Using Donor Human Milk in Extremely Premature Infants
Introduction

- Scott Eaker, Vice President of Quality and Regulatory Affairs
- Scott Elster, Chief Executive Officer
- David Rechtman, MD, Chief Medical Officer
Agenda

• About Prolacta
• Our Babies
• Our Products
• Prolacta Research
• Four Pillars of Safety
• Human Milk Regulation
About Prolacta

• Prolacta Bioscience is a life science company dedicated to Advancing the Science of Human Milk®

• Our mission is to make a meaningful difference in the lives of thousands of the most vulnerable infants through world class research and innovative products.

• Prolacta offers a suite of specialty formulations of human milk to meet the nutritional needs of premature infants born weighing less than 1250 g.
Our Babies: Tyler – BW 950g

December 6, 2010
FDA Pediatric Advisory Committee
Product Overview

Human Milk Fortifier
Prolact+ H^2 MF
The first and only 100% human milk-based fortifier for premature infants
Product Overview

Standardized Human Milk Products
Neo20
Ready to feed when mom’s milk or other donor milk is unavailable

Three fill volumes allow for appropriate mixing ratios with Prolact+ H²MF

December 6, 2010  FDA Pediatric Advisory Committee
Research is critical component of safety

• **In vitro**
  - Viral reduction studies of pasteurization
  - Fat, Ca, P loss during continuous feedings of Fortified Human Milk
  - Osmolality of mixed feeding solutions
  - Shelf-life studies

• **Human clinical research - completed**
  - Ca absorption in premature infants fed an exclusive human milk diet (n = 15)
  - Sheridan cohort study 66 patient open label study
  - 207 patient study comparing completely human diet to standard of care - published
  - 53 patient study comparing completely human diet with a formula diet

• **Human Clinical research - in progress**
  - Prolacta diet in babies with congenital anomalies of the gut (15 of 30 enrolled)
  - Case series investigating electrolytes in premature infants receiving Prolacta (23 infants completed scheduled to run until August 2011)
  - Impact of human oligosaccharides, pre- and probiotics on stool flora in VLBW infants (30 of 36)
The Four Pillars of Safety

Donor Screening

Final Product Testing

Specific Milk Testing

Processing and Pasteurization
Donor Screening

• Before milk is collected by Prolacta, donors undergo a rigorous qualification process
  - Donor completes a health/lifestyle interview
    ➢ Based on blood/plasma/tissue banking requirements
    ➢ Non-standard responses reviewed by Medical Director
  - Donor approval from primary care physician
  - Pediatrician certification of infant’s health
  - Donor confirms storage conditions of their milk
  - Blood draw for infectious disease testing (HIV-1, HIV-2, HTLV I, HTLV II, HBV, HCV and syphilis)
  - Donor submits a cheek swab to create a Donor DNA ID
Specific Milk Testing

- After milk is received by Prolacta, it undergoes direct safety testing
  - Each donation is pooled individually and tested for:
    - Drugs of abuse (amphetamines, marijuana, opiates, methamphetamines, benzodiazepine, cocaine, and primary metabolites)
    - Milk DNA ID – must match Donor DNA ID
    - *Bacillus cereus*
  - Only milk that passes all testing can be pooled for production
Prolacta’s manufacturing process is designed to ensure a safe product

- All processing occurs in certified cleanrooms that are regularly monitored for pathogens
- All manufacturing employees have experience working with biologic products
- Manufacturing and quality systems are designed to be compliant with pharmaceutical GMPs
- Processing produces a standardized product to ensure consistency in feeding
Highly controlled pasteurization process
- Vat pasteurization with jacketed temperature control
- Multiple points of temperature monitoring
- Validation of viral inactivation
  - Studies performed in-vitro using model virus
  - >5.8 to >7.7 log reduction of lipid enveloped viruses (HIV, HBV, HCV)
  - >2.6 log reduction of non-lipid enveloped virus (HAV)
Final Product Testing

- Samples are taken from each lot of product to test for:
  - Viral contamination – HIV, HBV, HCV by highly sensitive PCR methods
  - Microbial contamination – Total aerobic count, *B. cereus*, coliform and *E. coli*, *P. aeruginosa*, *S. aureus*, *Salmonella*, yeast and mold
  - Nutritional Panel – protein, fat, calories, minerals
    - These exact results are used to create lot-specific labeling
Exempt Infant Formula Labeling

- Prolacta labels its fortifiers in compliance with the requirements of the Infant Formula Act.
• Prolacta’s Neo20 is labeled in compliance with the Nutritional Labeling and Education Act

Food Labeling

Nutrition Facts

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<tr>
<th>Ingredient</th>
<th>Amount/serving</th>
<th>%DV*</th>
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<tbody>
<tr>
<td>Total Fat</td>
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<tr>
<td>Sodium</td>
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<tr>
<td>Potassium</td>
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<tr>
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<tr>
<td>Zinc</td>
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<tr>
<td>Chloride</td>
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<td>Protein</td>
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<tr>
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<tr>
<td>Manganese</td>
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Ingredients: Human Milk

Patent pending © 2009 Prolacta Bioscience. Prolacta Bioscience, Monrovia, CA 91016

www.prolacta.com

Directions for Preparation and Use:

Store at 5°-30°C (41°-86°F) until ready to use. Do not microwave. Great with cold cereal, fruit or yogurt. Mix before use.

Prolacta® Neo20

December 6, 2010

FDA Pediatric Advisory Committee
Regulatory Environment

• The regulatory environment for human milk products is complex
  - Infant formula regulations
  - Food regulations
  - Voluntary standards and recommendations (CDC, ADA, HMBANA)
  - State tissue banking regulations
Regulatory Environment

• Each state’s tissue banking regulations have slightly different requirements
  - Required blood tests for donors
  - Medical director licensing requirements
  - Record keeping requirements

• Differences in regulations present an impediment to breakthrough improvements in safety

• A single standard incorporating all requirements would improve confidence and acceptance of human milk in NICU
Questions