INFANT FORMULA

2014 FDA / JIFSAN FOOD AND NUTRITION WEBINAR

Carrie Assar, MS, PharmD
Infant Formula and Medical Foods Staff
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Why is infant formula regulated?
Need for Legislation

• 1978 — Addition of sodium chloride to infant formula discontinued by one manufacturer

• 1978-1979 — More than 130 infants developed hypochloremic metabolic alkalosis
Poll Question #1:

Is the following statement true or false?

FDA regulates infant formulas like drugs since they are for infants.

- True
- False
Infant Formula Act (IFA)

- Enacted 1980
- Amended 1986
- Section 412 of Federal Food, Drug, and Cosmetic Act
  - Safe production
  - Nutritional sufficiency
  - Adulteration
  - Mandatory recall authority
Answer to Poll Question #1: False

FDA regulates infant formulas as a food.
What is infant formula?

A product intended for use by infants that simulates human milk or is suitable as a complete or partial substitute for human milk.
Infant Formula

• Regulated as:
  – Food
  – Infant Formula

• Categories:
  – “Non-exempt”
  – “Exempt”
Poll Question #2:

Under FDA’s regulations, an infant is defined as a person that is:

A. Not more than 18 months of age
B. Not more than 6 months of age
C. Not more than 12 months of age
D. Not more than 9 months of age
Who are the intended users of infant formula?

What are the types of infant formulas in the market?
Intended Users

• Infants
  – Infants are defined in FDA regulations as persons not more than 12 months of age
Answer to Poll Question #2: C

An infant is a person not more than 12 months of age
Infant Formulas Marketed in the United States

- Formulas for term infants with generally good health status

- Formula products for infants with inborn errors of metabolism, low birth weight, or who otherwise have an unusual medical or dietary problem
Poll Question # 3:

Infant formula is a unique food because:

A. It only comes in powder form  
B. It may be an infant’s sole source of nutrition  
C. It must be tasty  
D. It must be mixed with water
What types of infant formula products are available for term infants?
Products for Generally Healthy Term Infants

- Milk-based formulas
- Partially hydrolyzed milk protein formulas
- Soy protein isolate-based formulas
How would a formula for the preterm infant differ from that of a term infant?
Preterm Infant Formula

• Milk-based formulas with increased levels of
  – Energy
  – Protein
  – Certain vitamins and minerals
Are there other products for preterm infants that are regulated as infant formulas?
Other Products for Preterm Infants

• Human milk fortifiers (powder or liquid)
  – Contain nutrients to **augment** human milk
  – Nutritionally incomplete

• Human milk fortifiers (liquid)
  – Concentrated products (30 kcal/oz)
  – Nutritionally complete
Products for Infants with Certain Types of Disorders (Gastrointestinal / Allergy)

• Casein hydrolysate formulas
  – extensively hydrolyzed
• Amino acid-based formulas
  – containing all amino acids
Products for Infants with Metabolic Disorders

- Products formulated with modifications in a macronutrient source, usually protein
  - Amino acid-based products formulated without:
    - phenylalanine for infants with phenylketonuria
    - isoleucine, leucine, and valine for infants with maple syrup urine disease
  - Nutritionally incomplete
  - Used in combination with a complete protein source
Answer to Poll Question #3: B

Infant formula is a unique food because it may be an infant’s sole source of nutrition.
Infant Formula
Regulatory Categories

• **Nonexempt**
  – Term infants
  – Otherwise not meeting exempt criteria

• **Exempt**
  – Low birth weight/preterm
  – Inborn errors of metabolism
  – Unusual medical or dietary problem
Provisions of the Infant Formula Act

• Current Good Manufacturing Practices (cGMP)

• Nutrition-oriented statute
  – Special conditions of use
  – Provide sole source of nutrition during a very vulnerable period
Poll Question #4:

Is the following statement true or false?

FDA approves infant formulas before they can enter into commerce.

- True
- False
Infant Formula Act
Nutrient Requirements

• Nutrient Requirements for Infant Formulas
  – Minimum levels for 29 nutrients
  – Maximum levels for 9 of the 29 nutrients
  – Exceptions for exempt products such as metabolic formulas and formulas for preterm infants
Infant Formula Act
Quality Factor Requirement

• Quality Factors
  – Manufacturer shows that formula provides nutrients in a form that is bioavailable and safe
  – Formula supports healthy growth when fed as sole source of nutrition
  – Final Rule: defines minimum requirements for quality factors
    • Normal physical growth
    • Sufficient biological quality of protein
Infant Formula Act
Conditions for Adulteration

• Does not provide nutrients as specified by law
• Processing is not in compliance with cGMP and quality control procedures
• Does not meet quality factor requirements
Infant Formula Act

Other Provisions

• Manufacturers must test product composition during production and shelf-life

• Manufacturers must keep records on production, testing, and distribution of each batch of infant formula
Inspections for Compliance

- FDA plant inspections
  - Yearly inspections of all facilities
    - cGMP
    - Quality control
    - Records and reports
  - Inspection of new facilities during early production runs
  - Special inspections
Infant Formula Act
Product Recalls

• If an infant formula does not provide required nutrients or is adulterated or misbranded in other ways:
  – Voluntary recalls initiated by firm
  – Mandatory recalls if FDA determines there is a risk to human health
Answer to Poll Question #4: False

FDA has pre-market *notification* requirements that is not a premarket *approval* process.
Infant Formula Act
Initial Requirements to Market Infant Formula in the U.S.

- Registration of manufacturer and product
- 90-day notification
When Are 90-Day Notifications Required?

- New formulas
  - Manufactured by person who has not previously manufactured infant formula
  - Manufactured by person who has not marketed in the U.S.
  - *Major change* in processing or formulation
  - Must submit 90-days before plan to market
What is meant by a “major change”? 
Major Change Examples

- New formula
- New manufacturer
- Addition of a new macronutrient
- Substantial quantitative change in macronutrient
- Addition of new ingredient added for potential nutrient contribution
- New technology
- New packaging
90-Day Premarket Notifications for Non-Exempt Formulas

• Explanation
• Quantitative formulation
• Change description
  – reformulation or processing
• Assurances
  – meets quality factors
  – meets nutrient content
  – processing complies with cGMPs and quality control
90-Day Premarket Notifications for Exempt Formulas

- Quantitative formulation
- Label and labeling
- Description of medical conditions for which formula is represented
- Medical, nutritional, scientific, or technological rationale for deviation from nutrient requirements
What types of reviews are needed for an infant formula notification?
Product Review by FDA

- Reviews needed:
  - Nutrition
  - Clinical
  - New ingredient
  - Food contact surface
  - Processing
  - Statistics
  - Special expertise/consultations
Notification Summary

- Premarket notification not premarket approval of product
- Objective of notification is to assure FDA
  - Nutrient content meets requirements
  - Manufactured according to cGMPs with appropriate quality control
  - Nutrient testing of finished product
  - Meets quality factors
Federal Regulations for Infant Formula Labels

- Nutrient levels per 100 kcal
- Preparation and use instructions include
  - Product storage
  - “Sterilization” of water, bottle, and nipples, when necessary
  - Dilution for powder and liquid concentrates, including pictogram showing major steps for preparation
The label is required to show in picture format:

- that water is boiled, if the infants’ physician says to do so, and
- how to combine the water with liquid concentrate in equal amounts to a baby bottle.

Powdered formula would show the level scoop of formula being combined with the appropriate amount of water.
Federal Regulations for Infant Formula Labels

• Other required information
  – “The health of your infant depends on carefully following the directions for preparation and use.”
  – “Use as directed by a physician.”
  – “Use by” date
Infant Formula Information

www.fda.gov
QUIZ QUESTION 1

Exempt infant formula must meet the same nutrient requirements as non-exempt infant formula.

- True
- False
QUIZ QUESTION 2

Infant formula must be tested at the final product stage for nutrients before it is permitted to enter into interstate commerce.

- True
- False
QUIZ QUESTION 3

Infant formula labels must list all of the required nutrients in the quantity per 100 kilocalories of formula.

- True
- False
QUIZ ANSWERS

1) FALSE
2) TRUE
3) TRUE
Questions?

Carrie Assar, MS, PharmD
Infant Formula and Medical Foods Staff
To begin shortly

2014 FDA/JIFSAN Food & Nutrition Webinar

Medical Foods

Shawne Suggs-Anderson, MMSc, RD
Infant Formula and Medical Foods Staff
ONLDS/CFSAN/FDA
September 23, 2014