Outline

• Center for Veterinary Medicine Introduction
  – Federal Food, Drug and Cosmetic Act

• Pre-Market Approval
  – Food Additive Petitions
  – GRAS
  – AAFCO Feed Ingredients

• Food Safety Modernization Act
  – Overview
  – Preventive Controls
CVM’s Vision / Mission

**Vision**

“Excellence, Innovation, Leadership”

**Mission**

“Protecting Human and Animal Health”
Division of Animal Feeds

- Monitors, sets standards for feed contaminants
- Assists with feed safety problems (recalls, emergencies, HHE preparation, diversions, import detention, etc.)
- Approves food additives
- Reviews GRAS notifications
- Manages medicated feed & pet food programs
- Review of animal feed labeling/medicated feed labeling
- Provides scientific support on animal feed matters
- Review of biotech plant notifications
Federal Food, Drug and Cosmetic Act (FDCA)

- Defines food as ‘articles used for food or drink for man or other animals’
- Defines a food additive as ‘any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in becoming a component or otherwise affecting the characteristics of any food’
  - Includes those used in producing, manufacturing, packing, processing, preparing, and treating food
  - Excludes substances generally recognized as safe
Basic FDCA Requirement

• Any substance added to an animal feed must be
  – Approved for the use as a food additive OR
  – GRAS for its intended use

• Other types of substances added include new animal drugs, color additives, pesticide chemicals, or prior sanctioned
Regulatory Examples...

• Feedstocks
  – Bioengineered Plant Products - *Biotechnology Consultation Note to the File*

• Manufacturing (Process) Ingredients - *Approved Food Additive, GRAS, AAFCO Feed Ingredient Definition*
  – Fermentation Microorganisms and Enzymes
  – Processing Aids
  – Antibiotic/ Antimicrobial Drugs
  – Post-Processing Aids

• Contaminants - *The FDA Compliance Program Guidance Manual contains information on the following: Pesticides/Industrial Chemicals; Elements; Mycotoxins; Microbes; and Dioxins*
Food Additive Petition Process

• FDCA requires premarket approval of food additives
  – Foods containing unapproved “food additives” are adulterated under Section 402
  – Section 409 provides for a food additive petition process to establish standards for safety and review of the petition

• Part 571 of Title 21 Code of Federal Regulations further describes the food additive petition process
■ Approved Animal Food Additives are in 21 CFR 573

http://ecfr.gpoaccess.gov
GRAS Exemption to the Definition of Food Additive

• FDCA exempts substances that are generally recognized as safe (GRAS) by:
  – experts qualified by scientific training and experience, to evaluate its safety as having been shown through scientific procedures to be safe under conditions of use
  – OR for a substance used in food prior to 1958 based on common use in food

• GRAS determinations are the firms responsibility
  – Premarket review by FDA is not required
  – Marketing of the substance is done at the firms risk
GRAS Exemption

• General recognition of safety is for a substance for an intended use
• GRAS determinations for a substance’s use in animal food must address intended use in the intended animal species
• GRAS status is more difficult to establish than a food additive regulation due to the requirement for general recognition
Locating GRAS Notices Reviewed by FDA

http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/ucm243845.htm
Association of American Feed Control Officials

• Abbreviated “AAFCO.”

• An Association of Feed Control Regulators in
  – The 50 States,
  – Canada, Puerto Rico,
  – USDA, & FDA.

• AAFCO has No Regulatory Authority.
  – It Does Make Recommendations or “Models” for State Laws and Regulations.
  – State Governments Must Adopt the Model Bills and Model Regulations Into State Laws for Regulatory Authority to exist. States enforce these laws and regulations.
Past Regulation and AAFCO Ingredient Definitions

• CVM participated in the AAFCO definition process for review of new ingredients for animal feed
  – No safety concerns for substance
  – All information was supplied to support establishment of a new definition

• Use of enforcement discretion by CVM for unapproved food additives
AAFCO OP – Distillers Ingredient Update

• Types of ingredients potentially reviewed as an ingredient definition
  – Distillers Oil, Feed Grade
  – De-oiled Distillers
  – Enzymes
  – Yeasts
  – Feedstocks (grains, forages)

• New Tentative Section: T73
  – Processing Aids
Food Safety Modernization Act...

- Directs FDA to build a new, modern food safety system that includes standards for preventing food safety problems; and
- Provides FDA with tools for gaining high rates of compliance with those standards.
To meet the vision FDA will...

- Promulgate new regulations that will provide the standards for protecting food from farm-to-table
- Develop guidance with and for the regulated industry to enhance understanding of what is needed to protect food
- Provide for a common understanding of how to comply with the standards through training
- Develop and apply the tools for gaining high rates of compliance with the standards
General Principles

• Science-based – Controls that are minimally necessary to protect public health
• Flexibility – where specific preventive controls are mandated, alternatives are accepted if validated
• Risk-based – burden tracks risk
• Small business sensitivity
  – Tiered effectiveness dates based on size
  – Some provisions not needed for smallest firms
    • in some cases exemptions from preventive controls
To meet the vision industry must..

• Be primarily responsible for food safety
  – Implement risk base preventive measures at all appropriate points
  – Manage supply chains to assure appropriate measures are being implemented as routine practice
Who is Covered?

• Facilities that manufacture, process, pack, or hold food
• In general, facilities required to register with FDA under sec. 415 of the FD&C Act
• Applies to domestic and imported food
• Some exemptions and modified requirements are being proposed
Human vs. Animal Food Preventive Controls

• Very similar, both establish new sections in CFR
• Animal PC established cGMPs
• Human PC modifies some cGMPs
• Animal PC does not include allergens as a hazard
• Potential for different definitions of very small business
Current Good Manufacturing Practices Elements*

- Personnel
- Plant and grounds
- Sanitary operations
- Sanitary facilities and controls
- Equipment and utensils
- Processes and controls
- Warehousing and distribution
Preventive Control Elements

Requirements for a food safety plan

- Hazard analysis
- Preventive controls for hazards that are reasonably likely to occur
- Plan must be written
- Recall plan for animal food in which there is a hazard that is reasonably likely to occur
- Monitoring
- Corrective action
- Verification
- Records required for preventive controls
- Control for supplies
Effective and Compliance Dates

Effective date:
60 days after the final rule is published

Compliance Dates:

• **Small Businesses**—a business employing fewer than 500 persons would have two years after publication.
Compliance Dates (cont.)

• **Very Small Businesses**—a business having less than $250,000 (or alternatively $500,000 or $1 million) in total annual sales of food would have three years after publication to comply.
  - Very small businesses are considered “qualified” facilities and subject to modified requirements

• **Other Businesses**—a business that does not qualify for exemptions would have one year after publication of the final rule to comply.
Regulations: Where are they now??

- Proposals published in Jan. 2013
  - Produce Safety Standards
  - Preventive Controls for Human Foods
- Proposals under review at OMB
  - Preventive Controls for Animal Foods
  - Foreign Supplier Verification Program
  - Third Party certification
Interactive and robust FSMA webpage

- 24,000+ viewers/month
- More than 8,000 subscribers
- It’s already the second most popular Foods Program page
- [www.FDA.gov](http://www.FDA.gov); link to FSMA is located in the box called Public Health Focus
Thank You