March 31, 2014

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852


Department of Health and Human Services Food and Drug Administration

Re: Comments of the Renewable Fuels Association (RFA); Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (78 Fed. Reg. 64,736)

RFA is the leading national trade association for the domestic ethanol industry. Its mission is to advance the development, production, and use of fuel ethanol by strengthening America’s ethanol industry and raising awareness about the benefits of renewable fuels. RFA’s members are working to help America become cleaner, safer, energy independent and economically secure.

BACKGROUND
The ethanol industry’s enormous contribution to the global feed market often goes unnoticed. The U.S. ethanol sector has become one of the largest contributors to the U.S. feed supply. Roughly one-third of every 56-pound bushel of grain that enters the ethanol process is enhanced and returned to the animal feed market, most often in the form of distillers grains, corn gluten feed, and gluten meal. These co-products are fed to beef cattle, dairy cows, swine, poultry, and fish in nations around the world. Today, more than 85% of dry mill ethanol plants also extract corn distiller’s oil, a product that is sold into the feed market or used to produce biodiesel.

Two processes are primarily used to make ethanol in the United States: dry milling and wet milling. Both the wet and dry mill processes utilize only the starch portion of the corn kernel for ethanol production. The remaining protein, fat, fiber and other nutritional components remain available for use as animal feed. While there are a variety of animal feed co-products manufactured at U.S. ethanol facilities, distillers grains are by far the most common.

Co-Products from the U.S. Grain Ethanol Industry

<table>
<thead>
<tr>
<th>Dry Mill Process</th>
<th>Wet Mill Process</th>
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<tr>
<td>Distillers Dried Grains with Solubles (DDGS)</td>
<td>Corn Gluten Feed (CGF)</td>
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<tr>
<td>Distillers Dried Grains (DDG)</td>
<td>Corn Gluten Meal (CGM)</td>
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<tr>
<td>Wet Distillers Grains (WDG)</td>
<td>Corn Germ Meal</td>
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<tr>
<td>Condensed Distillers Solubles (CDS)</td>
<td>Crude Corn Oil</td>
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<td>Corn Distillers Oil (CDO)</td>
<td>Heavy Steep Water</td>
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With over 50 years of successful feeding, ethanol co-products have a long history of being recognized as a highly nutritious animal feed ingredient and have consistently shown to be a safe and beneficial source of protein and energy.

Major marketers of ethanol feed co-products estimate that beef and dairy cattle accounted for about 79% of domestic distillers grains consumption in 2013, while swine consumed 12% and poultry 8%. Other species, such as fish, consumed approximately 1% of distillers grains. Though poultry and swine still represent a much smaller share of consumption than beef and dairy, usage among non-ruminant species is increasing.

As for the wet milling co-products, corn gluten feed is primarily fed to dairy and beef cattle, while corn gluten meal is used to feed a wide variety of species, including poultry and fish. Corn gluten meal, which features a very high concentration of protein, is often used as an ingredient in pet food as well.

The ethanol industry has been steadily growing and generated 35.5 million metric tons (mmt) of high-quality feed in the 2012/13 marketing year. Production is expected to rise to 37.8 mmt in 2013/14. To put these production volumes in context, consider that the amount of feed produced by the ethanol industry in 2012/13 would rank as the world’s fourth-largest corn crop, trailing only the United States, China, and Brazil. The feed produced by ethanol facilities in 2012/13 would be enough to produce nearly 45 billion quarter-pound hamburger patties—or six patties for every person on the planet.

COMMENTS ON PROPOSED RULE
We are pleased to provide comments on the proposed rules that will establish new provisions for current good manufacturing procedures and preventive controls for food for animals that apply to facilities that manufacture, process, pack, or hold animal food and are required to register as a food facility under section 415 of the Food Drug & Cosmetic Act. We expect the proposed rule would apply to most all of the ethanol manufacturers producing feed co-products like Distillers Grains, Corn Distillers Oil, Corn Gluten Feed, Corn Gluten Meal, etc., intended for use as animal feed.

In general, we believe the thresholds defining who qualifies as a “very small businesses” are set too low. Even under the largest annual sales of Option 3 (total annual sales of <$2,500,000) we would not expect facilities in our industry to fit this category. Unless the annual sales amount for very small business is increased to a much higher level we expect most of the industry to be considered small businesses.

FDA requested comment whether CGMPs related to human food are appropriate for animal food. At a fundamental level, we believe clear distinctions should be made between human food and animal feed for the purposes of establishing CGMPs. Some CGMPs currently in place for human food are totally unnecessary and inapplicable to animal food manufacturing. For example, personnel hygienic practices necessary for human food should not be universally applied for animal feed. For example:

§ 507.14 (a)(1) Personnel.
Any person who, by his own acknowledgement, by medical examination, or by supervisory observation, is shown to have, or appears to have any illness, open skin lesion, or other source of abnormal microbial contamination by which there is a reasonable possibility of animal food, animal food-contact surfaces, or animal food-packaging materials becoming contaminated, is excluded from any operations which may be expected to result in such contamination until the condition is resolved;
An ethanol plant employee with a head cold or a cut on his forearm, both of which would not cause harm to the animal through contact with animal food, could be excluded from working under the rule as written. The agency should not assume we have other jobs for this employee, he/she could possibly be sent home without pay.

More broadly, a number of CGMP programs and risk management tools focused on animal feed have already been developed and voluntarily implemented by the U.S. feed industry. We believe FDA’s final CGMP for animal feed producers should be instructed and shaped by existing programs developed by the feed industry.

The RFA is pleased the FDA is not including provisions for product and environmental testing programs or a supplier approval and verification program in this proposed rule. The facility should be provided the flexibility to determine its own needs and compliance strategy. While we do respect that these programs play an important role in quality operations, the individual facility can best develop in-house programs for these measures and incorporate into the facility written food safety plan. These programs work best if they are designed based on the specific products and activities of the facility. A detailed regulation pushing a “one size fits all” approach for these types of programs would be a burdensome and expensive to manage.

The regulations require the facility to prepare, or have prepared, and implement a written food safety plan. The written food safety plan must be prepared by (or its preparation overseen by) a “qualified individual”. We are pleased with the option provided that the “qualified individual” may be an employee of the facility or from a third party, such as individuals associated with universities, trade associations, and consulting companies. This flexibility is important for those facilities that have in-house expertise in these areas, as well as for those facilities with limited technical expertise.

While we believe the ethanol industry already uses good manufacturing practices and has a stellar track record of evaluating and mitigating potential risks and hazards, the RFA recognizes that guidance and technical assistance will be needed to ensure awareness of the detailed preventive controls requirements once the final rule is issued. Also, having a certified qualified individual at each facility may require a “train-the-trainer” type of program. We look forward to helping facilitate the educational and training needs by participating in the Alliance partnership.

Thank you for the opportunity to comment. We applaud FDA’s careful consideration of stakeholder feedback on this issue. If you have questions regarding the contents of this letter, please contact Kelly Davis at kdavis@ethanolrfa.org

Sincerely,

Bob Dinneen
President & CEO