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Guidance for Industry

Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration

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You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

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*See additional PRA statements in Section IV of this guidance

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

This guidance is intended to assist manufacturers on how to label beers that are subject to the Food and Drug Administration's (FDA's) labeling laws and regulations. This guidance is being issued in light of a ruling by the Tobacco Tax and Trade Bureau (TTB) (formerly the Bureau of Alcohol, Tobacco and Firearms (ATF) clarifying that certain beers do not meet the definition of a "malt beverage" under the Federal Alcohol Administration Act (FAA Act) (See TTB Ruling 2008-3, dated July 7, 2008) (Ref. 1). As discussed in more detail below, these beers are not subject to the labeling provisions of the FAA Act, but are subject to the food labeling provisions of the Federal Food, Drug, and Cosmetic Act (FD& C Act), 21 U.S.C. 341-415; the Fair Packaging and Labeling Act (FPLA), 15 U.S.C. 1451-1461; and FDA's implementing regulations. In addition, FDA reminds manufacturers that wine beverages containing less than 7 percent alcohol by volume are also subject to the labeling laws and regulations administered by FDA.²

¹ This guidance has been prepared by the Office of Nutrition, Labeling and Dietary Supplements in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

² Wine beverages containing less than 7 percent alcohol by volume, such as wine coolers, diluted wine beverages and ciders, and dealcoholized or partially dealcoholized wine, are not covered by the labeling provisions of the FAA

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FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

The definition of “food” under the FD&C Act includes “articles used for food or drink” and thus include alcoholic beverages. See 21 U.S.C. 321(f). As such, alcoholic beverages are subject to the FD&C Act adulteration and misbranding provisions, and implementing regulations, related to food. For example, manufacturers of alcoholic beverages are responsible for adhering to the registration of food facilities requirements in 21 CFR part 1 and to the good manufacturing practices in 21 CFR part 110. However, as reflected in the 1987 Memorandum of Understanding (MOU) between FDA and TTB’s predecessor agency (ATF) (Ref. 2), TTB is responsible for the promulgation and enforcement of regulations with respect to the labeling of distilled spirits, certain wines, and malt beverages pursuant to the FAA Act. In TTB Ruling 2008-3, dated July 7, 2008, TTB clarified that certain beers, which are not made from both malted barley and hops but are instead made from substitutes for malted barley (such as sorghum, rice or wheat) or are made without hops, do not meet the definition of a malt beverage

Act. (The definition of the term “wine” in the FAA Act (27 U.S.C. 211(a)(6) covers only products containing not less than 7% of alcohol by volume). Instead, these wines are subject to the labeling requirements under the FD&C Act and FPLA, and FDA’s implementing regulations. See FDA Compliance Policy Guide (CPG) 7101.04 (Dealcoholized Wine and Malt Beverages- Labeling) and CPG 7101.05 (Labeling –Diluted Wines and Cider with Less Than 7% Alcohol)

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under the FAA Act.³ Accordingly, TTB stated in its Ruling that such products (other than sake, which is classified as a wine under the FAA Act), are not subject to the labeling, advertising, and other provisions of the TTB regulations promulgated under the FAA Act.

In cases where an alcohol beverage is not covered by the labeling provisions of the FAA Act, the product is subject to ingredient and other labeling requirements under the FD&C Act and the implementing regulations that are administered by FDA. In addition, as provided for under the FPLA,⁴ alcohol beverages that are not covered by the labeling provisions of the FAA Act are subject to the provisions of the FPLA, which is administered by FDA.

Therefore, the beers covered by TTB's Ruling are subject to the labeling requirements under the FD&C Act and FPLA, and FDA's implementing regulations. In general, FDA requires that food products under its jurisdiction be truthfully and informatively labeled in accordance with the FD&C Act, the FPLA, and FDA's regulations. These requirements are explained below.

Importantly, it is your responsibility to comply with all applicable requirements under the FD&C Act and FPLA, as well as FDA's implementing regulations, regardless of whether or not we refer to them in this guidance.

Furthermore, some TTB labeling requirements, such as the Government Health Warning Statement under the Alcoholic Beverage Labeling Act (ABLA) and certain marking requirements under the Internal Revenue Code (IRC), continue to apply to these products.

³ The term "malt beverage" is defined in the FAA Act (27 U.S.C. 211(a)(7)) as a beverage made by the alcoholic fermentation of an infusion or decoction, or combination of both. In potable brewing water, of malted barley with hops, or their parts, of their products, and with or without other malted cereals, and with or without the addition of unmalted or prepared cereals, other carbohydrates or products prepared therefrom, and with or without the addition of carbon dioxide, and with or without other wholesome products suitable for human food consumption.

⁴ The term "consumer commodity" is defined under the FPLA, 15 U.S.C. 1459(a)(4), in part as any "food" as defined under the FD&C Act, but excludes "any beverage subject to or complying with packaging or labeling requirements" imposed under the FAA Act.

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III. Discussion

Labels of beers that are subject to FDA's labeling requirements must conform to the requirements in 21 CFR part 101. For example, these labels must bear:

- (1) on the principal display panel: a statement of identity (21 CFR 101.3). The statement of identity can be similar to the statement of composition that is required for certain malt beverages under the FAA Act regulations such as "Beer made from sorghum" or "Sorghum Beer";
- (2) an accurate statement of the net quantity of contents in inch/pound units (e.g., 12 fl oz). The statement of the net quantity of contents must appear in the lower 30 percent of the principal display panel. The type size used for the net quantity of contents statement is dependent on the size of the principal display panel (21 CFR 101.105). We also recommend that manufacturers declare net quantity of contents statement in metric units in addition to inch/pound units;
- (3) the name and place of business of the manufacturer, packer or distributor (e.g., Imported by ABC Brewers, Chicago, IL 52705) (21 CFR 101.5);
- (4) in the statement of ingredients: the common or usual name of each ingredient if the product is made from two or more ingredients, in descending order of predominance by weight (e.g., Ingredients: sorghum, water, rice, yeast, molasses, FD&C Yellow No. 5) (21 CFR 101.4). This includes, but is not limited to, the following ingredients: (a) name of any chemical preservatives present and a description of the function of the preservative (e.g., Ingredients: sorghum, water, rice, yeast, molasses, ascorbic acid to promote color retention), as specified in 21 CFR 101.22(j); (b) a declaration of any added coloring, as specified in 21 CFR 101.22(k), and (c) a declaration of added flavor, such as any spices, natural flavors, or artificial flavors, as specified in 21 CFR 101.22(h);

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(5) nutrition labeling (21 CFR 101.9) unless exempt. (Note: Some products are exempt under the provisions in 101.9(j));⁵

All of the FDA mandatory label information must appear either on the principal display panel (21 CFR 101.1) or the information panel (21 CFR 101.2) unless otherwise specified by FDA regulation. Furthermore, all information appearing on the information panel must appear in one place without other intervening material (21 CFR 101.2(e)).

There are other FDA labeling provisions in addition to the requirements listed above. Under the FD&C Act, as amended by the Food Allergen Labeling and Consumer Protection Act of 2004, the food source name of any “major food allergen” present must be declared (section 403 (w)(1) of the FD&C Act, 21 U.S.C. 343(w)(1)). Section 201(qq) of the FD&C Act, 21 U.S.C. 321(qq), defines “major food allergen” as milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of them, with the exception of highly refined oils. For additional information on the labeling of food allergens, we refer you to FDA’s “Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004.”

There are FDA requirements for labeling to ensure the safe use of food additives.⁶ For more information on the labeling of specific ingredients, including food additives, color additives, and ingredients that are generally recognized as safe, we refer you to 21 CFR parts 1-99 and parts 170-199.

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⁶ For example, if a product contains aspartame, its label must bear on the principal display panel or the information panel the following statement: PHENYKLETONURICS: CONTAINS PHENYLANINE, as specified in 21 CFR 172.804.

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In addition, there are FDA labeling requirements for voluntary claims, such as, nutrient content claims and health claims, and other labeling statements. For more information regarding FDA's general labeling requirements, we refer you to FDA's "Food Labeling Guide."

There are no preclearance labeling requirements or certificate of label approvals for FDA regulated food products.⁷ Instead, manufacturers are responsible for ensuring that their labels conform to all applicable FDA labeling laws and regulations. Products that do not meet these labeling requirements may be subject to regulatory action (e.g., warning letter, seizure, etc.).

There are also labeling requirements for these products that are enforced by other government agencies. These include requirements under the ABLA and IRC, which are both enforced by TTB, and U.S. Customs and Border Protection requirements applicable to imported products. For questions about TTB's labeling requirements and the requirements of the IRC and ABLA, please contact the Advertising, Labeling and Formulation Division, TTB, toll free at (866) 927-2533. For requirements of the U.S. Customs and Border Protection, please contact the Tariff Classification and Marketing Branch, Regulations and Rulings, U.S. Customs and Border Protection, U.S. Department of Homeland Security, at 1-800-232-5378.

FDA previously recognized that manufacturers of the beers covered by the TTB Ruling may need time to change their labels to comply with FDA's applicable laws and regulations. FDA exercised enforcement discretion and allowed manufacturers until January 1, 2012 to revise the

⁷ By contrast, TTB has alcohol beverage labeling and taxing authorities that include, for example, premarket label review and approval.

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labels on their non-malt beverage beers. FDA expects that all labels for these products now comply with all applicable laws and regulations.

IV. Paperwork Reduction Act of 1995

This guidance contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 30 minutes per disclosure for 21 CFR 101.3, 1 hour per disclosure for 21 CFR 101.4, 15 minutes per disclosure for 21 CFR 101.5, 4 hours per disclosure for 21 CFR 101.9, 30 minutes per disclosure for 21 CFR 101.22, 30 minutes per disclosure for 21 CFR 101.105, 1 hour per disclosure for section 403(w)(1) of the FD&C Act, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in §§ 21 CFR 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 have been approved under OMB Control No. 0910-0381.

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An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-[xxxx] (expires [xx/xx/xxxx]).

V. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday. As of [Insert date], FDA had verified the Web site address for the references it makes available as hyperlinks from the Internet copy of this guidance, but FDA is not responsible for any subsequent changes to Non-FDA Web site references after [Insert date].

1. FDA Compliance Policy Guide (CPG) 7101.04 (Dealcoholized Wine and Malt Beverages- Labeling), and CPG 7101.05 (Labeling --Diluted Wines and Cider with Less Than 7% Alcohol)
2. TTB Ruling 2008-3, July 7, 2008
3. Memorandum of Understanding 225-88-2000 between FDA and Bureau of Alcohol, Tobacco and Firearms