December 15, 2014

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

**Re: Docket No. FDA-2011-N-0922/RIN 0910-AG10: Supplemental Proposed Rule Regarding Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals**

Dear Sir or Madam:

The Brewers Association (BA) appreciates the continued efforts of the FDA to establish workable regulations to implement the Food Safety Modernization Act. BA supports and concurs with the joint comment filed by several alcohol beverage industry trade associations (Joint Industry Comment) including Part III of the comment, which asks that the FDA eliminate the distinction made in the supplemental rulemaking between wet and dry grain. BA offers this additional comment to focus on some practical issues faced by small brewers with respect to spent grain, as the BA membership has by far the largest number of small entities (over 3000), that may be subject to the animal food regulations.

A positive development noted in the supplemental rulemaking is that FDA officials recognized and attempted to address the parallel regulatory regimes that human food producers faced if byproducts of the human food process are used as animal food. The position articulated in the supplemental rulemaking is a sensible approach to avoid duplicative and potentially conflicting regulations while maintaining a safe food supply for humans and animals. BA also supports the revised definitions for "Known or reasonably foreseeable hazard," "Significant hazard," "Hazard" and "Very small business."

Brewers already operate in one of the most heavily regulated industries in the United States. The federal government and all fifty states have developed an extensive and extraordinarily complex regulatory regime that governs basic product safety, traceability, labeling, and a variety of industry trade practices. The Food Safety Modernization Act (FSMA) has already led to publication of thousands of pages of new guidance and regulations on top of the multiple layers brewers currently face. Small brewers are often spend inordinate time and effort to navigate complex regulatory requirements applied to a small business. That is why BA mobilized in an effort (1) to eliminate one more layer of regulation for a process that the FDA acknowledges is

low risk and (2) to obtain clarity on application of FDA regulations once spent grain leaves a brewery.

The proposed supplemental proposed rules do not extend the exemption granted by Congress to brewers for the production of human food to the disposal of spent grain for use as animal food as requested in the comments filed by the BA in response to the original animal food rulemaking. As a result, the FDA's proposed regulation and the supplemental regulation convert a largely informal business practice dating back centuries to a federally regulated process that occurs routinely at more than 3000 unique breweries across the nation. While the FDA made some accommodations in the supplemental rulemaking notice, brewers are still subject to yet another regulatory system. That scheme requires some level of FDA enforcement activity and ongoing compliance by brewers. It will inevitably lead to longer and more detailed regulations and/or additional agency guidance to address questions that inevitably arise when a federal agency enacts a set of regulations governing a large, diverse, and dynamic industry. In the BA's experience, the federal rulemaking process often cannot accommodate industry changes. Over time, practices not contemplated by regulations lead to uncertainty, delay in new processes, variable training and lots of informal and inconsistent decisions by agency personnel who are required to make day-to-day decisions in the field.

Under modern regulatory processes implemented by any government agency, businesses must comply with statutes, regulations, agency decisions, industry circulars, newsletters, enforcement manuals, and thousands of pages of information on agency web sites. The brewing industry is already subject to similar situations with issues such as brewery design, product formulation, labeling, taxation, environmental controls, workplace safety, and other aspects of brewing that are heavily regulated by numerous federal, state, and local government agencies.

In the case of spent grain used as animal food, brewers (and distillers) will have limited but specific compliance obligations that will require some level of FDA enforcement. Brewers whose facilities are inspected by the FDA also face the fundamental issue that FDA enforcement personnel may not know that they do not have to inspect the rest of the brewery for compliance with FSMA regulations governing animal food and they may assume that human food regulations apply because the statutory exemption for the brewing facility (and other alcohol beverage facilities) is not referenced in the animal food regulations. The brewing facility exemption should be made clear in the final regulations and in inspector training materials.

The preamble to the FDA human food regulation correctly stated the rationale of Congress in granting an exemption for alcohol beverage manufacturers. Excerpt from FDA Notice 78 Fed. Reg. at 3709:

> FDA tentatively concludes that Congress intended to exempt certain alcohol-related facilities from section 418 of the FD&C Act because it found that, in light of the relatively low public health risk presented by the manufacturing, processing, packing, and holding of alcoholic beverages and their joint regulation by both FDA and TTB, the current regulatory scheme was sufficient to control the hazards associated with the manufacturing, processing, packing, and holding of alcoholic beverages.

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> FDA concludes that Congress must have considered identifying hazards and implementing preventive controls for the manufacturing, processing, packing, and holding of alcoholic beverages to warrant lower priority from a public health perspective than other foods. Congress may have made such a conclusion in light of the potential antimicrobial function of the alcohol content in such beverages and the concurrent regulation of alcoholic beverage-related facilities by both FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB).

78 *Fed. Reg*. at 3709

Section 116 exemptions specifically encompass "the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages." FSMA exempted alcohol-related facilities to avoid duplicative regulatory schemes implemented by both FDA and the Tax and Trade Bureau. Decades before FSMA was enacted, Congress and federal agencies had established a comprehensive regulatory system of controls for breweries and other beverage alcohol facilities.

BA respectfully reiterates its argument that the rationale for the exemption in FSMA for human food should apply to the materials used to produce beer and the spent grains that remain, which are utilized for animal food. We are now in a situation where Congress has granted the industry an exemption from the human food regulations. But a byproduct of the brewing process is regulated as animal food and subject to at least some compliance obligations. The result is that hundreds of longstanding and informal brewer-farmer relationships are subject to new federal regulation even though the FDA acknowledges that the activity does not pose a significant risk to humans or animals.

The Brewers Association comment proposed that spent grain used for animal food would be subject to the exemption in Section 116 of the FSMA until delivery to a third party. BA sought to establish a clear line of responsibility for compliance that began at the transfer of the spent grain from a brewery to a farm or other user. The FDA did not address that request directly, and we have to presume that they rejected the BA proposal. BA's March 2014 comment and a joint industry comment on the animal food regulations asked the FDA to clarify the scope of the exemption for breweries in FSMA and to provide a bright-line test that would avoid ambiguity and wasted effort in the future.

The Brewers Association comment also asked that brewpubs be expressly exempted because they qualify for the exemption in Section 116 and they are retail premises excluded in the FSMA, and they are already subject to inspections by state alcohol beverage control agencies, state and local health departments, TTB, and OSHA.

Without a clear exemption in the FDA regulations, brewpubs may also be visited by FDA inspectors who will assume that they have legal authority to conduct a full animal food facility inspection because of the presence of spent grain. We have anecdotal reports that FDA inspections are already occurring and that FDA inspectors or state inspectors acting on behalf of

the FDA are not aware of the exemption for alcohol beverage facilities or the parallel regulatory systems in federal and state law. So the BA's concern is real and the animal food regulations, however narrow, will be a continuing source of confusion. Even if breweries are not identified as high risk facilities and FDA inspections are occasional, they are not consistent with the intent of Congress, nor are they an efficient use of finite FDA resources, as breweries are subject to other inspection regimens.

Following the comment period, the FDA did engage in significant outreach to our organization. However, we did not get the relief we requested and the revised regulations raise new questions.

The revised FDA regulations that apply to spent grain would be reasonable in the absence of other regulations and the fact that breweries (and other alcohol beverage producers) are producing human food. If the FDA is unwilling to extend the FSMA exemption for alcohol beverage facilities to spent grain prior to its delivery to a third party, the FDA should add the proposed regulation governing holding and distribution of human food by-products for use in animal food (proposed new section at 21 CFR § 117.95) to the human food regulations as compliance is straightforward and an FDA or state inspector checking for compliance with human food regulations would already have an understanding of the overall facility and could readily ascertain that the by-products stored for delivery to farms or food processors are being handled in a safe manner.

BA supports the following revisions in the proposed new regulation. The same proposed revisions are also included in the Joint Industry Comment and should be made by the FDA to clarify responsibility for compliance:

Holding and distribution of human food by-products for use in animal food.

(a) Human food by-products held for distribution as animal food ~~without additional manufacturing/processing without additional manufacturing/processing by the human food processor, as identified in § 507.12 of this chapter,~~ must be held under conditions that will protect against contamination ~~including the following~~ **as follows**:

(1) Containers **owned and** used **by the human food processor** to hold animal food before distribution must be designed, constructed of appropriate material, cleaned, and maintained to prevent the contamination of animal food;

(2) Animal food held for distribution **by the human food processor** must be held in a way to prevent contamination from sources such as trash and garbage; and

(3) **Where feasible, the human food processor should** label~~ing identifying~~ the by-product by the common and usual name~~. must be affixed to or accompany animal food.~~ **If labeling is not feasible, the human food processor may provide a written description of the by-product.**

(b) **S**hipping containers (for example, totes, drums, and tubs) and bulk vehicles **owned and** used **by the human food processor** to distribute animal food must be inspected **by the human food processor** prior to use to ensure ~~the~~ **that its** container or vehicle will not contaminate the animal food. **Shipping containers that are owned by the party transporting or receiving animal food from a human food processor must be cleaned, maintained, and inspected by that party to prevent the contamination of animal food.**

These changes will affix responsibility for compliance with the party that is utilizing the by-products. So a farmer or a carrier utilized by a farm or a food processor is responsible for conducting the inspection, as the brewer may not be available or even present when the grain is picked up. In most cases we are aware of, a farmer or a third-party transporter picks up spent grain in a vehicle on an "as-needed" basis. The vehicles that transport the spent grain do not usually belong to the brewery, and in larger breweries (and other alcohol beverage production facilities), the grain may be loaded in bulk onto a truck. Generally the vehicles belong to a farmer, a common carrier, or a food processor.

Finally, the supplemental rulemaking preamble incorrectly states in at least two places that limited data is available on human food by-products used as animal food, [cite Fed. Reg. pages] although the FDA tentatively concluded, "that while there are biological, chemical, and physical hazards that may be present in the human food by-products, the information reviewed indicates these hazards rarely occur." In its March 2014 comments, BA submitted information on sources on the volume of spent grain produced by brewers and distillers collected by the United States Department of Agriculture (USDA) dating back to the 1930s. This is credible information published annually by a federal agency that is directly responsible for oversight of the farms that utilize the spent grain. The data on use of spent grain clearly shows that it has been widely used for as long as USDA has maintained records of grain production. The evidence of widespread use over decades with no identifiable records of significant hazards to animal health substantiates the FDA's conclusion that this is a low-risk activity that does not warrant additional federal regulation.

BA is not overreacting to the FDA proposal as some FDA officials suggested. Brewers know the challenges that occur when new laws are imposed and that state and federal regulations and agency official and informal policies change frequently. Each change requires our members to revise internal policies, educate their work force, and take other compliance steps.

BA's March 2014 comment and a joint industry comment on the animal food regulations asked the FDA to clarify the scope of the exemption for breweries in FSMA and to provide a bright-line test that would avoid ambiguity and wasted effort in the future.

But Congress enacted an exemption for the alcohol beverage industry because the primary goals of FSMA were already being achieved through longstanding regulations by other federal and state agencies.

BA continues to believe that application of FSMA regulations to alcohol beverage manufacturers that provide spent grain for use as animal feed is unnecessary and unwarranted. Our position is

based on the law, the low risk in the process, and the fact that other existing regulations adequately protect the public.

Respectfully submitted,

Paul Gatza

Director

Brewers Association