

TABLE OF CONTENTS

Summary	1
Administrative Data	2
History.....	2
Interstate Commerce	3
Jurisdiction.....	3
Individual Responsibility and Persons Interviewed.....	3
Firm's Training Program	4
Manufacturing/Operations	4
Sanitation	6
Manufacturing Codes.....	7
Complaints	8
Recall Procedures.....	8
Objectionable Conditions and Management's Response	8
Refusals/Samples	8
Additional Information	8
Voluntary Corrections.....	8
Exhibits Collected.....	9
Attachments	9

SUMMARY

This GMP inspection of a food manufacturer was conducted per FACTS assignment #1356105 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.

There were no previous inspections listed in FACTS or TURBO for this smaller specialized facility of Blue Bell Creameries, LP.

On 4/4/12, FDA credentials were shown and a FDA 482 and RFR Brochure were issued to Jason D. Jenkins, Plant Manager. The current inspection found the firm operating as a manufacturer of dairy and ice-water, and combo novelties on sticks. During the inspection, Dream Bars, Crème Pops, Moo Bars and Fudge Bars were being manufactured and observed. A field exam was conducted on Dream Bars 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

Establishment Inspection Report
Blue Bell Creameries, LP, Snack Plant
Brenham, TX 77833

FEI: **3004323519**
EI Start: 04/04/2012
EI End: 04/04/2012

FDA" was provided to Jason D. Jenkins, Plant Manager. At the conclusion of 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 main plant mailing address below.

ADMINISTRATIVE DATA

Inspected firm: Blue Bell Creameries, LP, Snack Plant
Location: 802 Creamery St
Brenham, TX 77833
Phone: 979-830-1805
FAX:
Mailing address: 1101 S. Blue Bell Road
Brenham, TX 77833

Dates of inspection: 4/4/2012
Days in the facility: 1
Participants: Robert T. Lorenz, Investigator

On 4/4/12, FDA credentials were shown and a FDA 482 and RFR Brochure were issued to Jason D. Jenkins, Plant Manager. On 4/4/12, I provided Jason D. Jenkins, Plant Manager 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. (b) (3) (A)
(b) (3) (A).

HISTORY

The company has been in business since 1907 as a family business and started as a private corporation. The inspected facility was the original location of the firm which now only manufactures ice cream and ice water novelties on sticks. The main plant was constructed in 1972 and is located nearby at 1101 S. Blue Bell Road. 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 at this facility are (b) (4) (b) (4) using (b) (4) of employees and lines. There are currently about ^(b) production employees and ^(b) office employees at this location. Sales are (b) (4) wholesale. Daily volume at this facility is about (b) (4) dozen units

Establishment Inspection Report
Blue Bell Creameries, LP, Snack Plant
Brenham, TX 77833

FEI: 3004323519
EI Start: 04/04/2012
EI End: 04/04/2012

per day; annual volume at the main facility is (b) (4) gallons. Total sales are about \$(b) (4) annually. The other two other related Blue Bell ice cream main plants are located in Broken Arrow, OK and Sylacauga, AL, with production of (b) (4) gallons at all three main plants combined. The firm maintains a webpage at www.bluebell.com.

There were no previous inspections of this plant listed in FACTS or TURBO.

INTERSTATE COMMERCE

The corn sugar and high fructose corn sugar comprise about (b) (4) % of the ice water novelties. High fructose corn sugar and corn sugar are shipped to the firm by railcar and pumped into tanks from a railway spur. Shipping documents and a certificate of analysis for invertose high fructose corn sugar shipped by rail from (b) (4) in (b) (4) to the firm were collected as **Exhibit 1**.

Other raw ingredients such as color and flavor concentrates, chocolate, and coconut oil are shipped from interstate commerce. Milk used in dairy mix is primarily purchased from (b) (4) (b) (4) within a (b) (4) mile radius of the facility.

Finished products are shipped to the nearby main plant in freezer trucks for distribution. About (b) (4) % of the finished product ice creams and stick novelties are shipped to distribution centers in (b) (4) surrounding states from the main plant.

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 4/4/12, FDA credentials were shown and a FDA-482 and RFR Brochure were issued to Jason D. Jenkins, Plant Manager (**Attachment 1**). Mr. Jenkins identified himself as the most responsible at the facility. He is normally present on a day-to-day basis, oversees all aspects of production and manufacturing, and has overall authority to detect, prevent and correct problems at the plant. Mr. Jenkins said he reports to Mr. Greg Bridges, VP Operations, at the main plant nearby. Mr. Jenkins has been in his current positions for about 16 years.

Establishment Inspection Report
Blue Bell Creameries, LP, Snack Plant
Brenham, TX 77833

FEI: 3004323519
EI Start: 04/04/2012
EI End: 04/04/2012

Also present and accompanying me during the inspection and at the closing meeting were Andrew (Andy) F. Kollman, Quality Control Manager and (b) (6) Quality Control. Mr. Kollman has been at his present position for 6 years and with the company for 14 years. Mr. Paul W. Kruse, CEO is the most responsible person of the company and presides at the nearby main plant. An organizational chart is attached as **Exhibit 2**.

FIRM'S TRAINING PROGRAM

(b) (6) Quality Control, stated that 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.

The firm also receives training from the (b) (4) on food protection.

MANUFACTURING/OPERATIONS

The firm is located on approximately ^{sq} acres encompassing (b) (4) buildings. The first building encompasses the manufacturing facility and consists of about (b) (4) SF with concrete floors and brick walls. This facility was the original building utilized since 1907 by the founders of the company.

The second adjacent building was recently acquired from an old cotton gin and was converted into a warehouse area consisting of about (b) (4) SF with concrete floor and metal beam construction. The warehouse was inspected and holds packaging boxes, wooden sticks for novelty products, cartons, and labels for the production plant on metal pallet racks. A third building is primarily used as an unloading dock whereby packaging material is received then moved to the warehouse. The warehouse has ^{tin} tin cats on the interior and ^{bait} bait boxes around the perimeter under contract from (b) (4) for pest control. There were no observations noted for the warehouse.

The main plant nearby (1101 S. Blue Bell Road) manufactures about ^{gal}(b) (4) gallons of ice cream products annually and is also the corporate headquarters for Blue Bell Creameries, Inc. There are

Establishment Inspection Report
Blue Bell Creameries, LP, Snack Plant
Brenham, TX 77833

FEI: **3004323519**
EI Start: 04/04/2012
EI End: 04/04/2012

two other manufacturing facilities in Broken Arrow, OK and Sylacauga, AL. that produce about (b) (4) gallons annually and numerous frozen warehouse distribution center throughout (b) (4) states.

This manufacturing facility is specialized and operates as a manufacturer of dairy ice cream, ice water novelty products, and combination products on sticks only. There are (b) (4) lines that typically specialize in the different products such as ice water novelties only (i.e. Bullets, Fruiti Bars), combination product with ice water and ice cream mix (Crème Pop or Dream Bar) or ice cream mixes only (Fudge Bar and Moo Bar). The ice cream mix is manufactured at the nearby main plant and trucked to this facility in (b) (4) gallon refrigerated tanker trucks, pumped and stored in refrigerated tanks until use, and manufactured into the various novelty products.

The firm utilizes (b) (4) stainless steel tanks, ranging from (b) (4) gallons for storage of the ice cream mix, refrigerated to about (b) (4) F. The ice cream mix is premade at the main plant to be pasteurized, homogenized and chilled. Milk comprises about (b) (4)% of the ice cream mix and is purchased by contract from (b) (4) located within a (b) (4) mile radius of the firm.

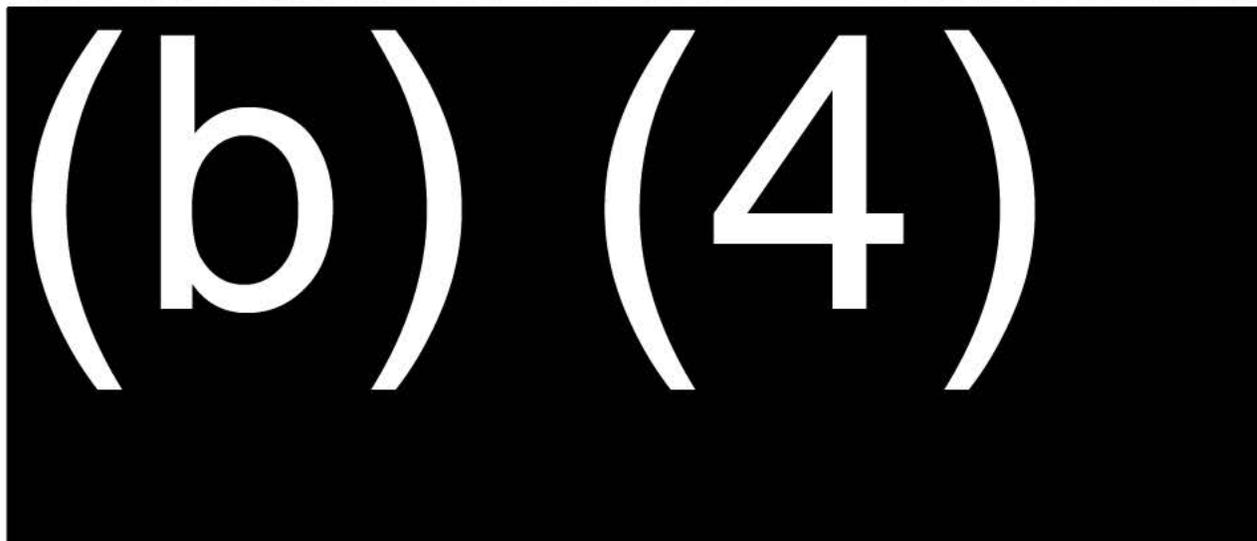
Corn sugar and high fructose corn sugar comprise about (b) (4)% of the ice water novelties. High fructose corn sugar and corn sugar are shipped to the firm by railcar and pumped into (b) (4) tanks from a railway spur adjacent to the plant.

A list of all products currently manufactured at this facility was collected as **Exhibit 3**. The production schedule for 4/4/12 during the inspection was collected as **Exhibit 4**. The largest volume products manufactured at this facility are (b) (4) and (b) (4). The firm's top Customers include; (b) (4).

During the inspection, the manufacturing of Moo Bars, Fudge Bars, Crème Pops, and Dream Bars was observed. Packaging for these products was collected as **Exhibits 5-8**, respectively.

The general process for manufacturing of the Dream Bar and Crème Pop is similar and as follows:

(b) (4)



Moo Bars use the same basic process where (b) (4)
The manufacturing of Fudge Bars is similar to Moo Bars but they are (b) (4)

The chilling brine for stick novelties is composed of (b) (4) about (b) (4). The (b) (4) the (b) (4) and (b) (4) (b) (4) or (b) (4). Ingredients such as flavors and colors are inventoried and used on a (b) (4). Flavors and colors are supplied by (b) (4) (b) (4) and (b) (4). A field exam was conducted on Crème Pops and (b) (4).

There are (b) (4) employees in Quality Control from the main plant who oversee testing, certificates of analysis and incoming product evaluations. Milk at receiving is tested for (b) (4) (b) (4) and (b) (4). Samples are taken at fillers at (b) (4) and tested for (b) (4) using (b) (4). Environmental swabs are taken with (b) (4) on a (b) (4) in random areas of the production plant such as drains, catwalks, airvents and condensate and sent to (b) (4) for analysis. Water samples are tested for (b) (4).

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. Full sanitation is conducted (b) (4) (b) (4). Sanitation of equipment for (b) (4) is conducted (b) (4).

Cleaning and sanitation chemicals include; (b) (4) cleaner for manual cleaning, (b) (4) (b) (4) used for the HTST pasteurizer in CIP, (b) (4) sanitizer for COP, (b) (4) (b) (4) cleaner for CIP and COP, (b) (4) a (b) (4) detergent (b) (4) for exteriors, (b) (4) and (b) (4) detergent (b) (4) for exteriors, (b) (4) detergent for manual cleaning, (b) (4) for painted surfaces, (b) (4) sanitizer for CIP, (b) (4) and environmental sanitizer, (b) (4) a (b) (4) sanitizer for floors and doorways, (b) (4), a sanitizer for fruit buckets, (b) (4) a (b) (4) sanitizer for pre-op CIP systems, freezer circuits, and draw lines. A list of sanitation chemicals was collected as **Exhibit 9**.

CIP cleaning is generally conducted with (b) (4) COP cleaning is generally conducted with (b) (4)

COP cleaning of a ice cream mix storage tank was occurring during the inspection. An SOP for washing mix storage tanks was collected as **Exhibit 10**. There were no observations noted for cleaning and sanitation.

Floors are concrete with drains within the manufacturing areas. Employees were observed wearing hairnets, gloves, 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).

Pest control is contracted to (b) (4) and administered (b) (4). Pest control records were reviewed for the previous 6 months and there was typical activity noted. (b) (4) were observed in various areas of the plant and perimeter of the building and were in good repair. There is (b) (4) at the entrance to the production area. There were no observations noted for pests.

MANUFACTURING CODES

Manufacturing codes are pressure-branded into the cardboard packages. Individually wrapped bars are not lot coded. The lot codes are changed (b) (4) by the floor Production Manager and are verified by Quality Control personnel.

Establishment Inspection Report
Blue Bell Creameries, LP, Snack Plant
Brenham, TX 77833

FEI: 3004323519
EI Start: 04/04/2012
EI End: 04/04/2012

On 4/4/12, the lot code for products was "040414" "A-F" where '04' designates the month of April, '04' designates the 4th day of the month, '14' designates the year 2014 (as a 2 year expiration date). The lot code has an additional code, the letter A, B, C, D, E, or F, (b) (4) (b) (4).

COMPLAINTS

There were no complaints for this facility listed in FACTS to follow-up.

Labeling on packaging refers to the address of the main plant on 1101 S. Blue Bell. The firm has a procedure for documenting and investigating complaints. All complaints received by the firm are handled by (b) (6) at the main plant and documented on a complaint form. The most common complaints are quality related such as crystallization of the packaged products.

RECALL PROCEDURES

The firm has had no recalls per Andrew Kollman, QC Manager.

The firm conducts mock recalls (b) (4). (b) (4) focused on a raw ingredient and (b) (4) is that of a finished product.

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.

Establishment Inspection Report
Blue Bell Creameries, LP, Snack Plant
Brenham, TX 77833

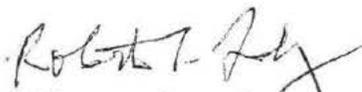
FEI: 3004323519
EI Start: 04/04/2012
EI End: 04/04/2012

EXHIBITS COLLECTED

1. Corn sugar interstate shipping documents (2 pages).
2. Org chart (1 page).
3. List of products manufactured (1 pages).
4. Manufacturing schedule for 4/4/12 (1 pages).
5. Packaging for Moo Bar (1 pages).
6. Packaging for Fudge Bar (1 pages).
7. Packaging for Creme Bar (1 page).
8. Packaging for Dream Bar (1 page).
9. List (b) (4) sanitation chemicals (1 page).
10. Mix storage tank cleaning SOP (1 page).

ATTACHMENTS

1. FDA 482 was issued to Jason D. Jenkins, Plant Manager.
2. FACTS assignment sheets.


Robert T. Lorenz, Investigator