FDA Regulation of Distillers Products, Animal Feed Update

Marla Luther, Ph.D.
Division of Animal Feeds
Center for Veterinary Medicine, FDA

FDA

FDA FOOD SAFETY MODERNIZATION ACT

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

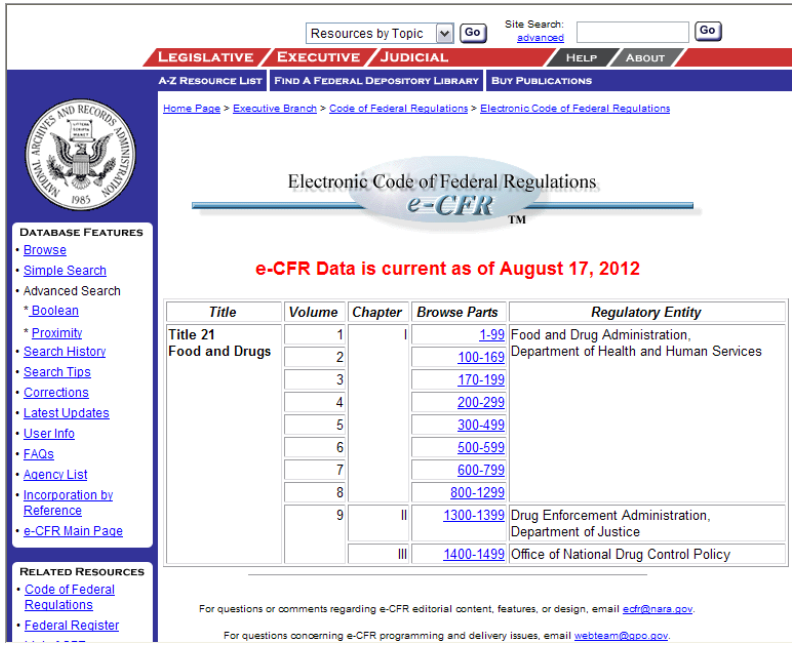
Regulatory Examples…

- 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

Locating Approved Food Additives



http://ecfr.gpoaccess.gov

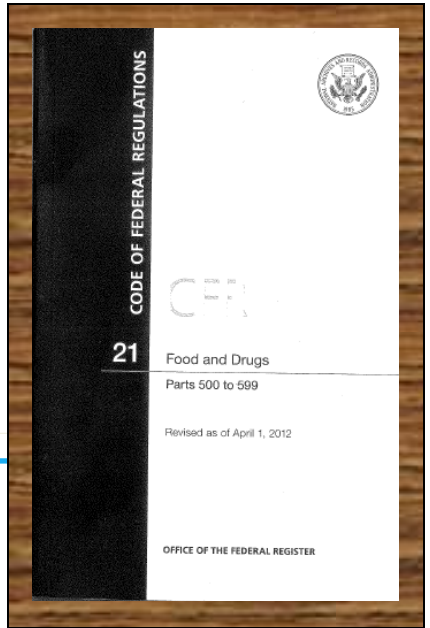
TITLE 21--Food and Drugs

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER E--ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

Part	*Table of Contents*	*Headings*
500	500.23 to 500.1410	GENERAL
501	501.1 to 501.110	ANIMAL FOOD LABELING
502	502.5 to 502.19	COMMON OR USUAL NAMES FOR NONSTANDARDIZED ANIMAL FOODS
509	509.3 to 509.30	UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL
510	510.3 to 510.600	NEW ANIMAL DRUGS
511	511.1 to 511.3	NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE
514	514.1 to 514.235	NEW ANIMAL DRUG APPLICATIONS
515	515.10 to 515.40	MEDICATED FEED MILL LICENSE

- Approved Animal Food Additives are in 21 CFR 573



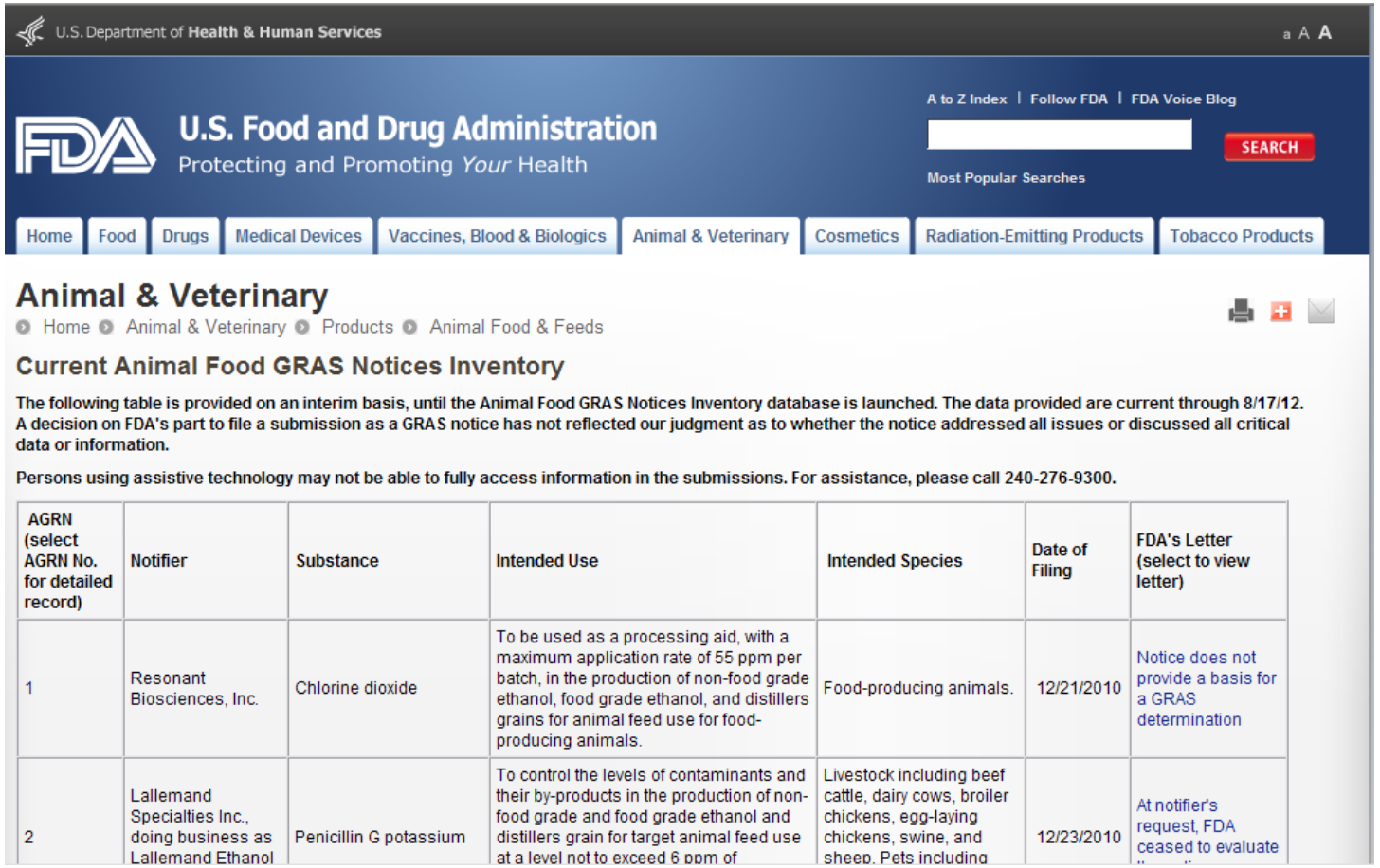
GRAS Exemption to the Definition of Food Additive

- 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



U.S. Department of Health & Human Services

a A A

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | FDA Voice Blog

SEARCH

Most Popular Searches

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

Animal & Veterinary

Home › Animal & Veterinary › Products › Animal Food & Feeds

Current Animal Food GRAS Notices Inventory

The following table is provided on an interim basis, until the Animal Food GRAS Notices Inventory database is launched. The data provided are current through 8/17/12. A decision on FDA's part to file a submission as a GRAS notice has not reflected our judgment as to whether the notice addressed all issues or discussed all critical data or information.

Persons using assistive technology may not be able to fully access information in the submissions. For assistance, please call 240-276-9300.

AGRN (select AGRN No. for detailed record)	Notifier	Substance	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
1	Resonant Biosciences, Inc.	Chlorine dioxide	To be used as a processing aid, with a maximum application rate of 55 ppm per batch, in the production of non-food grade ethanol, food grade ethanol, and distillers grains for animal feed use for food-producing animals.	Food-producing animals.	12/21/2010	Notice does not provide a basis for a GRAS determination
2	Lallemand Specialties Inc., doing business as Lallemand Ethanol	Penicillin G potassium	To control the levels of contaminants and their by-products in the production of non-food grade and food grade ethanol and distillers grain for target animal feed use at a level not to exceed 6 ppm of	Livestock including beef cattle, dairy cows, broiler chickens, egg-laying chickens, swine, and sheep. Pets including	12/23/2010	At notifier's request, FDA ceased to evaluate

http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/ucm243845.htm

FDA FOOD SAFETY MODERNIZATION ACT

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.)

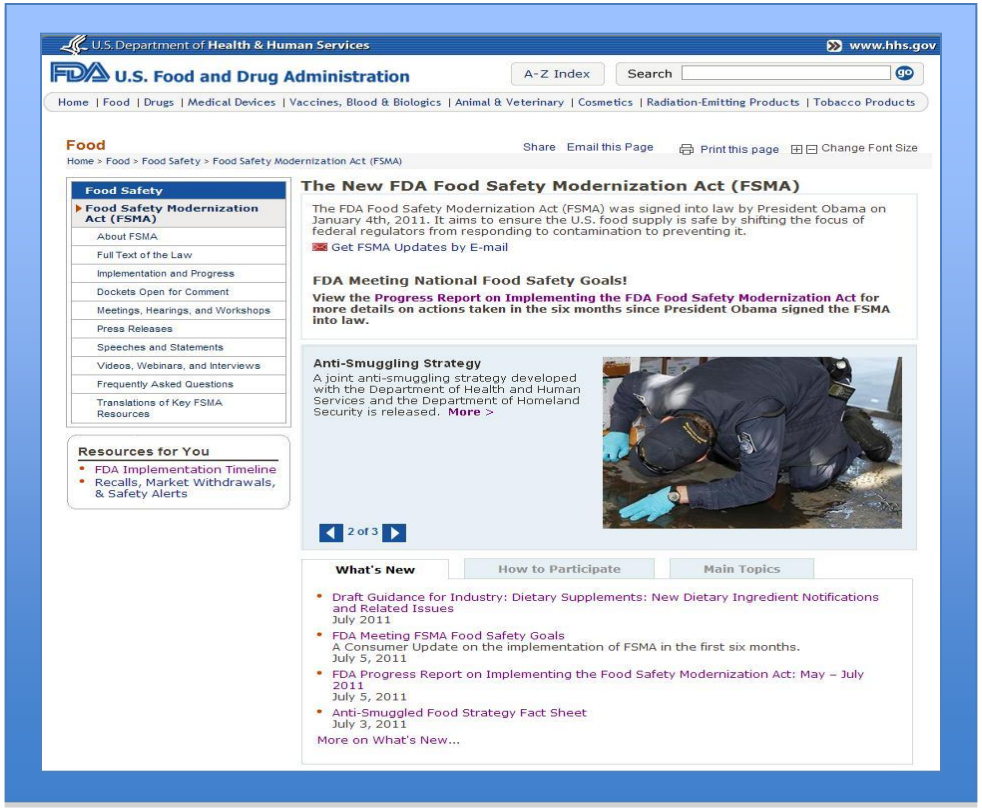
- **Very Small Businesses**—a business having less than $250,000 (or alternatively $500,000 or $1 million) in total annual sales of food would have three years after publication to comply.
  - Very small businesses are considered “qualified” facilities and subject to modified requirements
- **Other Businesses**—a 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; link to FSMA is located in the box called Public Health Focus



FDA FOOD SAFETY MODERNIZATION ACT

Thank You

FDA FOOD SAFETY MODERNIZATION ACT