FoodIndustry
COUNSEL LLC

Shawn Stevens
Food Industry Consultant and Lawyer
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920.698.2561

FDA Inspection Readiness

What To Do Before, During & After Your FDA Inspection

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FDA INSPECTIONS

FDA required by law
to inspect food facilities

FDA performs unannounced
inspections of food facilities

FDA records violations it
observes on a **FORM 483**

If company fails to respond,
FDA issues a **Warning Letter***

*FDA also has authority to immediately withdraw registration

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FDA INSPECTIONS

Nature of FDA Inspections
is changing drastically

THE
"FSMA AFFECT"

THE
"PATHOGEN PARADIGM"

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THE "FSMA AFFECT"

KNOW FDA LISTERIA CONTROL GUIDANCE

1 Incoming Ingredients

s Lm reasonably foreseeable?

Implement Supplier Controls:

- Supplier Approval Program
- Certificates of Conformance
- Require Raw Material Testing
- Require Environmental Monitoring
- Conduct Audits and Verification Activities

2 Operational Controls

- Personnel
- Plant Design, Construction and Operation
- Equipment Design, Construction and Operation
- Cleaning and Sanitation
- Process Controls (Listericidal or Other Controls)
- Storage, Time, Temperature and Transportation
- Environmental Monitoring
- Analysis of Trends and Maintenance of Records
- Training

3 Finished Products

Finished Product Testing

FDA Recommends Testing:

- Verification Purposes
- Periodic Testing
- Sample for Lm
- Test and Hold

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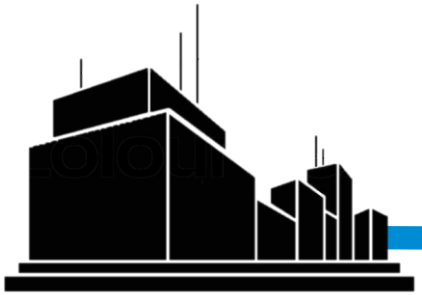
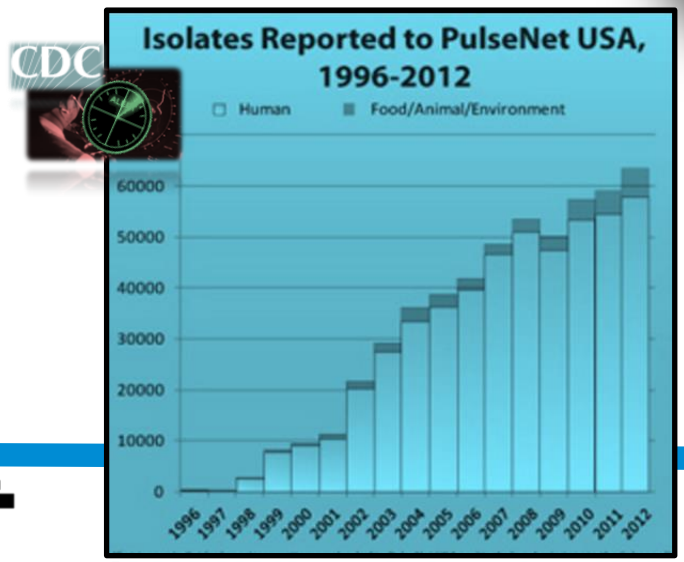
THE "PATHOGEN PARADIGM"





*1,000,000 Human Isolates since 1998

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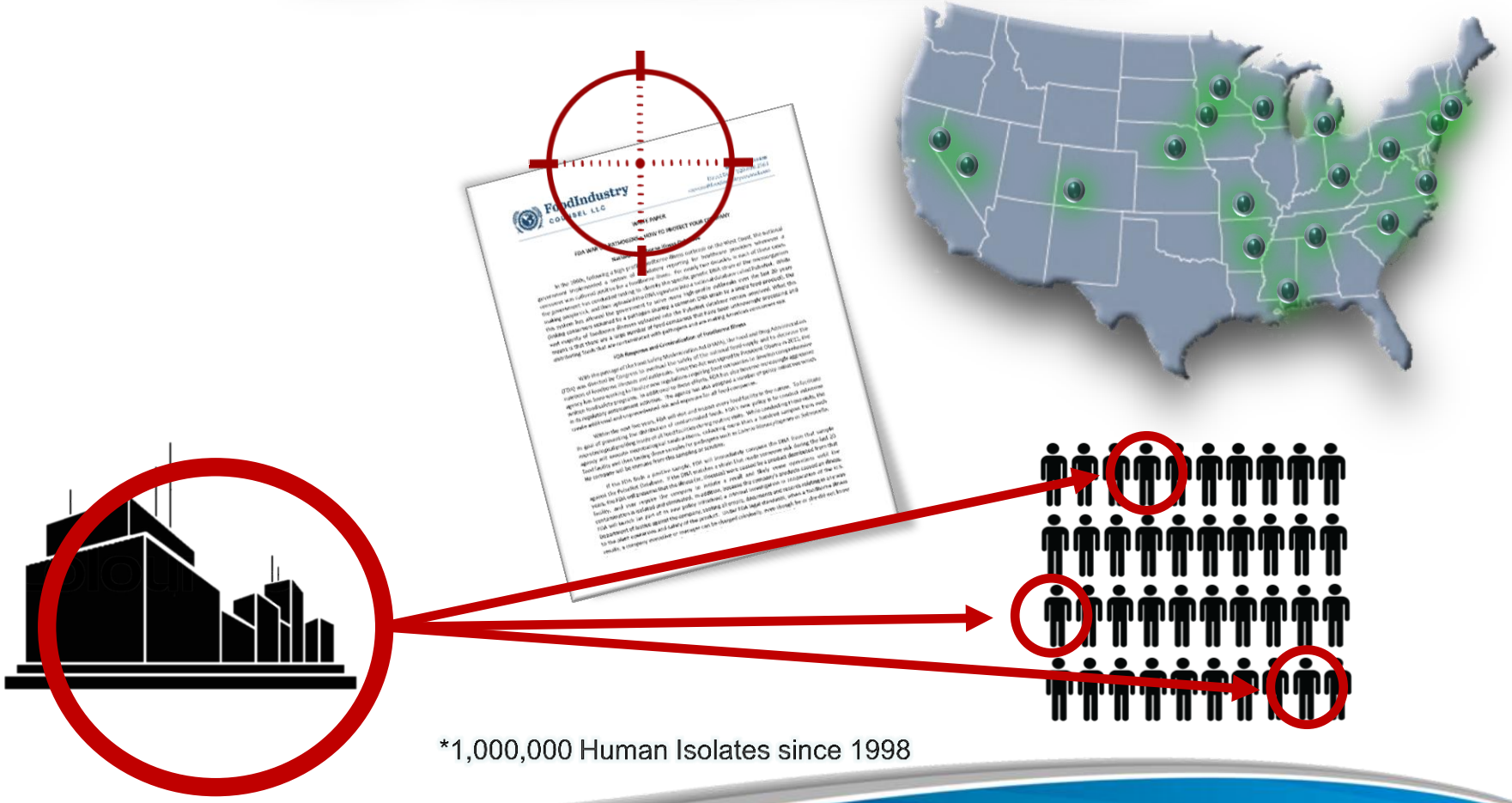

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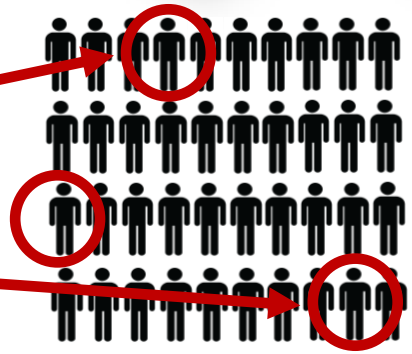

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FSMA RECORD REVIEW

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FDA SWAB-A-THON
(HIGH-INTENSITY-TESTING)

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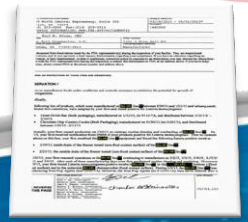

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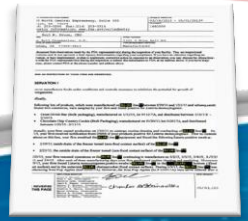
FOOD SAFETY INVESTIGATION



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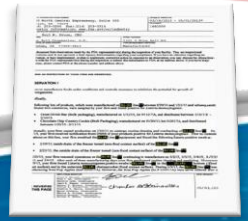

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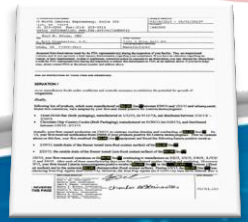

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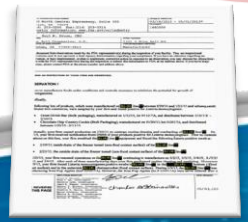

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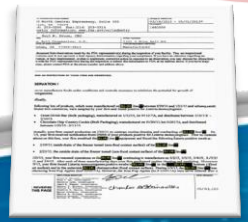

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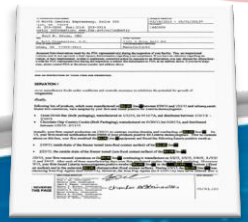

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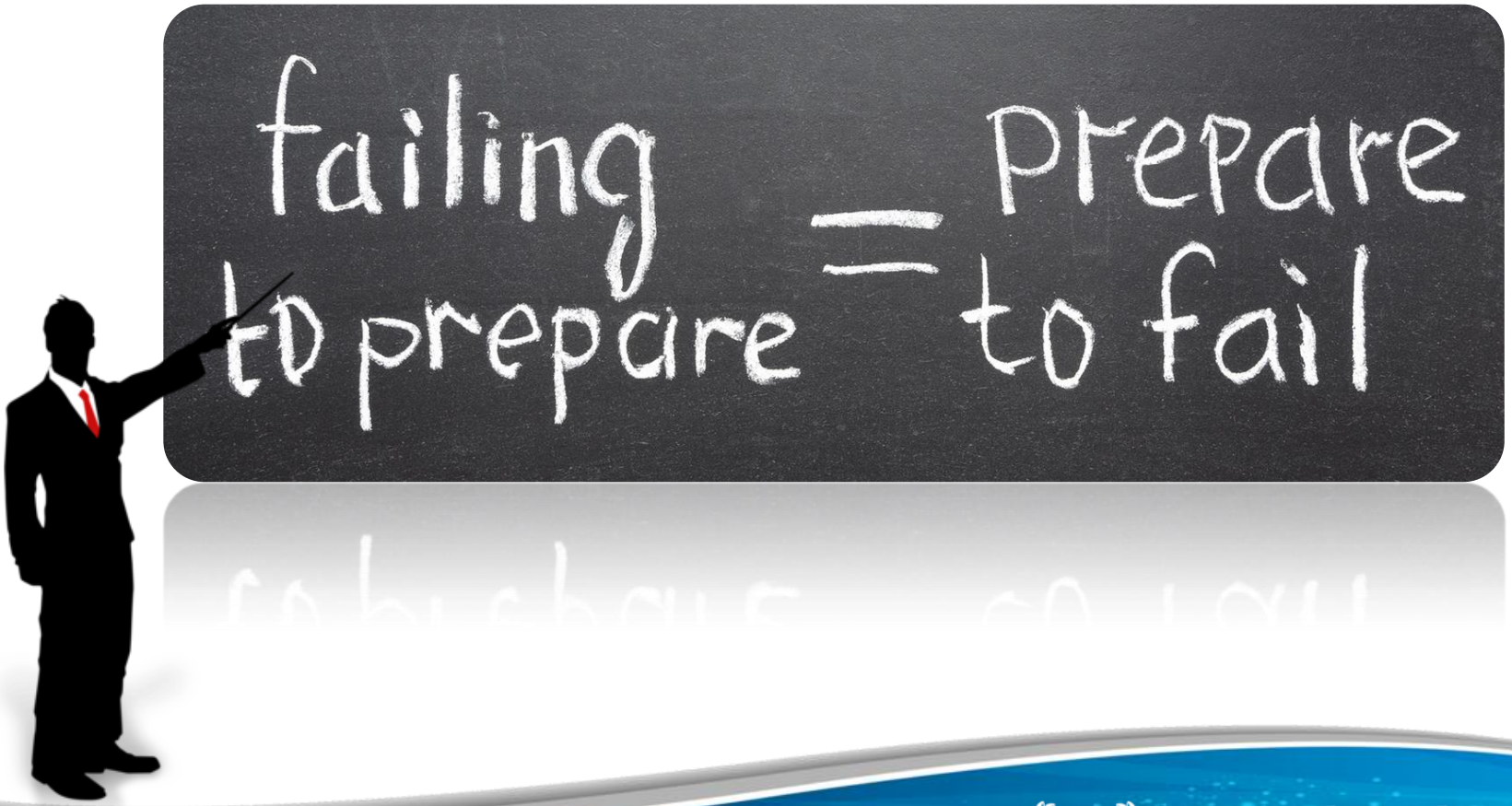
PREPARING FOR THE FDA INSPECTION



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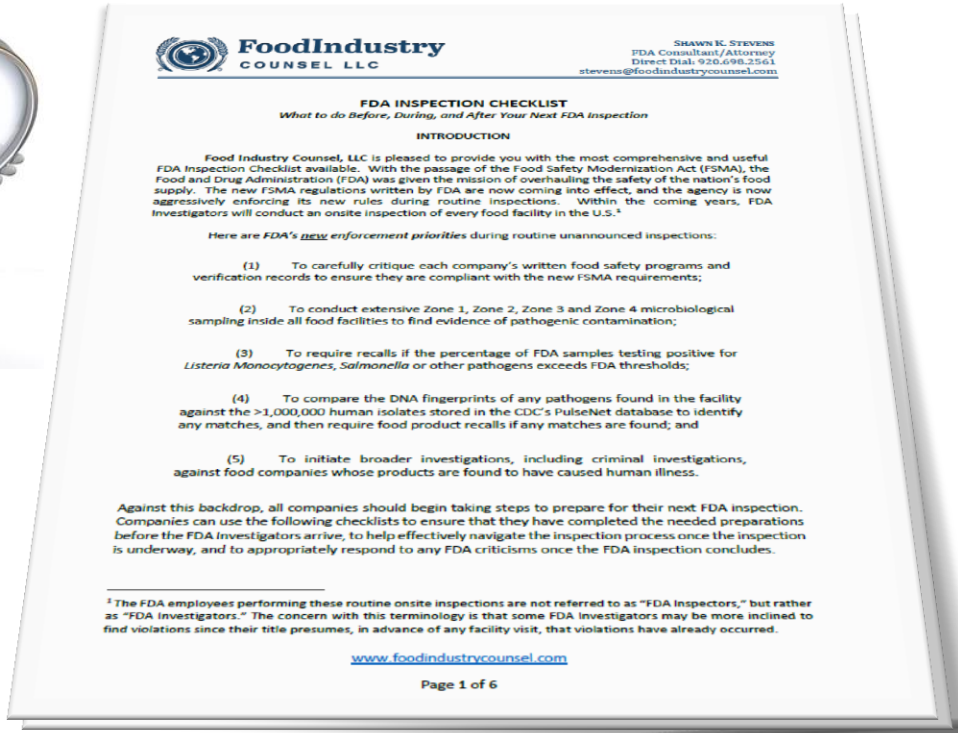
THE FDA INSPECTION CHECKLIST

BEFORE – DURING – AFTER



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FDA INSPECTION CHECKLIST

What to do Before, During, and After Your Next FDA Inspection

INTRODUCTION

Food Industry Counsel, LLC is pleased to provide you with the most comprehensive and useful FDA Inspection Checklist available. With the passage of the Food Safety Modernization Act (FSMA), the Food and Drug Administration (FDA) was given the mission of overhauling the safety of the nation's food supply. The new FSMA regulations written by FDA are now coming into effect, and the agency is now aggressively enforcing its new rules during routine inspections. Within the coming years, FDA investigators will conduct an onsite inspection of every food facility in the U.S.[1]

Here are ***FDA's new enforcement priorities*** during routine unannounced inspections:

(1) To carefully critique each company's written food safety programs and verification records to ensure they are compliant with the new FSMA requirements;

(2) To conduct extensive Zone 1, Zone 2, Zone 3 and Zone 4 microbiological sampling inside all food facilities to find evidence of pathogenic contamination;

(3) To require recalls if the percentage of FDA samples testing positive for *Listeria Monocytogenes*, *Salmonella* or other pathogens exceeds FDA thresholds;

(4) To compare the DNA fingerprints of any pathogens found in the facility against the >1,000,000 human isolates stored in the CDC's PulseNet database to identify any matches, and then require food product recalls if any matches are found; and

(5) To initiate broader investigations, including criminal investigations, against food companies whose products are found to have caused human illness.

Against this backdrop, all companies should begin taking steps to prepare for their next FDA inspection. Companies can use the following checklists to ensure that they have completed the needed preparations before the FDA Investigators arrive, to help effectively navigate the inspection process once the inspection is underway, and to appropriately respond to any FDA criticisms once the FDA inspection concludes.

[1] *The FDA employees performing these routine onsite inspections are not referred to as "FDA Inspectors," but rather as "FDA Investigators." The concern with this terminology is that some FDA Investigators may be more inclined to find violations since their title presumes, in advance of any facility visit, that violations have already occurred.*

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PRE-INSPECTION CHECKLIST

IDENTIFY A MEETING SPACE

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PRE-INSPECTION CHECKLIST

ASSIGN DESIGNATED INDIVIDUALS

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PRE-INSPECTION CHECKLIST

COMPLETE PCQI TRAINING

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PRE-INSPECTION CHECKLIST

FINALIZE WRITTEN FOOD SAFETY SYSTEMS

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PRE-INSPECTION CHECKLIST

ENSURE EASE OF RECORDS ACCESS

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PRE-INSPECTION CHECKLIST

DOCUMENT CORRECTIVE ACTIONS CORRECTLY

"MICROBIOLOGICAL INDEPENDENCE"

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PRE-INSPECTION CHECKLIST

UPDATE SANITATION FLASHLIGHTS

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PRE-INSPECTION CHECKLIST

REVIEW ALLERGEN CONTROLS

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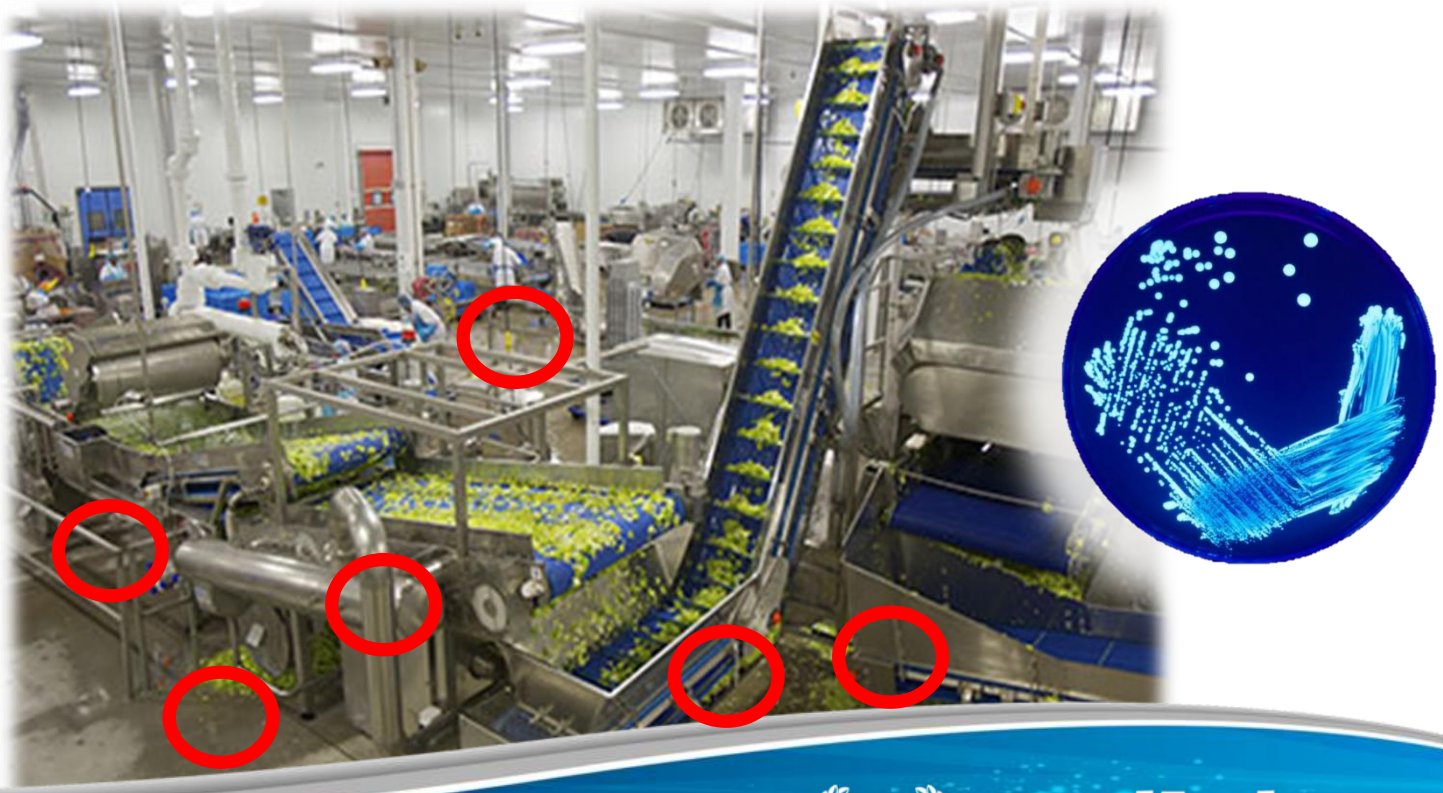
PRE-INSPECTION CHECKLIST

CONDUCT ENVIRONMENTAL MONITORING



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PRE-INSPECTION CHECKLIST

DEVELOP A MICROBIOLOGICAL RETAIN SAMPLE POLICY

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PRE-INSPECTION CHECKLIST

DEVELOP A COMPANION SAMPLE POLICY

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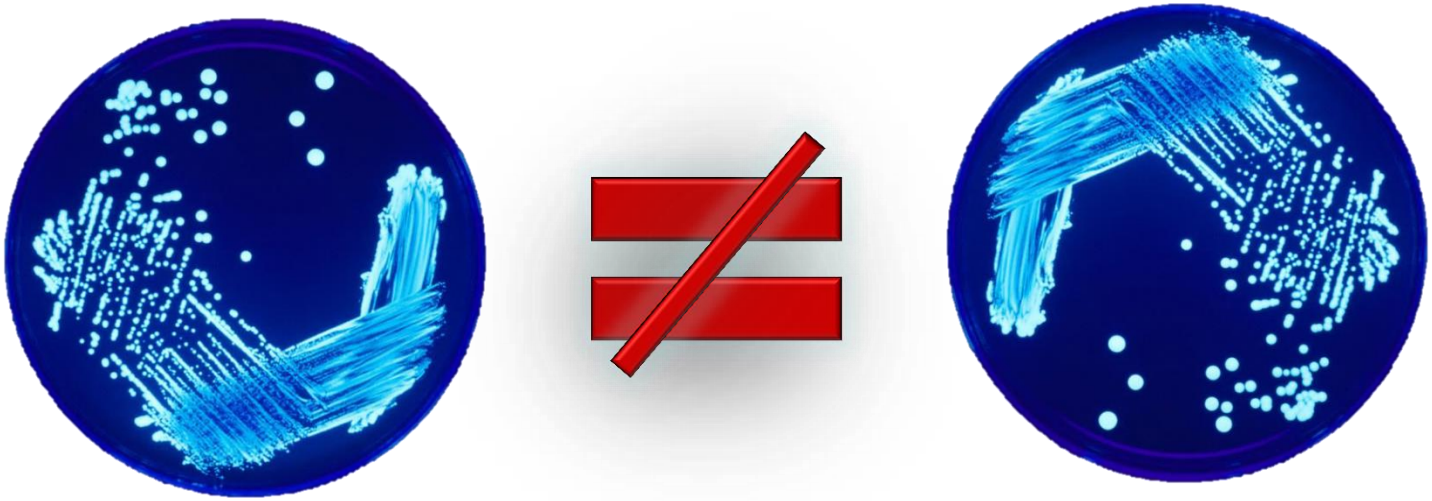
PRE-INSPECTION CHECKLIST

DEVELOP A COMPANION SAMPLE POLICY



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PRE-INSPECTION CHECKLIST

DEVELOP A "NO PHOTOGRAPHS" POLICY

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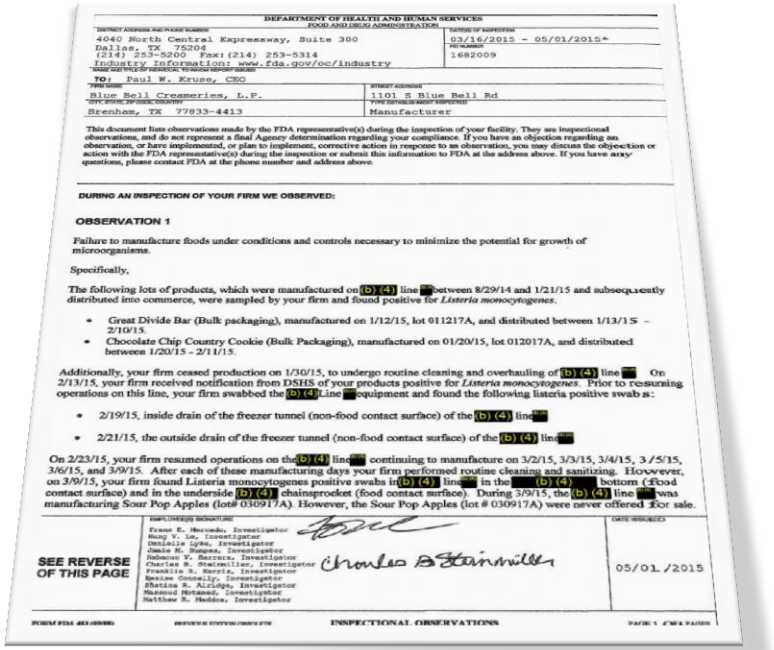
PRE-INSPECTION CHECKLIST

DEVELOP A "DO NOT SIGN" POLICY



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

4040 North Central Expressway, Suite 300
Dallas, TX 75204
(214) 253-5200 Fax:(214) 253-5314
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION: 03/16/2015 - 05/01/2015
FEI NUMBER: 1682009

TO: Paul W. Kruse, CEO

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

STREET ADDRESS: 1101 S Blue Bell Rd
TYPE ESTABLISHMENT INSPECTED: Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Failure to manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganisms.

Specifically,

The following lots of products, which were manufactured on (b)(4) line [redacted] between 8/29/14 and 1/21/15 and subsequently distributed into commerce, were sampled by your firm and found positive for *Listeria monocytogenes*.

- Great Divide Bar (Bulk packaging), manufactured on 1/12/15, lot 011217A, and distributed between 1/13/15 – 2/10/15.
- Chocolate Chip Country Cookie (Bulk Packaging), manufactured on 01/20/15, lot 012017A, and distributed between 1/20/15 - 2/11/15.

Additionally, your firm ceased production on 1/30/15, to undergo routine cleaning and overhauling of (b)(4) line [redacted]. On 2/13/15, your firm received notification from DSHS of your products positive for *Listeria monocytogenes*. Prior to resuming operations on this line, your firm swabbed the (b)(4) Line [redacted] equipment and found the following listeria positive swabs:

- 2/19/15, inside drain of the freezer tunnel (non-food contact surface) of the (b)(4) line [redacted]
- 2/21/15, the outside drain of the freezer tunnel (non-food contact surface) of the (b)(4) line [redacted]

On 2/23/15, your firm resumed operations on the (b)(4) line [redacted] continuing to manufacture on 3/2/15, 3/3/15, 3/4/15, 3/5/15, 3/6/15, and 3/9/15. After each of these manufacturing days your firm performed routine cleaning and sanitizing. However, on 3/9/15, your firm found Listeria monocytogenes positive swabs in (b)(4) line [redacted] in the [redacted] (b)(4) [redacted] bottom (food contact surface) and in the underside (b)(4) chainsprocket (food contact surface). During 3/9/15, the (b)(4) line [redacted] was manufacturing Sour Pop Apples (lot# 030917A). However, the Sour Pop Apples (lot # 030917A) were never offered for sale.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE: Charles B Stairwalter
Irene E. Hernado, Investigator
Hung V. Le, Investigator
Danielle Lyke, Investigator
Jamie M. Burgess, Investigator
Rebecca V. Herrera, Investigator
Charles B. Stairwalter, Investigator
Franklin S. Harris, Investigator
Emaine Connelly, Investigator
Shatina R. Aridge, Investigator
Masoud Motamed, Investigator
Matthew R. Medina, Investigator

DATE ISSUED: 05/01/2015

INSPECTIONAL OBSERVATIONS

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PRE-INSPECTION CHECKLIST

IDENTIFY A FOOD INDUSTRY LAWYER

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PRE-INSPECTION CHECKLIST

CONDUCT A MOCK INSPECTION

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INSPECTION DAY CHECKLIST

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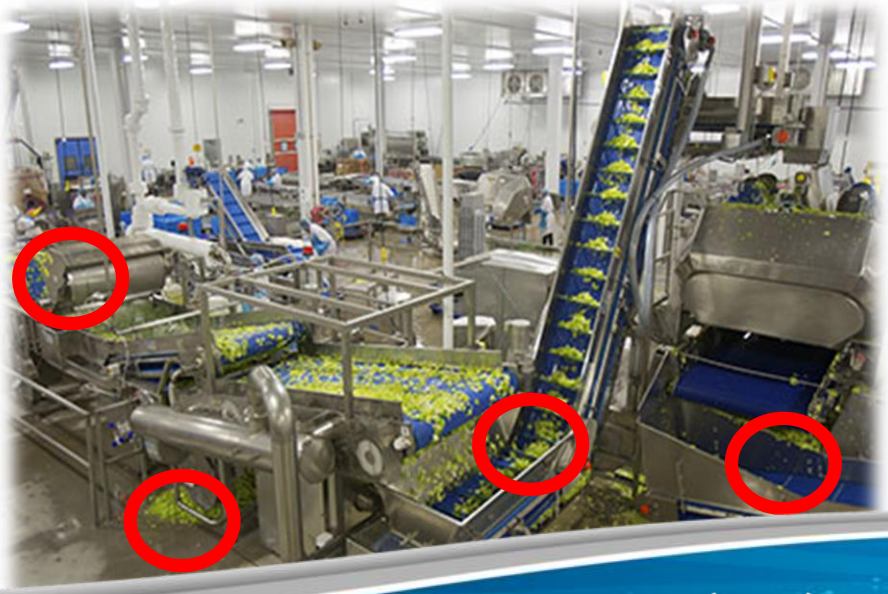
INSPECTION DAY CHECKLIST

ATTEMPT TO NEGOTIATE AREAS TO BE SAMPLED



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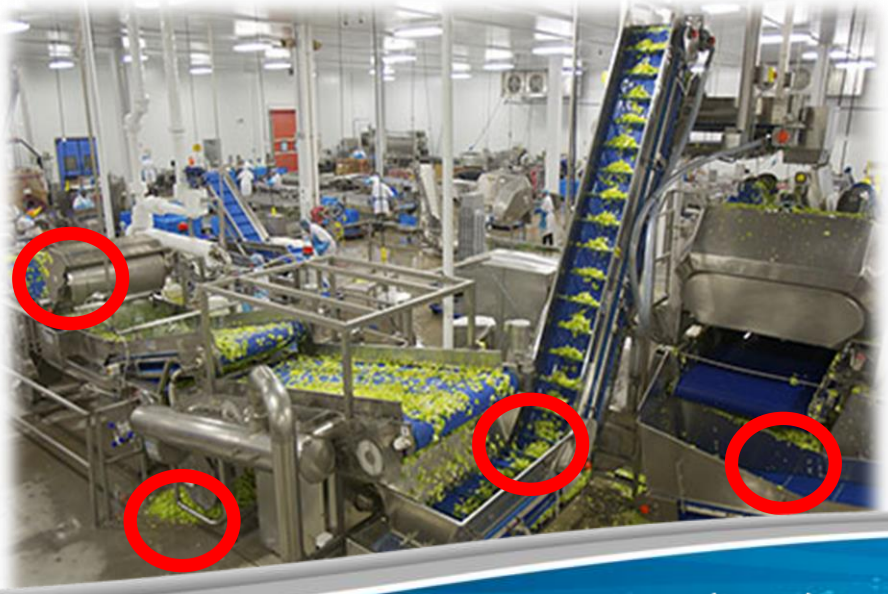
INSPECTION DAY CHECKLIST

CAREFULLY DOCUMENT AREAS SAMPLED BY FDA



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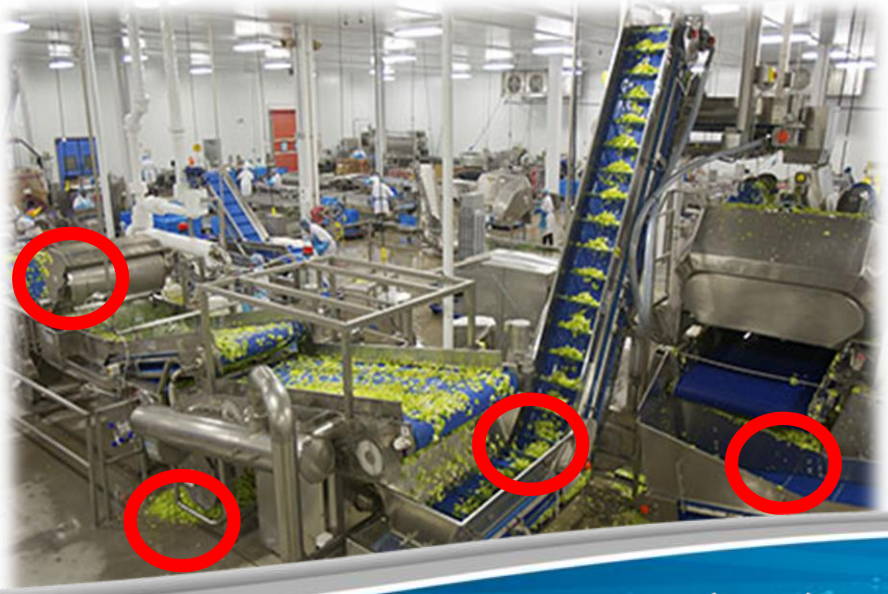
INSPECTION DAY CHECKLIST

HOLD ANY PRODUCT THAT FDA SAMPLES



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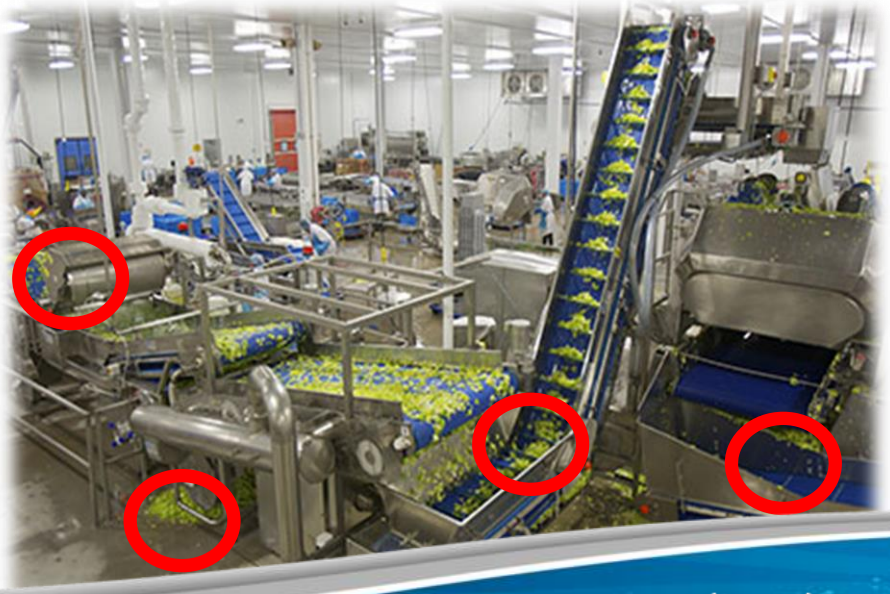
INSPECTION DAY CHECKLIST

AGGRESSIVELY CLEAN AND SANITIZE ALL AREAS FDA SAMPLES



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INSPECTION DAY CHECKLIST

PROTECT YOUR RECORDS

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INSPECTION DAY CHECKLIST

DO NOT LEAVE INVESTIGATORS UNACCOMPANIED

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INSPECTION DAY CHECKLIST

DO NOT SIGN ANY STATEMENTS

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AFTER THE INSPECTION

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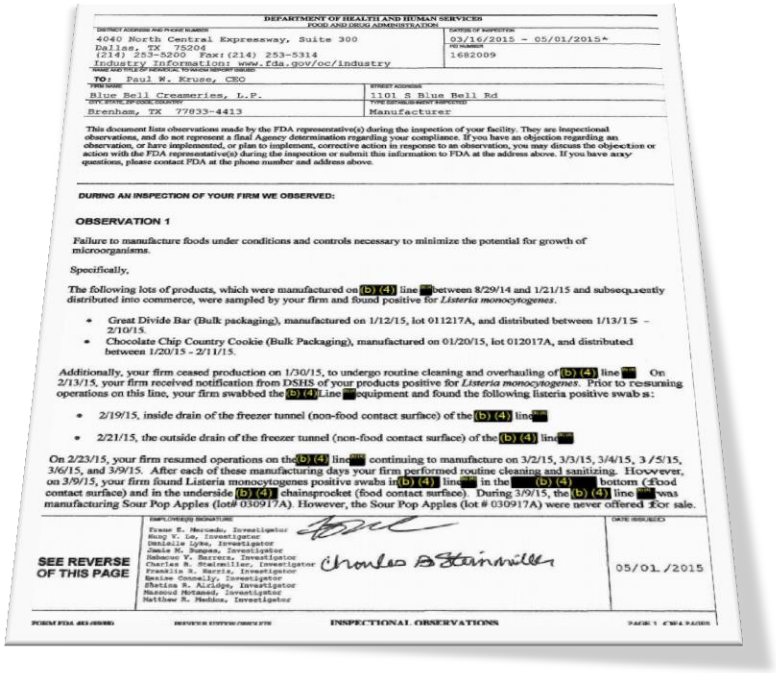
AFTER THE INSPECTION

Respond Appropriately to all FDA Criticisms



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FOOD AND DRUG ADMINISTRATION

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FEI NUMBER: 1682009

TO: Paul W. Kruse, CEO

FIRM NAME: Blue Bell Creameries, L.P.
STREET ADDRESS: 1101 S Blue Bell Rd
CITY, STATE, ZIP CODE, COUNTRY: Brenham, TX 77833-4413
TYPE ESTABLISHMENT INSPECTED: Manufacturer

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EMPLOYEE(S) SIGNATURE: Charles B Stainmiller

Frane E. Mercado, Investigator
Hung V. Le, Investigator
Danielle Lyda, Investigator
Jamie K. Burgess, Investigator
Rebecca V. Serrero, Investigator
Charles B. Stainmiller, Investigator
Franklin S. Harris, Investigator
Emaine Connelly, Investigator
Shatina N. Aridge, Investigator
Masoud Motamed, Investigator
Matthew R. Medina, Investigator

DATE ISSUED: 05/01/2015

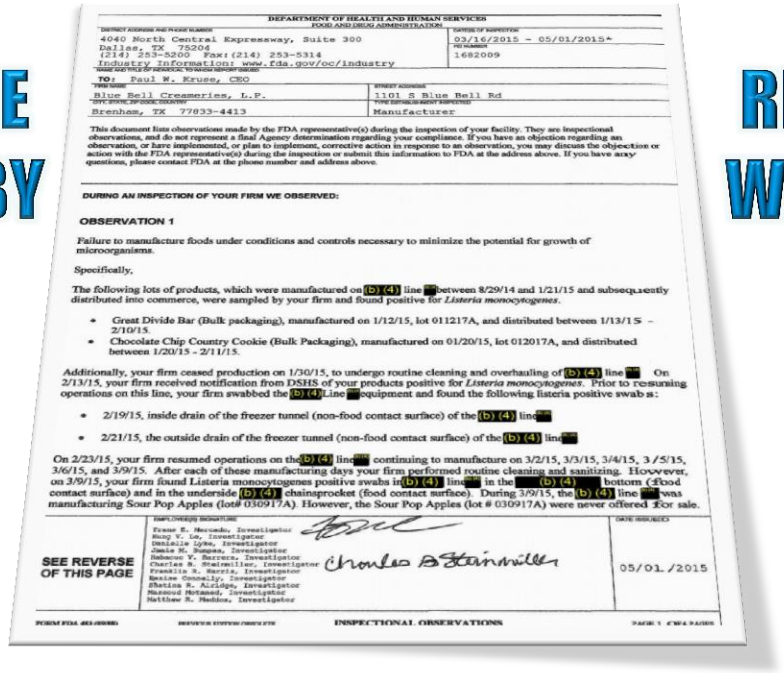
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 OF 4 PAGES

FoodIndustry COUNSEL LLC

AFTER THE INSPECTION

Respond Appropriately to all FDA Criticisms

RESPONSE MUST BE WELL SUPPORTED BY STATEMENTS



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

4040 North Central Expressway, Suite 300
Dallas, TX 75204
(214) 253-5200 Fax:(214) 253-5314
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION: 03/16/2015 - 05/01/2015
FEI NUMBER: 1682009

TO: Paul W. Kruse, CEO

FIRM NAME: Blue Bell Creameries, L.P.
STREET ADDRESS: 1101 S Blue Bell Rd
CITY, STATE, ZIP CODE, COUNTRY: Brenham, TX 77833-4413
TYPE ESTABLISHMENT INSPECTED: Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Failure to manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganisms.

Specifically,

The following lots of products, which were manufactured on (b) (4) line [redacted] between 8/29/14 and 1/21/15 and subsequently distributed into commerce, were sampled by your firm and found positive for *Listeria monocytogenes*.

- Great Divide Bar (Bulk packaging), manufactured on 1/12/15, lot 011217A, and distributed between 1/13/15 - 2/10/15.
- Chocolate Chip Country Cookie (Bulk Packaging), manufactured on 01/20/15, lot 012017A, and distributed between 1/20/15 - 2/11/15.

Additionally, your firm ceased production on 1/30/15, to undergo routine cleaning and overhauling of (b) (4) line [redacted]. On 2/13/15, your firm received notification from DSHS of your products positive for *Listeria monocytogenes*. Prior to resuming operations on this line, your firm swabbed the (b) (4) Line [redacted] equipment and found the following listeria positive swabs:

- 2/19/15, inside drain of the freezer tunnel (non-food contact surface) of the (b) (4) line [redacted]
- 2/21/15, the outside drain of the freezer tunnel (non-food contact surface) of the (b) (4) line [redacted]

On 2/23/15, your firm resumed operations on the (b) (4) line [redacted] continuing to manufacture on 3/2/15, 3/3/15, 3/4/15, 3/5/15, 3/6/15, and 3/9/15. After each of these manufacturing days your firm performed routine cleaning and sanitizing. However, on 3/9/15, your firm found Listeria monocytogenes positive swabs in (b) (4) line [redacted] in the [redacted] (b) (4) bottom (food contact surface) and in the underside (b) (4) chainsprocket (food contact surface). During 3/9/15, the (b) (4) line [redacted] was manufacturing Sour Pop Apples (lot# 030917A). However, the Sour Pop Apples (lot # 030917A) were never offered for sale.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE: Charles B Stainmiller
Tresse E. Hernando, Investigator
Hung V. Le, Investigator
Danielle Lyda, Investigator
Jamie M. Simpson, Investigator
Rebecca V. Serrero, Investigator
Charles B. Stainmiller, Investigator
Franklin S. Harris, Investigator
Emaine Connelly, Investigator
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Matthew R. Medina, Investigator

DATE ISSUED: 05/01/2015

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 OF 4 PAGES

RESPONSE MUST BE WELL SUPPORTED BY EVIDENCE

FoodIndustry COUNSEL LLC

AFTER THE INSPECTION

Respond Appropriately to all FDA Criticisms

RESPONSE MUST BE WELL SUPPORTED BY STATEMENTS

RESPONSE MUST BE WELL SUPPORTED BY EVIDENCE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	03/16/2015 - 05/01/2015* FEI NUMBER 1682009

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Paul W. Kruse, CEO

FIRM NAME	STREET ADDRESS
Blue Bell Creameries, L.P.	1101 S Blue Bell Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Brenham, TX 77833-4413	Manufacturer

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	EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	Frans E. Mercado, Investigator Hung V. Le, Investigator Danielle Lyke, Investigator Jamie M. Bumpas, Investigator Babacue V. Barrera, Investigator Charles B. Stairmiller, Inv... Franklin R. Harris, In... Denise Connelly, In... Shatina R. Alri... Massoud Motam... Matthew R. ...	05/01/2015

FORM FDA 483 (09/08) PAGE 1 OF 4 PAGES

CLOSURE

FoodIndustry COUNSEL LLC

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