



## TEXAS DEPARTMENT OF STATE HEALTH SERVICES

JOHN HELLERSTEDT, M.D.  
COMMISSIONER

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### ENFORCEMENT AGREEMENT

July 25, 2016

BETWEEN THE TEXAS DEPARTMENT OF STATE HEALTH SERVICES  
AND  
BLUE BELL CREAMERIES LP, BRENHAM TEXAS

#### I. JURISDICTION

The Department of State Health Services (DSHS) regulates in-state frozen dessert manufacturers as authorized by Chapters 431 and 440 of the Texas Health and Safety Code (HSC) and the Department rules at 25 Texas Administrative Code Chapter 229 which apply to frozen dessert manufacturers. DSHS is also the state public health agency established to protect and promote the health of the people of Texas.

#### II. BLUE BELL CREAMERIES LP

Blue Bell Creameries LP, with corporate and manufacturing facilities at 1101 South Blue Bell Rd, Brenham, Texas 77833, is licensed (In-state Frozen Dessert Manufacturer License # 480702) to manufacture and sell frozen desserts in the State of Texas and is subject to the Texas Health and Safety Code and Texas Administrative Code; hereinafter "the Company".

#### III. COMPLETE AGREEMENT

Subsequent to the events of February 2015 involving the voluntary recall of ice cream products containing *Listeria monocytogenes (Lm)*, a Voluntary Agreement was reached between DSHS and the Company whereby the parties agreed to proscribed procedures and protocols before the Company began reentering ice cream products into commerce.

*An Equal Opportunity Employer and Provider*

Whereas the Company has successfully re-entered products into commerce, an informal conference was held between DSHS and the Company on May 11, 2016 to discuss matters pertaining to a continuation of the terms of the Voluntary Agreement and a settlement of unresolved regulatory issues and requirements. Both DSHS and the Company have determined that a settlement of these matters is in the best interests of both parties. By entering into this Agreement, the Company does not admit wrongdoing or unlawful conduct.

This Agreement is made pursuant to Government Code, §2001.056, which authorizes the Department to dispose of a case informally, and the procedural rules adopted by the Department.

The Company understands the terms of this Agreement, enters into the Agreement freely, and agrees to the terms and conditions of this Agreement.

The complete terms of this settlement are contained in this Agreement, and this Agreement supersedes all prior agreements and understandings between DSHS and the Company.

All conditions and periods of time set out in this Agreement are based upon the date of the signature of the Assistant Commissioner for the Division for Regulatory Services.

#### **A. NO WAIVER WITH REGARD TO OTHER VIOLATIONS**

The Department does not waive the right to enforce this Agreement or to pursue enforcement of any other violations that the Company may commit. The Department may consider this Agreement in the processing of any other enforcement actions.

#### **B. COMPLETE UNDERSTANDING**

This Agreement represents the complete settlement of all outstanding regulatory issues between DSHS and the Company through May 31, 2016.

### **IV. TERMS OF AGREEMENT**

The Company shall:

1. Retain an independent sanitation and/or microbiology expert qualified by background, education, training and experience to determine that the methods, facilities and controls necessary are in place that will prevent the introduction of contamination. This expert should also, to the extent possible based on the best science available, help the Company assure that the plant and the equipment are properly prepared, maintained and operated to produce products that are free from pathogens and other contamination.

2. Preserve all environmental, product and ingredient testing results and make such results available for DSHS to review upon request.
3. Notify DSHS of the following testing results within the specified timeframes:
  - a. Within 24 hours of receiving a laboratory report of any presumptive positive test result for *Lm* found in finished product produced by the Brenham facility, the Company will notify DSHS of such result;
  - b. Within 24 hours of receiving a laboratory report of any presumptive positive test result for *Lm* found in an ingredient produced by the Brenham facility or intended for use in a product produced by the Company at its Brenham facility, the Company will notify DSHS of such result;
  - c. Within 24 hours of receiving a laboratory report of any presumptive positive test result for *Lm* found on food contact surfaces, the Company will notify DSHS of such result; and
  - d. On a weekly basis, the Company will notify DSHS of any presumptive positive test results for *Listeria species* found through its routine environmental monitoring program in any "high care" area of the Brenham plant (other than food contact surfaces) during the preceding week.

For purposes of this paragraph, if a test result requiring 24-hour DSHS notification is received by the Company on a weekend or holiday, the 24-hour period would expire at the end of the next business day. Reporting under this paragraph shall continue for a period of eighteen months from the final date of execution of this Agreement. This reporting period may be extended by mutual agreement of the Parties.

4. Provide DSHS full access to the Brenham facilities for purposes of collecting ingredient, finished product, or environmental samples. It is understood that DSHS would seek to take any presumptive positive test results for *Listeria species* through to final confirmation for *Lm* and maintain any confirmed *Lm* isolates in the DSHS laboratory in Austin.
5. Should the Company identify in identical or contiguous areas of the Brenham facility more than two consecutive presumptive positive tests for *Listeria species* through its routine environmental monitoring program in areas designated "high care" by the Company or for *Lm* through routine food contact surface testing, the Company shall conduct a root cause analysis of the contamination, in consultation with the Company's independent sanitation and/or microbiology expert, for the purposes of identifying potential or actual sources of contamination. The Company shall allow DSHS to review the documentation of any such root cause analysis.
6. Ensure that the Company's Pathogen Monitoring Program (PMP) for *Lm* includes plans on how the Company will respond to presumptive positive tests for *Listeria species* when and where found.

7. Make available for DSHS' review upon request:
  - a. Plant cleaning and on-going sanitation policies, procedures and records;
  - b. Company staff training curriculum and records, along with plans for new hire orientation and ongoing training of existing staff; and
  - c. Plans for plant modifications made for the purpose of controlling potentially harmful bacteria within the plant operating environment and/or food handling machinery.
8. Maintain a "test and hold" program for all finished product to be introduced into commerce for a period of eighteen months from the final date of execution of this Agreement. The test and hold program may be modified or extended by mutual agreement of the Parties.
9. Continue the practice of holding regularly scheduled information sharing phone calls or meetings with DSHS Inspection and Policy, Standards, and Quality Assurance staff. The schedule and frequency of these calls will be mutually agreed upon by the Company's representative(s) and DSHS Inspection staff, but will not be less frequent than monthly.
10. Within 30 days of the execution of this agreement, provide a schedule for completion of all production line shielding, including filler locations, and notify DSHS in writing when that has been accomplished.
11. Notify DSHS whenever there is a need for a product recall or public notice regarding product safety.

Based on experience gained under this Agreement, DSHS and the Company may agree to convert provisions of this Agreement that require actions based on presumptive positive test results to instead require actions based on confirmed positive test results. Should that occur, actions required under paragraphs 3, 5 and 6 above would be adjusted accordingly.

In addition, the Company agrees that all future food processing and distribution activities will be undertaken pursuant to, or in reflection of, the following industry recognized standards for plant performance:

- (1) Sanitation Standard Operating Procedures (SSOPs);
- (2) Good Manufacturing Practices (GMPs);
- (3) a Pathogen Monitoring Program (PMP) for *Lm*, which includes environmental, ingredient and finished product testing; and
- (4) a Hazard Analysis and Critical Control Points (HACCP) plan and/or a written Food Safety Plan, including sections on:
  - a. verifiable product trace-back procedures,
  - b. comprehensive analysis of process risks and associated critical control points,
  - c. sufficient product recall practices,
  - d. allergen identification/labeling monitoring.

## V. ADMINISTRATIVE PENALTIES

The Company agrees to an administrative penalty of \$850,000.00. The Company will remit \$175,000 not later than 30 days from the date this Agreement is signed, with the remaining \$675,000 held in abeyance. The parties agree that the balance of \$675,000 will be held in abeyance for a period of eighteen months predicated upon ongoing DSHS inspections and reviews of relevant documentation verifying that procedures and practices are in adherence to the terms and conditions expressed in this Agreement.

Upon successful completion of the eighteen-month term, the remaining balance of funds held in abeyance will be forgiven by DSHS.

The Company shall comply with this Agreement and with all applicable laws, rules, and regulations. Failure to comply may result in additional enforcement action. DSHS shall inform the Company within three business days of any preliminary findings that, if not corrected, would be sufficient to warrant an order for the balance, or any portion thereof, of the administrative penalty being held in abeyance to be assessed as due.

Upon being informed of such preliminary findings, the Company shall have 10 business days to respond to DSHS with an explanation of how the findings were corrected or with a plan to correct the findings, and the Company shall have the opportunity to meet with DSHS at a mutually agreeable time upon the Company's request to discuss the preliminary findings and corrective actions.

If, after reviewing the Company's response and holding a meeting (if requested), DSHS concludes that the Company is unable to develop and implement corrective actions sufficient to correct the findings, DSHS shall document its conclusion and provide the Company with such documentation, including documentation of the basis for the amount of the administrative penalty DSHS believes should become due.

The Company shall thereafter have 5 business days to raise with DSHS any objections with respect to DSHS's conclusions.

Upon consideration of same, DSHS may affirm or modify its conclusions and order to be due the balance, or any portion thereof, of the administrative penalty being held in abeyance.

**VI. EXECUTION**

The parties below by signature represent they hereby acknowledge an understanding regarding the terms of this Agreement; enter into it freely; and agree to its terms and conditions.

SO AGREED on this 28<sup>th</sup> day of July, 2016.

Texas Department of State Health Services

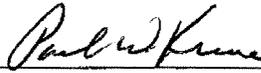


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KATHRYN C. PERKINS  
ASSISTANT COMMISSIONER  
REGULATORY SERVICES

SO AGREED on this 22<sup>nd</sup> day of July, 2016.

Blue Bell Creameries, Inc.



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PAUL W. KRUSE  
PRESIDENT AND CEO