

Distillers' Grains Opportunities and Challenges



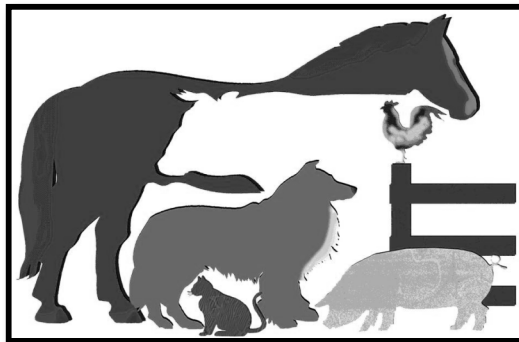
RFA
National Ethanol Conference
February 26, 2008

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FDA/Center for Veterinary Medicine

Center for Veterinary Medicine

- ✓ Approves safe food additives for animal feed, including pet food
- ✓ Approves drugs for animals including those used in animal feed
- ✓ Monitors and establishes limits for feed contaminants
- ✓ Ensures animal feed, including pet food, are labeled correctly

A safe animal feed supply helps ensure healthy animals and people





Federal Food, Drug and Cosmetic Act

The United States Federal Food, Drug and Cosmetic Act (FFDCA) is a set of laws passed by Congress in 1938 giving authority to the Food and Drug Administration (FDA) to oversee the safety of *food*, drugs and cosmetics.

FFDCA Definitions



- The FFDCA defines “*food*” as (1) an article used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.
- The FFDCA defines “*food additive*” as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food.....
- The FFDCA defines “*animal feed*” as an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

Food/Feed Ingredient

- Food
- Food additives
- Color additives
- GRAS substances
- Prior-sanctioned substances
- Regulatory discretion substances, i.e. AAFCO feed ingredients

FFDCA Requirements ...

- The FFDCA sets forth requirements for foods in the Sections 402 and 403. Failure to meet these requirements can result in a product being deemed “adulterated” or “misbranded”.
- Although FDA has the responsibility for regulating the use of animal food/feed products, *the ultimate responsibility for the production of safe and effective animal food/feed products lies with the manufacturers and distributors of the products.*

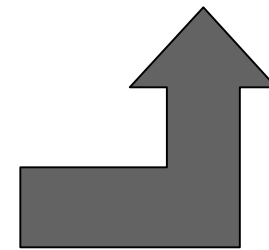
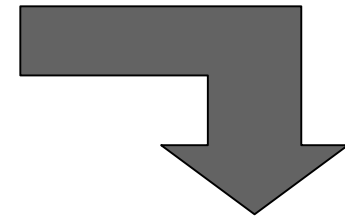
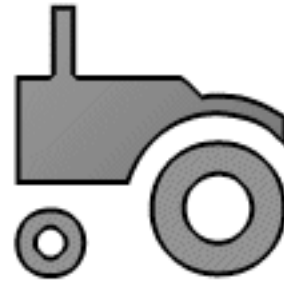
FDA Letter to Feed and Feed Ingredient Manufacturers



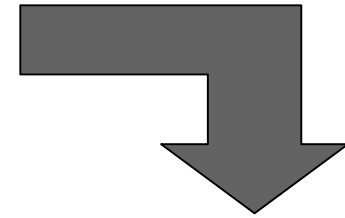
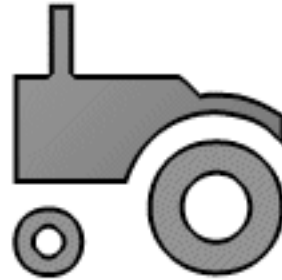
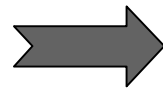
May 16, 2007

- The U.S. Food and Drug Administration (FDA) is taking this opportunity to remind feed and feed ingredient manufacturers of their *legal responsibility* to ensure that *every ingredient used in their products is safe* for its intended use, whether the product is meant to be used to feed animals intended for human consumption or non-food animals such as pets.
- *Manufacturers are responsible for taking their own measures to ensure the safety of their products.* Manufacturers should not wait for possible FDA testing of their materials as manufacturers bear the responsibility of ensuring only safe products are put on the market.

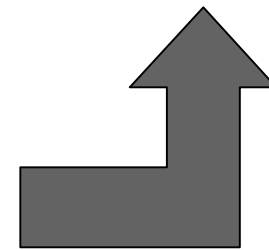
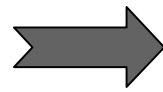
Are You a Feed or Feed Ingredient Manufacturer?



Are You a Feed or Feed Ingredient Manufacturer?



Yes



What Does This Mean.....



Regulatory Requirements



Distillers' Grains

- **Genetically Modified Plants** - *Biotechnology Notification File*
- **Manufacturing (Process) Ingredients** - *Approved Food Additive, GRAS, AAFCO Feed Ingredient Definition, or Regulatory Discretion*
 - Fermentation Microorganisms and Enzymes
 - Processing Aids
 - Antibiotic/ Antimicrobial Drugs
 - Post-Processing Aids
- **Novel Co-Products** - *Approved Food Additive, GRAS, or AAFCO Feed Ingredient Definition*
- **Contaminants** - *The FDA Compliance Program Guidance Manual contains information on the following: Pesticides/Industrial Chemicals; Elements; Mycotoxins; Microbes; and Dioxins*

Bioterrorism Act

The “Public Health Security and Bioterrorism Preparedness and Response Act of 2002” (the Bioterrorism Act) requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with the FDA by **December 12, 2003**.

Who must register?

- Owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States are required to register the facility with the FDA.
- Domestic facilities are required to register whether or not food from the facility enters interstate commerce.

<http://www.cfsan.fda.gov/~furls/ovffreg.html>

Opportunities and Challenges

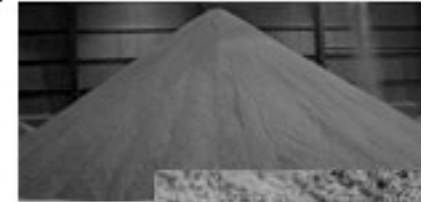
- Water Quality

- Source, re-cycling
- Flocculating agents



- DDG Identity

- Does co-product meet current AAFCO definitions?
- Is co-product co-mingling with other plant streams?



Questions



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