November 15, 2013

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

Re: Docket No. FDA-2011-N-0920: Proposed Rule Regarding Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

Dear Madame/Sir:

On behalf of the undersigned trade associations representing wine, beer and distilled spirits, we welcome the opportunity to respond to the Food and Drug Administration's proposed new "preventive controls" provisions to implement the Food Safety Modernization Act. (78 Fed. Reg. 3646 (January 16, 2013).) Section 116 of that Act provides several exemptions for alcohol-related facilities from the new system for domestically-produced and imported foods to, among other things, avoid duplicative regulatory schemes implemented by both FDA and the Tax and Trade Bureau; the latter of which has a well-established, comprehensive regulatory system of controls for beverage alcohol facilities, as well as in recognition of the low risk of food-borne illness associated with the manufacturing, processing, packing, and holding of beverage alcohol products.

Executive Summary

In this rulemaking, the Agency discusses the rationale underpinning the exemptions for beverage alcohol facilities and sets forth its interpretation of the scope of those exemptions, with a request for comments regarding the FDA's interpretations of the alcohol-related facilities exemptions under Section 116 of the Food Safety Modernization Act. To that end, we support FDA's interpretation that the scope of the beverage alcohol exemption applies equally to domestic facilities and foreign facilities. This interpretation is sound and provides "national treatment" for foreign facilities consistent with international trade obligations and the dictates of the Food Safety Modernization Act.

FDA also proposes to exclude the manufacturing of "non-alcohol food" where the use of that food (e.g., grapes, grains, etc.) is used in the manufacturing of beverage alcohol products. We fully support FDA's interpretation that the raw materials used to produce beverage alcohol products ("non-alcohol food") should not render these alcohol-related facilities ineligible for the Section 116 exemptions. Any other interpretation unjustifiably would extend the Section 116 exemptions only to alcohol-related facilities that "hold/warehouse" beverage alcohol products ready for sale to the

marketplace, but not to those alcohol-related facilities that actually produce these products. Consequently, FDA's interpretation is sound and any other approach would nullify the alcohol-related facilities exemptions enacted by Congress that specifically encompass "the activities of such facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages."

We, however, disagree with FDA's interpretation of the Section 116 exemptions in terms of FDA's proposal to apply the "preventive controls" provisions to the residues of the grapes, grains and other agricultural products that are used to produce beverage alcohol products. FDA uses as a "demarcation line" to circumscribe the Section 116 alcohol-related facility exemptions when these "non-alcohol foods" become "physically separate" from the beverage alcohol production processes. Based upon the facts of the production processes that dictate otherwise, we urge the Agency to revisit the scope of the Section 116 exemptions.

Spent grains, distillers' grains, grape pomace, and other "by-products" of the manufacturing processes (which are referred to as coproducts by the United States Department of Agriculture) are a natural and necessary consequence, as well as "part and parcel," of the production process. As described more fully below, after the removal of alcohol from the fermented grain mash that is produced by the grains and mixed with yeast to convert the starch into alcohol, what is referred to as "stillage" in the distilling process (the grains and liquid effluent remaining after distillation)—spent grains—may be sold as liquid or dried animal feed, used as fertilizer or otherwise disposed of via landfill. Spent grains and distillers' grains, for example, are inseparable from the brewing or distilling process and consist of proteins, fats, minerals, vitamins, and fibers that are concentrated by the removal of the grain starch in the mashing and fermentation process.

To effectuate the alcohol-related facility exemptions of Section 116 of the Food Safety Modernization Act and in keeping with subsection (c) of that Section, all aspects of the beverage alcohol production processes, including their respective "coproducts," should be exempted from the proposed "preventive controls" provisions of this rulemaking. Any other interpretation would lead to unintended consequences, such as rendering an otherwise exempt facility non-exempt.

Simply put, the beverage alcohol facility exemption logically should extend to the entire "life cycle" of the raw materials used to produce wine, beer and distilled spirits. Distillers, brewers and vintners are in the business of producing their respective products—distilled spirits, beer and wine—not producing by-products/residues, such as spent grains, that are a secondary, inevitable result of the beverage alcohol manufacturing process.

I. Equal Treatment for Domestic and Foreign Beverage Alcohol-Related Facilities

FDA proposes that the exemptions pertaining to domestic beverage alcohol facilities also should extend to foreign facilities. We fully support FDA's interpretation of the Section 116(a)(1) beverage alcohol exemptions and their resulting conclusions.

First, FDA appropriately interprets that Section 116(a)(1) applies to all domestic beverage alcohol facilities, as well as foreign beverage alcohol facilities. The proposed approach to exempt beverage alcohol from the "preventive controls" rule thus covers all domestic facilities that "obtain a

permit or register" with the Department of Treasury, as well as those facilities that must adhere to functionally similar requirements as a condition of doing business in the United States. (See 78 Fed. Reg. at 3707.) To that end, we support FDA's interpretation for its proposed approach to implement Section 116, which is as follows:

> FDA is aware that some facilities that manufacture, process, pack, or hold alcoholic beverages are required to obtain what is technically called a ''permit'' from the Secretary of the Treasury (''Treasury'') and some are required to ''register'' (such as ''dealers'' under 26 U.S.C. 5124) with Treasury. Others must adhere to functionally similar requirements by submitting a notice or application and obtaining approval from Treasury prior to commencing business.
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> Because Treasury informs FDA that these are functionally similar requirements, and because FDA has not identified a public health basis or an indication that Congress intended for these various facilities to be treated differently for the purposes of section 116 of FSMA, FDA tentatively concludes that the phrase ''obtain a permit or register'' is ambiguous and should be interpreted broadly, to include not only facilities that must obtain what is technically named a ''permit'' or must ''register'' with Treasury, but also those facilities that must adhere to functionally similar requirements as a condition of doing business in the United States, namely, by submitting a notice or application to Treasury and obtaining Treasury approval of that notice or application. Proposed § 117.5(i)(1)(i) would provide that obtaining approval of a notice or application from the Secretary of the Treasury as a condition of doing business in the United States under the relevant statutes would be treated the same as obtaining a permit or registering with Treasury under those statutes for the purposes of section 418 of the FD&C Act.

(78 Fed. Reg. at 3707.)

Second, FDA appropriately interprets that Section 116(a)(1) exempts foreign facilities, as well as domestic facilities, which is consistent with the risk-based public health principles underlying the Food Safety and Modernization Act and with Section 404 of the Act providing that none of its provisions "shall be construed in a manner inconsistent with the agreement establishing the World Trade Organization or any other treaty or international agreement to which the United States is a party." (78 Fed. Reg. at 3708.) FDA's reasoning for this conclusion effectuates Section 116 of the Food Safety Modernization Act and is as follows:

> FDA tentatively concludes that it is reasonable to construe section 116(a)(l) to refer not only to domestic firms, but also to foreign firms in order to be consistent with the risk-based public health principles

> underlying section 418 of the FD&C Act and FSMA generally, and to avoid any inconsistency with treaties or international agreements to which the United States is a party. Accordingly, proposed §117.5(i)(l)(i) would apply the exemption not only to domestic facilities that are required to secure a permit, registration, or approval from Treasury under the relevant statutes, but also to foreign facilities of a type that would require such a permit, registration, or approval if they were domestic facilities.

(78 Fed. Reg. at 3708.)

We support FDA's conclusions regarding the alcohol-related facility exemptions set forth in Section 116 and urge that they be adopted as set forth in proposed §117.5(i)(1)(i).

II. "Non-Alcohol Food" Integral to Beverage Alcohol Production

In interpreting Section 116(b) of the Food Safety Modernization Act, FDA states that "[a]t times, the manufacturing, processing, packing, or holding of alcoholic beverages is inseparable from the manufacturing, processing, packing, or holding of food other than alcoholic beverages." In that regard, FDA "tentatively concludes that section 418 of the FD&C Act does not apply to such inseparable activities." (78 Fed. Reg. at 3709.) We support this conclusion that is in sync with the Congressional intent underpinning the Section 116 exemptions and commercial realities. Any other approach would nullify the Section 116 beverage alcohol exemptions and result in an irrational regulatory scheme where only those facilities "warehousing" finished products (and not those facilities producing the products) would fall within the exemption.

While we fully support FDA's interpretation that the raw materials used to produce beverage alcohol products ("non-alcohol food") should not render these facilities ineligible for the Section 116 exemptions, we respectfully submit, however, that FDA's proposed intent to apply the provisions of this rulemaking to the coproducts (or otherwise referred to as residues/by-products, such as spent grains, distillers' grains, grape pomace, etc.) of the manufacturing process only would provide a partial exemption that is both untoward and untenable. The Section 116 exemptions apply "with respect to the activities of such [alcohol-related] facility that relate to the manufacturing, processing, packing, or holding of alcoholic beverages." Where spent grains are residues of the exempted category (beverage alcohol products) in the Food Safety Modernization Act, FDA should defer to the plain language of the exemption.

In that regard, FDA states in the rulemaking that it "tentatively concludes that section 418 applies to the food other than alcoholic beverages starting at the point at which it becomes physically separate from the alcoholic beverage because section 116(c) demonstrates Congress's intent to limit the reach of the exemption to alcoholic beverages. Thus, in the case of the brewery manufacturing animal feed, section 418 of the FD&C Act would apply to the spent grain sold as animal feed once the spent grain is physically separated from the beer, but not before that point." (78 Fed. Reg. at 3709.) We urge

that the Agency revisit this proposed approach to ensure that the intent of Congress is fulfilled and respectfully submit that a full understanding of the production process for beverage alcohol products warrants a different conclusion.

FDA's above-referenced discussion regarding "spent grains" only serves to create an unjustified and ambiguous interpretation regarding the scope of the alcohol-related facility exemptions under Section 116. The beverage alcohol-related facility exemptions also should apply to the coproducts/by-products of producing wine, beer and distilled spirits. We fully appreciate that FDA stated in its "preventive controls" rulemaking that animal food will be addressed in a separate rulemaking, noting the differences between human and animal food that should be addressed separately. We do intend to respond to FDA's proposed "animal feed" rulemaking; nevertheless, FDA's discussion about "spent grains" in the instant rulemaking appears to require any facility that produces food for animals to adhere to the same safety measures and prevention controls as facilities that produce food for humans and requests comments in that regard.

The same premium, high food-grade grains used to produce various beverage alcohol products are the same grains that result in "spent grains." To exclude the handling and distribution of such grains when used in beverage alcohol facilities to produce products yet have those same facilities fall out of the exemption when "spent grain is physically separated from the beer" defies a commonsensical, rational approach in implementing the Food Safety Modernization Act. Spent grains (along with other remaining mixtures of raw materials used to produce beverage alcohol products) are a natural coproduct/by-product of the production process and are produced in the same facility where, for example, the fermentation and distillation process occur. These coproducts are part of the "life cycle" of producing beverage alcohol products—be it grape pomace, brewers' spent grains or distillers' grains—and are made available to farmers or otherwise disposed.

The "life cycle" of the raw materials, such as the grains, grapes and other agricultural products, used to produce beverage alcohol products are the "food stocks" for these products, as well as the "food stocks" for our nation's farmers. The proposal to apply Section 418 "preventive controls" provisions for an alcohol-related facility "once the spent grain is physically separated from the beer" would subsume the exemption itself and result in an illogical approach from both a regulatory and production standpoint. This interpretation not only is inconsistent with the Congressional intent underpinning the Food Safety Modernization Act, but also undermines the very rationale for the alcohol-related facilities exemptions set forth in Section 116.

The "life cycle" of "non-alcohol foods" in alcohol-related facilities is very different from the scenario discussed in the rulemaking about the production of non-alcoholic beverages in terms of the scope of the Section 116 exemption:

> [I]f an alcoholic beverage distillery also <u>makes</u> non-alcoholic beverages,…the alcoholic beverage distilling activities would be exempt from section 418 of the FD&C Act, but the activities related to nonalcoholic beverages would be subject to section 418…

(78 Fed. Reg. at 3708; emphasis supplied.) In this illustration, the beverage alcohol facility is making a non-alcohol product and the manufacture of this product would not be exempt from the proposed "preventive controls" provisions—a conclusion that we do not dispute.

Conversely, a description of the production process used to manufacture distilled spirits, beer or wine dictates a very different conclusion. For example, in whisky production, grains are mashed and fermented to produce an alcohol/water solution that is distilled to concentrate the alcohol. (Mashing consists of cooking the grain to solubilize the starch from the kernels and to convert the soluble starch to grain sugars with barley malt and/or enzymes.)

The distillation process separates and concentrates the alcohol from the fermented grain mash. After the removal of alcohol, the stillage—spent grains—may be sold as liquid "wet" or dried feed, or other secondary products described above. Distillers, brewers and vintners are not in the business of making by-products/residues from their respective distilling, brewing or winemaking manufacturing process—they are in the business of making beverage alcohol products.

Exempting the full cycle related to producing beverage alcohol products is fully consistent with the risk-based, public health principles underpinning Congress' Section 116 alcohol-related facility exemptions. In that regard, the Agency appropriately recognized that intent per the following points:

> [A]lcoholic beverages are regulated by TTB under the Federal Alcohol Administration Act and Chapter 51 of the Internal Revenue Code, which together establish "a comprehensive system of controls of alcoholic beverages, including on-site inspections and procedures that require the advance approval of statements of process and of formulas showing each ingredient to be used in the product."
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> 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.)

For all these reasons, the alcohol-related facility exemptions in Section 116 of the Food Safety Modernization Act should apply to all aspects of the production process, including their respective coproducts—spent grains, distillers' grains and grape pomace. Any other result would mean bringing costly plans/processes to existing operations and increasing farmers' cost of purchasing animal feed, with no commensurate safety benefits. Beverage alcohol producers already work under hundreds of rules and Congress recognized that the current oversight is sufficiently extensive when promulgating the Section 116 exemptions.

Conclusion

Thank you for providing us with an opportunity to comment upon FDA's proposal. We stand ready to assist FDA in these important endeavors and, if you have any questions regarding our submission, please do not hesitate to call.

Sincerely,

Mr. Wendell Lee
Wine Institute

Ms. Victoria I. McDowell
Presidents' Forum

Ms. Lynne J. Omlie
Distilled Spirits Council

Mr. Mark Chandler
WineAmerica

Mr. Paul Gatza
Brewers Association

Mr. William T. Earle
National Association of Beverage Importers