mini Country Cones. See **Exhibit #4** for a list of all Blue Bell Creameries Products.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Upon arriving at the firm I issued a FDA 482-Notice of Inspection to Mr. Paul W. Kruse, Chief Executive Officer and President of Blue Bell Creameries, who identified himself as the most responsible person at the firm. Mr. Kruse then introduced me to Mr. Tommy Supak, Food Safety; Mr. Andy F. Kollman, Quality Control Manager; and Mrs. Stacy L. Thiel, Quality Control Supervisor, all of whom then accompanied me throughout the inspection because Mr. Kruse was otherwise occupied. Mr. Supak, Mr. Kollman, and Mrs. Thiel were present throughout the inspection answering questions and providing documents.

Mr. Tommy Supak, Food Safety, was formerly the Quality Control Manager and is now in this new position to guide and train Mr. Andy Kollman as the new Quality Control Manager. In this position Mr. Supak is responsible for overseeing new people, Food Safety, quality control, Hazard Analysis & Critical Control Points (HACCP), audits, housekeeping inspection, and Standard Operating Procedures (SOP's). Mr. Supak reports to Greg Bridges, Plant Manager. He has hire and fire ability and stated that there is an open door access to the president of company. Mr. Supak has been with Blue Bell Creameries for 38 years.

Mr. Andy F. Kollman, Quality Control Manager is responsible for testing all raw ingredients, overseeing Food Safety, Hazard Analysis & Critical Control Points (HACCP), audits, regulatory inspection, and quality issues. Mr. Kollman has hire and fire ability but is not allocated a budget. Mr. Kollman reports to Greg Bridges, Plant Manager. Mr. Kollman has been with the firm for 14 years and in this current position a little over a year.

Mrs. Stacy L. Thiel, Quality Control Supervisor, is responsible for overseeing the lab, signing off on testing, and sitting in on audit and regulatory inspections. Mrs. Thiel is in charge of all Mock

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009
EI Start: 05/11/2010
EI End: 05/12/2010

Withdrawals (the firm calls Recalls Withdrawals). She is the Food Safety training class's coordinator and has recently been certified in Bioterrorism. Mrs. Thiel does not have hire and fire ability and reports to Mr. Andy Kollman. She has been with Blue Bell Creameries for 5 years.

Mr. Paul Prazak, Assistant Plant Supervisor, is responsible for overseeing all plant operations and personnel.

FIRM'S TRAINING PROGRAM

The firm 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. According to firm management, every employee receives 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 receives training from (b) (4) on food protection.

MANUFACTURING/DESIGN OPERATIONS

The firm is located on approximately (b) (4) acres with several buildings. The firm has one milk truck receiving bay with (b) (4) building and (b) (4) silos. The firm has one cream bay with (b) (4) cream silos. The firm has one major production building used for the primary manufacturing of all ice cream products, office space, tour center, and small retail area. Refer to **Exhibit #5** for firm layout to see locations of milk bay, cream bay, and major production building. The minor production building is known as the warehouse, but also consists of the bakery area for cookies that go into the ice cream products. There is a fleet maintenance building and a Rail Car dock for receiving corn syrup.

The firm maintains their own fleet of trucks to deliver products directly to distribution centers and stores. The firm uses (b) (4) for maintenance and checks temperature on trucks (b) (4) (b) (4)

The firm uses (b) (4) for most of production and when used as an ingredient. The firm uses (b) (4) (b) (4) for cleaning.

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI:

1682009

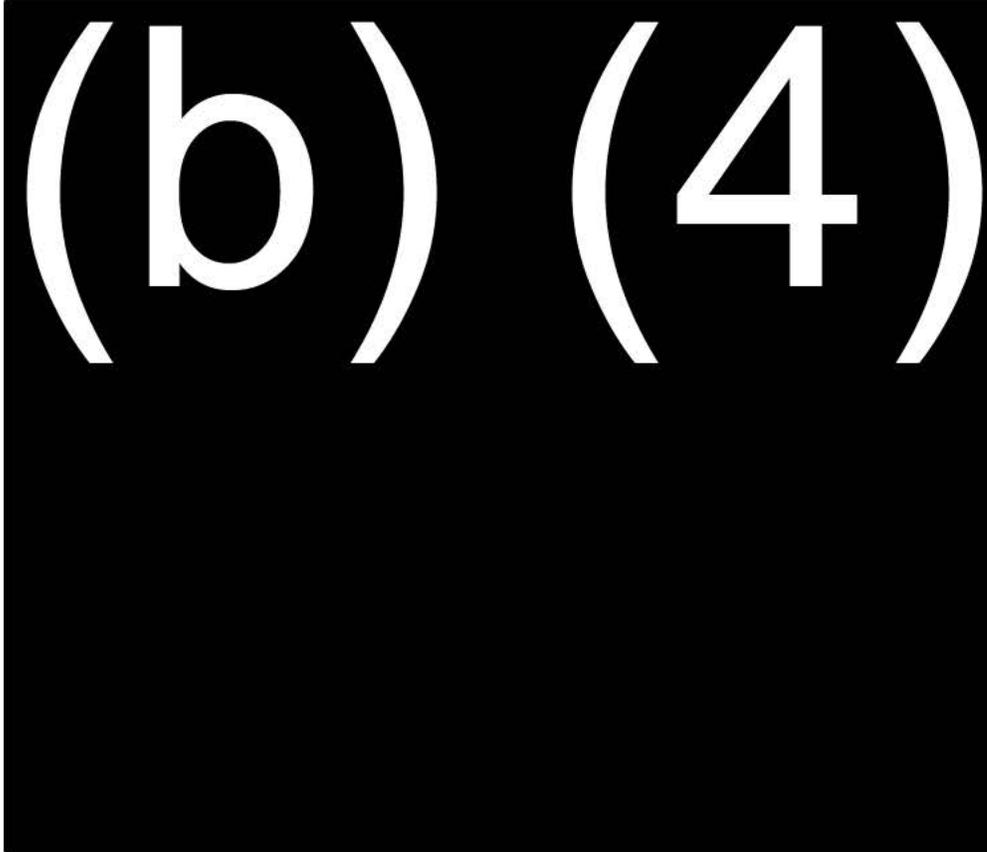
EI Start:

05/11/2010

EI End:

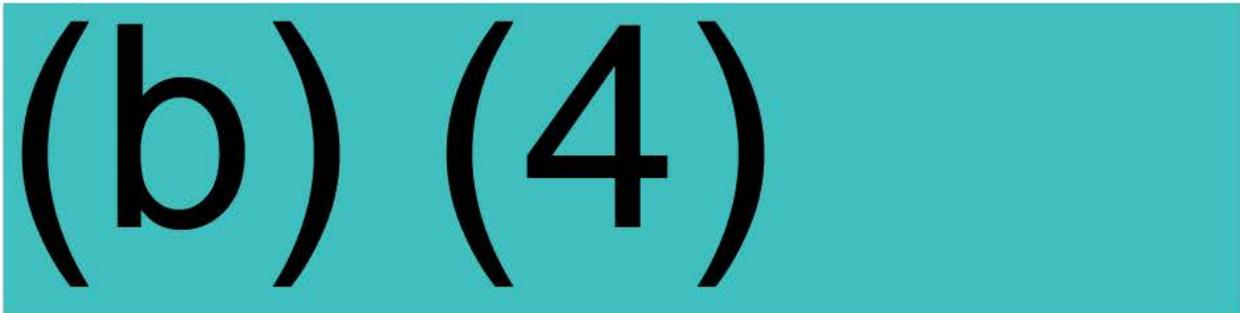
05/12/2010

The general overview of the ice cream manufacturing flow is as follows:



Receiving:

The firm receives around (b) (4) tanker loads of (b) (4) gals of milk per tanker. The firm has (b) (4) milk silos and (b) (4) condensed skim milk silos. When a tanker of milk arrives at the firm, the seals on the dome and back valve are checked and verified. The firm employee then breaks the seals and (b) (4) (b) (4) A sample is then collected and tests are run. The following tests are done on the milk sample:



Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009

EI Start: 05/11/2010

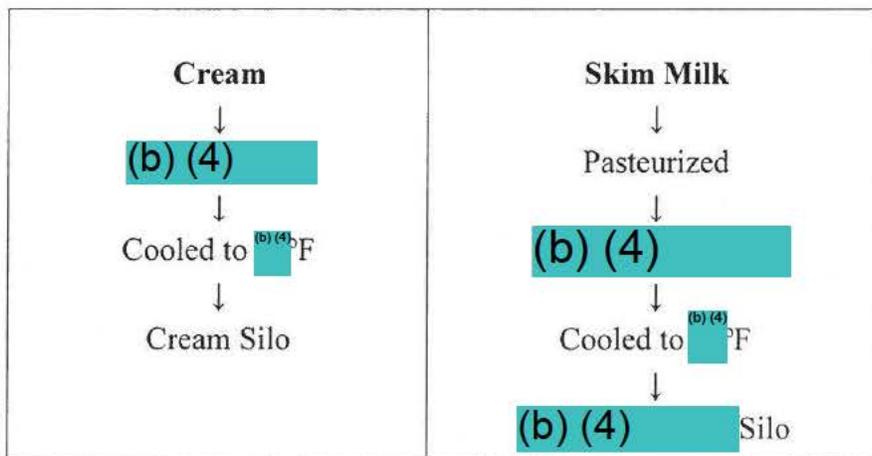
EI End: 05/12/2010

(b) (4)

After testing is done and if satisfactory results are achieved, the milk is unloaded to silo.

I looked at the *Milk Lab Report* of all the tests run on loads of milk on 5/11/10. The Lab Report will be checked by lab supervisor. Mr. Kollman showed me the *wash tag* that verified that the tanker had been washed. The *wash tag* had the time it was washed, date, trailer number and seal. The lab technicians are trained by Mr. Kollman and Mrs. Thiel.

The milk will go from the silo to a **Milk Separator**. The Milk Separator is a (b) (4) which separates the **Cream** from the **Skim Milk**. The (b) (4) and sent to one of the cream silos. The skim milk is pasteurized and then goes through an (b) (4) where it is (b) (4). The skim milk is then sent to one of the (b) (4) skim milk silos.



The firm also receives cream tankers. When the cream tanker arrives, a sample is tested to make sure the cream has (b) (4). The cream tankers are (b) (4) and receive all tests that the milk tankers do except the (b) (4) and the (b) (4) because these test are run at the milk stage. The cream goes directly to cream silo. The firm has (b) (4) cream silos and each silo holds (b) (4) (b) (4).

Sanitation:

The firm washes silos (b) (4) which works out to be between (b) (4) or (b) (4). The firm has the following sanitation process for this area:

Clean-in-Place (CIP) system



(b) (4)

Establishment Inspection Report

Blue Bell Creameries Inc

Brenham, TX 77833-4413

FEI:

1682009

EI Start:

05/11/2010

EI End:

05/12/2010

(b) (4)

Blender Room #1:

The firm was blending a liquid mix labeled Mix #: (b) (4) - Cheesecake Mix. According to firm management, all the ingredients are (b) (4) in to the blend tank. Each batch blended will have a unique batch/mix number. The firm uses a barcode scanner to scan barcodes of Lot numbers of each ingredient added to each unique batch. The silos are (b) (4) tracked.

The firm stated that (b) (4) are made (b) (4) then they (b) (4) to water, and then (b) (4). The firm uses (b) (4) if line is used for allergen, with allergens (b) (4). The firm also has an allergen (b) (4).

The firm does (b) (4) blends at a total of (b) (4) gallons of blended mix per day.

The firm uses a Clean-in-Place (CIP) system to sanitize everything (b) (4).

Blender

(b) (4)

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI:

1682009

EI Start:

05/11/2010

EI End:

05/12/2010

(b) (4)

Production Areas:

Mr. Paul Prazak, Assistant Plant Supervisor joined the inspection at this time. He showed responsibility by answering questions and directing employees to address any issues. The firm has (b)(4) fill lines that consist of 3 gallon, ½ gallon, pints, 3oz cups, sandwiches, and other frozen novelties. I observed (b)(4) lines currently in production during inspection. The following is a list of production lines I observed. For the first production line, I have given a detailed flow chart. The rest of the lines, if not described in detail, have a similar flow and only differences or observations will be given below name of product.

Establishment Inspection Report

Blue Bell Creameries Inc

Brenham, TX 77833-4413

FEI:

1682009

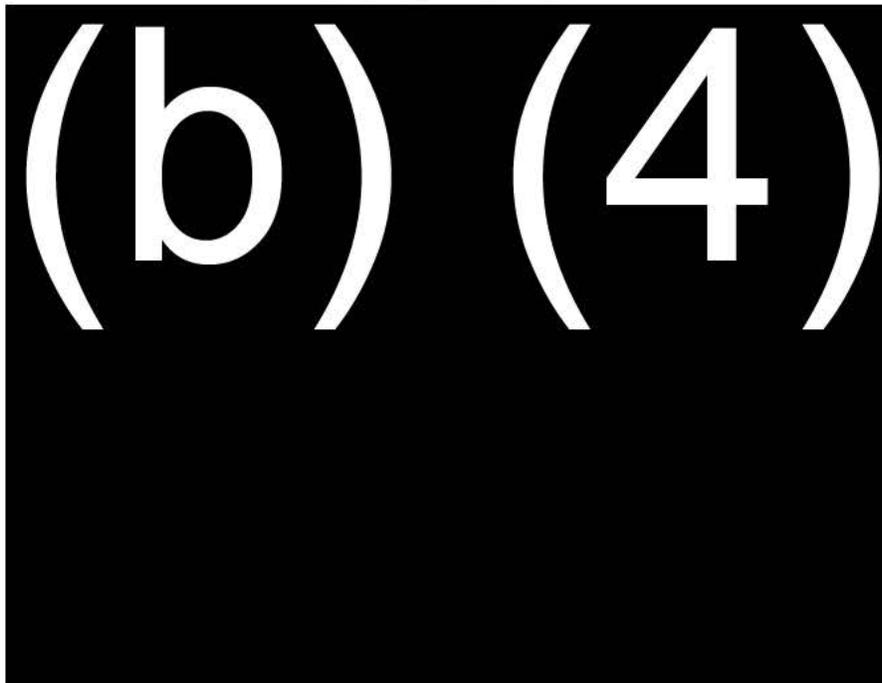
EI Start:

05/11/2010

EI End:

05/12/2010

Banana Split ½ Gallon



Homemade Vanilla ½ gallon

On production line ^{(b) (4)} the firm uses a (b) (4) to mark manufacturing code on carton. This is (b) (4) production lines have a printed manufacturing code with an ink stamp.

Buttered Pecan ½ gallon

The firm uses an ink stamp for printing manufacturing code on carton.

Mini Cones (Mini Country Cones)

Employee's sign off that they are dealing with an allergen when working on this line.

Dispense Cone



(b) (4)

Dutch Chocolate ½ gallon –Dual Pint

This line (b) (4) that is why it is called Dual Pint.

Ultimate Neapolitan ½ gallon

On this line Chocolate Ice Cream, Vanilla Ice Cream and Strawberry Ice Cream each from different flavor tanks are pumped into ½ gallon container, making three distinct sections of each flavor.

Ice Cream Sandwich

I observed (b) (4) lines of Ice Cream Sandwiches. Following the diagram below, (b) (4)

(b) (4)

(b) (4)

I noticed a drip of condensate near Ice Cream Sandwich line and conveyed my concern.

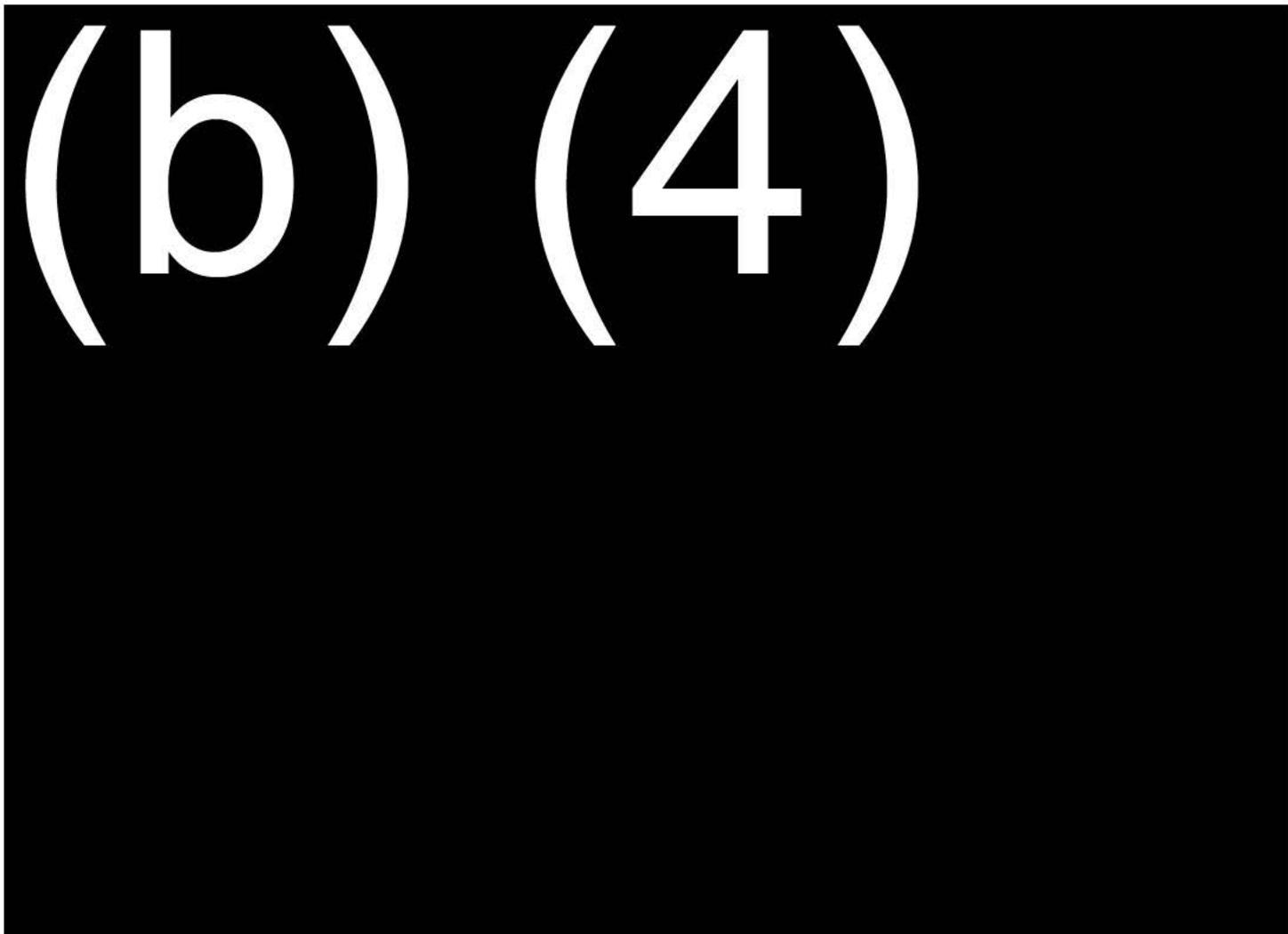
Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009
EI Start: 05/11/2010
EI End: 05/12/2010

Fudge Bomb

This is a frozen novelty that is created in a mold with a layer of chocolate, then a layer of banana then a layer of chocolate. A non hazardous (b) (4) (b) (4) and (b) (4) layer as it is added. The solution is (b)(4) (b) (4), so the firm (b) (4) by (b) (4) under (b) (4). The molds are washed (b) (4). The following is the flow of the process.



Rainbow Bar

This is a frozen novelty that is created in a mold with layers of a variety of water based colored, flavored mixtures. Similar process as the Fudge Bomb is used with more layers and each a different color and flavor. The Rainbow Bar is packed with 3 dozen individually wrapped Rainbow Bars to a box for bulk retail sales. The manufacturing code is printed on outside of the box.

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009
EI Start: 05/11/2010
EI End: 05/12/2010

Strawberry Fruit Bar

This is also a frozen novelty composed of mainly pureed strawberries. I observed that the lid was missing at the beginning of the fruit bar line where strawberry puree is added. Mr. Prazak immediately instructed employee to replace lid and the lid was put in place to cover the open fruit puree port. The fruit puree is then shot into molds in (b) (4) to freeze, released, individually wrapped and 6 individually wrapped bars are placed in a box. Mr. Prazak said that an (b) (4) is done before set up. I observed a wire hanging over the fruit bar line and pointed this out to Mr. Prazak.

3oz cups Homemade Vanilla Ice Cream

These are packaged 12-3oz cups each with manufacturing code stamped on bottom in plastic bag.

Banana Split- Dual Pint

This product has chocolate, strawberry and pineapple syrups introduced into ice cream via (b) (4) (b) (4) It introduces them in a fashion that swirls them into the ice cream without fully mixing in.

Cookies n Cream- Dual Pint

Cookies that the firm manufactures are mixed into vanilla ice cream. In filling areas employees rotate to different areas from loading lids, loading containers, filling. I observed employees rotating to different areas from loading lids, loading containers, filling. The employees were not consistently using gloves and were moving from different tasks without changing gloves, adding gloves or washing hands. I discussed this with the firm.

Homemade Vanilla Ice Cream

3 Gallon Strawberry Ice Cream

The label is placed on the outside of the 3 gallon tub and manufacturing code is printed on top of the lid. Refer to **Exhibit #3** to see label of 3 Gallon Strawberry being manufactured at the time of the inspection. I verified that previous 483 item from past inspection were corrected. The firm rerouted the whole line and it was not dripping over or even located near open containers of 3 gallon Strawberry Ice Cream.

(b) (4)

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009
EI Start: 05/11/2010
EI End: 05/12/2010

Sanitation:

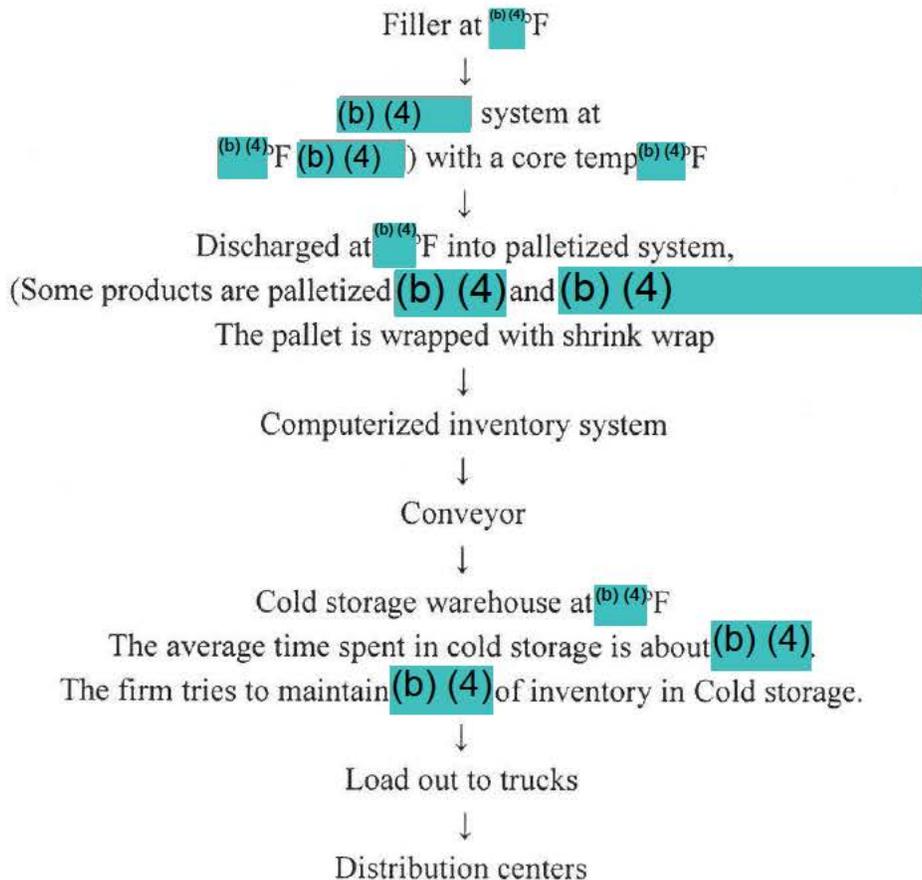
(b) (4) the firm (b) (4) everything is taken apart including gaskets, and fill area is washed by hand using a COP (Cleaned-Out-of- place) system. The freezers are cleaned using the CIP (Clean-In-Place) system. (b) (4) the firm sanitizes with a (b) (4) solution. The cleaning products used by the firm are all for food use and are as follows:

- (b) (4) **Cleaner**- is used as the primary cleaner in CIP and COP systems.
- (b) (4) Sanitizer is used for pre-operations and start-up.
- (b) (4) - is used as an (b) (4) sanitizer in the CIP system.
- (b) (4) **Sanitizer**/(b) (4) **Sanitizer**- is used for manually sanitizing of equipment.
- (b) (4) Cleaner used for (b) (4) cleaning equipment.

I observed both the employees men and women's restroom and no observations where found.

Cold Storage:

After products are filled and packaged they go through the following process:



Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009
EI Start: 05/11/2010
EI End: 05/12/2010

The firm has (b) (4) dock doors used for the firm's (b) (4) Multi Route Trucks. These Multi route trucks deliver straight to local stores. The firm also has (b) (4) dock doors for the firms Tractor Trailers which deliver product directly to Blue Bell Distribution centers. The firm has around (b) (4) Tractor trailers.

South end Dry Storage

The firm uses a (b) (4) system. All dry goods have a tag and scanner with lot number located on them. There are (b) (4) dry storage areas: Area (b) (4) Dry Storage holds mainly flavorings and Area (b) (4) Dry Storage is mainly used to store sugar cones. I observed boxes of sugar cone on the floor, which I discussed with firm management. I discussed with the firm that a bag of brown sugar had a hole in it. I discussed with firm that in staging area, items were packed in tightly and not easily inspected.

Warehouse:

This Warehouse/Bakery is in a separate building from the main production area. This Warehouse/Bakery is located on the northeast corner of the facility of Blue Bell. This warehouse stores around (b) (4) % packaging for products.

When the firm receives a shipment, the first thing they do is check the seals on the truck. The incoming items get inspected and scanned into system. The firm uses (b) (4) and (b) (4) computer systems to enter and then assign a slot. This system was implemented at this location about a year ago. The computer helps with (b) (4)

I observed a ripped open bag of sugar. Mr. Supak instructed employee to get tape and close up bag. I observed the following items and discussed them with the firm: spider webs and spider near confectioner's sugar, leaning boxes against bags of (b) (4) buttermilk, and bags of citric acid which left no space for me to walk around.

Bakery:

The firm's Bakery is located mainly on the second floor of the warehouse building located on the facility of Blue Bell. The firm has been producing cookies which are placed in Cookies n Cream Ice Cream for around 10 years. All Bakery products manufactured at this facility are only used in ice cream products.

The firm used the following process for the production of cream filled cookies:

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI:

1682009

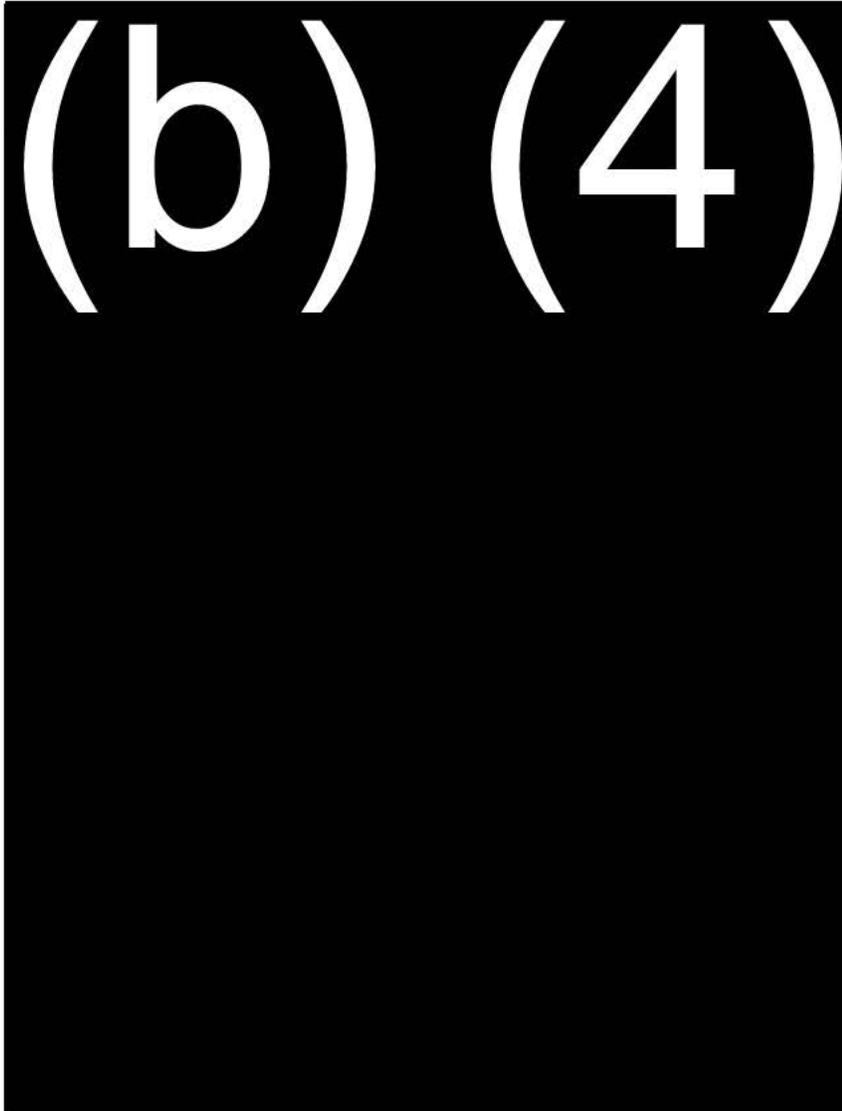
EI Start:

05/11/2010

EI End:

05/12/2010

Chocolate Cookies



The firm has Preventative Maintenance of scales, water safety, air filters that can be retrieved from the computer. The firm has a lab technician come through and check every scale (b) (4). Mrs Karen Harmel, showed me temperature logs, scales, check finished product moisture, (b) (4) and weight. Mrs. Harmel said that a QC technician in bakery documents from start to finish, box temperatures. She checks metal detectors (b) (4).

At the end of the day the (b) (4) to the (b) (4) to keep a (b) (4). The filling is made of sugar, fat, confectioner's sugars and soy shortening. I verified that soy was indicated on the label of Cookies n Cream Ice Cream. The filling parts and mixing bowls are (b) (4) washed. The firm cleans all surfaces of the cookie line by (b) (4). The floors are swept. All the belts on the conveyor are cleaned

Establishment Inspection Report

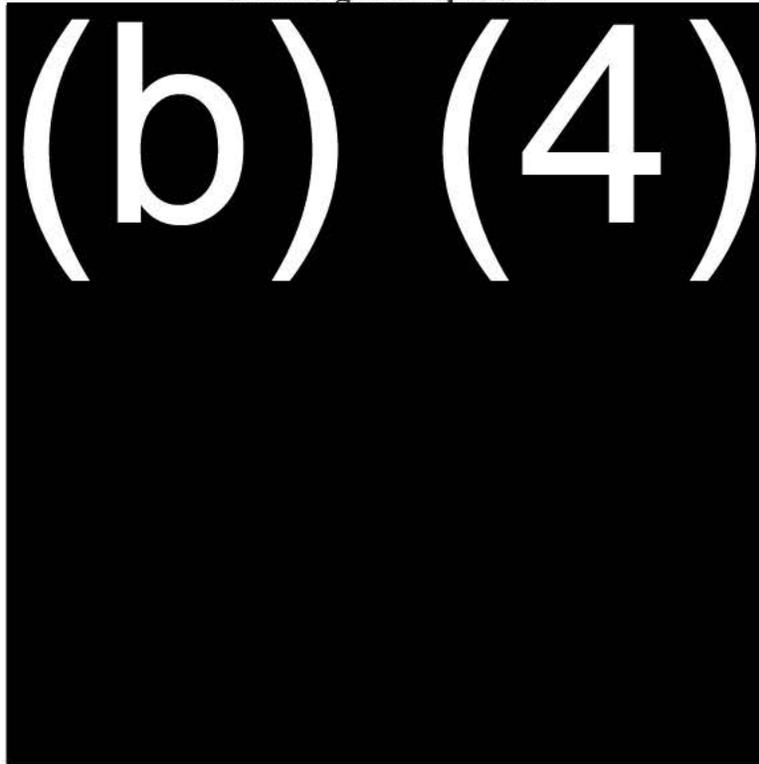
Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009
EI Start: 05/11/2010
EI End: 05/12/2010

(b) (4) I observed and discussed with the firm that the fans used to cool the cookies needed to be cleaned.

The firm uses the following process for production of Mini Sugar Crisp Cones use in Mini Country Cones:

Mini Sugar Crisp Cones



The manufacturing codes used in this area are as follows:

(b) (4) [Redacted]
[Redacted]
[Redacted]

051210 = Date Produced

Reconciliation Exam:

I conducted a reconciliation exam on **(b) (4)** Cocoa. The **(b) (4)** bags were accounted for when matched with the Bill of Lading and no unexplainable discrepancies were noted. I verified that **(b) (4)** Cocoa from **(b) (4)** contained **(b) (4)** bags in good and sound condition. The bags were located in **(b) (4)** the staging area in the dry storage warehouse. Refer to the copy of the Invoice/ Bill of lading, the copy of the Certificate of Analysis/ Receipt traveler and the copy of the load inspection in **Exhibit #2**.

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009
EI Start: 05/11/2010
EI End: 05/12/2010

MANUFACTURING CODES

Below is an example the manufacturing codes the firm uses.

<p>Homemade Vanilla Ice Cream Code Date: 051112A Batch #: 220586</p>

Code Date Breakdown:

0511 = May 11th, the day the product was manufactured

12 = Code date expiration of 2 years (2010-2012)

A = (b) (4)

Other letters have the following designation:

(b) (4)

Batch # 220586 is automatically generated by computer.

COMPLAINTS

Consumer Complaints come into the firm and are given to one employee. That employee then contacts customer to find out further information. The most common complaint that is received is about reporting foreign objects.

RECALL PROCEDURES

The firm refers to the recall of products as Withdrawals. The firm performs mock Withdrawals (b) (4) and they alternate between finished product and raw ingredients. The last Mock Withdrawal was on 2/12/2010 and had (b) (4) distribution sites. I received a copy of the mock withdrawal from Mrs. Thiel showing units and the location of product distribution sites. Refer to copy of *W/D Withdrawal Summary- Finished Goods* in **Exhibit #6**. I also received a sheet showing mix tanks that were used, amounts from each tank and flavors used. Refer to copy of *Production Withdrawal Summary* in **Exhibit #6**. I verified that the firm had a procedure for the withdrawal of product.

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009

EI Start: 05/11/2010

EI End: 05/12/2010

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

No FDA-483 Inspectional Observations was issued during the current inspection.

REFUSALS

No refusals were encountered during the current inspection.

GENERAL DISCUSSION WITH MANAGEMENT

Mr. Tommy Supak, Food Safety, Mr. Andy F. Kollman, Quality Control Manager; and Mrs. Stacy L. Thiel, Quality Control Supervisor; were all present for the closing general discussion. They called Mr. Paul W. Kruse, President of Blue Bell Creameries and Mr. Kruse was busy so he asked if it would be acceptable for them to relay the information of items discussed.

No FDA-483 was issued, however the following items that I had previously discussed during inspection were discussed with management was reviewed:

1. There was a small drip of condensation around one of the Ice Cream Sandwich lines. The firm corrected this during the inspection by making a bigger drip catch plate. I verified that this correction was done.
2. I observed a wire hanging over the fruit bar line and pointed this out to Mr. Prazak.
3. In filling areas I observed employees rotating to different areas from loading lids, loading containers, filling. The employees were not consistently using gloves and were moving from different tasks without changing gloves, adding gloves or washing hands. I discussed this with firm management and they said they would work on this through training employees.
4. I observed that the lid was missing at the beginning of the fruit bar line where strawberry puree is added. Mr. Prazak immediately instructed employee to replace lid and the lid was put in place to cover the open fruit puree port.
5. I observed boxes of sugar cones on the floor in warehouse area.

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009
EI Start: 05/11/2010
EI End: 05/12/2010

6. I discussed with the firm that a bag of brown sugar had a hole in it. The issue was corrected by taping bag closed.

7. I discussed with firm that, in staging area, items were packed in tightly and not easily inspected. Mr. Kollman said they would correct this by re-organizing areas so the areas would not be so cluttered.

8. I observed a ripped open bag of sugar. Mr. Supak instructed employee to get tape and close up bag.

9. I observed and discussed the following items found in warehouse: spider webs and spider near confectioner's sugar, leaning boxes against bags of (b) (4) buttermilk, and bags of citric acid which left no space for me to walk around. Mr. Kollman said that he would take care of cleaning the warehouse and re-organize to reduce clutter.

10. I observed and discussed with the firm that the fans used to cool the cookies needed to be cleaned. Mr. Kollman said that he would put the fans on the cleaning schedule.

(b) (3) (A) For additional information the ALERT card and Reportable Food Registry (RFR) at a Glance was given to the firm.

I read this warning statement at the closing discussion: *"The conditions listed may after further review by the Agency be considered to be violations of the Food, Drug and Cosmetic Act or other statues. Legal sanctions available to FDA may include seizure, injunction, civil money penalties and prosecution, if your firm does not voluntarily correct conditions."*

ADDITIONAL INFORMATION

Pest Control:

The firm uses (b) (4) located out of (b) (4) I looked at the (b) (4) Customer service log. (b) (4) services the firm (b) (4) internally and externally (b) (4). (b) (4) uses (b) (4) which is traps (b) (4) (b) (4)

(b) (4) Traps - that was done on 5/6/10. There was one mouse caught and five sites inaccessible out of (b) (4) traps- the other warehouse is where the inaccessible traps were.

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI:

1682009

EI Start:

05/11/2010

EI End:

05/12/2010

I did not observe any pest activities during the current inspection.

SAMPLES COLLECTED

No samples were collected at the firm during the current inspection.

VOLUNTARY CORRECTIONS

The previous inspection had two 483 items which I verified had been corrected. The Ice Cream Sandwich line had been corrected with a drip platform to cover area over sandwiches. The firm rerouted the whole 3 gallon line so it no longer was dripping over open containers of 3 gallon Strawberry Ice Cream.

EXHIBITS COLLECTED

Exhibit #1: A copy of Invoice from Blue Bell showing product to be delivered to Walmart, 2008 W. Grant, Pauls Valley, OK 73075 (1 page)

Exhibit #2: A copy of the Straight Bill of Lading, Certificate of Analysis, Receipt Traveler, Load Inspection for reconciliation of (b) (4) Cocoa from (b) (4) Lot (b) (4) (4 pages)

Exhibit #3: Labels of 3 gallon Strawberry Ice Cream (4 pages)

Exhibit #4: A copy of Blue Bell Creameries Product List (10 page)

Exhibit #5: A copy of Blue Bell Creameries Main Building Layout (1 pages)

Exhibit #6: A copy of Blue Bell Creameries *W/D Withdrawal Summary- Finished Goods* and *Production Withdrawal Summary* (2 pages)

ATTACHMENTS

Attachment 1: Form FDA 482, Notice of Inspection dated 5/11/2010 (1 page).

Establishment Inspection Report

Blue Bell Creameries Inc

Brenham, TX 77833-4413

FEI:

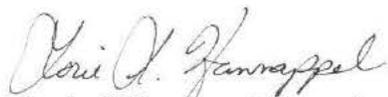
1682009

EI Start:

05/11/2010

EI End:

05/12/2010



Lorie S Hannappel, Investigator