

# Blue Bell Creameries

Update to FDA and Path Forward

Dallas District Office, Dallas TX

July 1, 2015



# Agenda

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- Introductions
- Company Philosophy
- Update on Corrective Actions
- Cleaning and Sanitation Update
- Sampling and (b) (4) Procedures
- Path Forward
- Dialogue and Discussion

# Introductions

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- Paul Kruse, President and CEO
- Greg Bridges, Vice President Plant Operations
- Paul Prazak, Brenham Manager of Plant Operations
- Andy Kollman, Director of Quality Assurance & Food Safety
- Marty Kilgore, Broken Arrow Facility, General Manager
- Kevin Wood, Sylacauga Facility, General Manager
- (b) (4)
- Gary Jay Kushner, Partner, Hogan Lovells
- Elizabeth Barr Fawell, Counsel, Hogan Lovells
- Brian D. Eyink, Associate, Hogan Lovells

# Company Philosophy

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- Broad, comprehensive approach to corrective and preventive actions
- Looking well beyond the observations in the 483s
- Cooperation and transparency
- Committed to getting this right

# Update on Corrective and Preventive Actions

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- Key Infrastructure and Equipment Changes
- SOPs, GMPs, and HACCP Plans
- Supplier approval program
- Employee training

# Cleaning and Sanitation

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- Deep cleaning throughout all facilities
- (b) (4) and sanitization of equipment
- (b) (4)
- Special startup sanitation procedures

# Sampling and Test and Hold Procedures

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- Environmental testing program
  - Zones 2-4
  - Corrective actions for positive samples
- (b) (4) program
  - Food contact surfaces (*i.e.*, Zone 1) and finished product
  - Testing for *Listeria monocytogenes*
  - (b) (4) pending negative results
  - Intensified sampling if positives found

# Path Forward

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- Blue Bell is committed to ensuring FDA and the States are comfortable before resuming operations
- Until then, (b) (4) will not begin
- Tentatively planning to begin at Sylacauga facility
  - (b) (4)
  - (b) (4)
- Plan to begin (b) (4) to evaluate and refine procedures

# Dialogue and Discussion

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