

Guidance for FDA Staff

Compliance Policy Guide Sec. 510.800 Beverages – Serving Size Labeling

Draft Guidance

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition at 301-436-1450.

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Regulatory Affairs
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Contains Nonbinding Recommendations
Draft - Not for Implementation

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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:

The purpose of this document is to provide guidance for FDA staff on serving size labeling for certain beverages that are packaged in containers larger than 20 fluid ounces and that display calories per 12 fluid ounce serving on the Principal Display Panel (PDP) of the container.

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:

FDA regulations require that the serving size for beverages be determined from the Reference Amounts Customarily Consumed (RACC), which is 240 ml (8 fluid ounces) (21 CFR 101.12(b)); that the declared nutrient values are based on a single serving; and that the Nutrition Facts panel reflects the number of servings in the container (21 CFR 101.9(b)).

In a May 27, 2010 letter, the American Beverage Association (ABA) requested that FDA exercise its enforcement discretion for industry to describe 12 fluid ounces as a “serving” on the front of beverage containers larger than 20 fluid ounces and to make conforming changes to the Nutrition Facts panel on such containers to reflect a 12 fluid ounce “serving size.” In a subsequent letter dated June 24, 2010, the ABA clarified that its request was limited to: (1)

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sports drinks; (2) bottled water and water beverages; (3) soft drinks and diet soft drinks; (4) energy drinks; (5) juice drinks; and (6) ready-to-drink teas. ABA indicated that its request did not include 100 % juices, alcoholic beverages, or 100% milks.

In FDA's July 12, 2010 response to ABA, we stated "that the agency intends to exercise enforcement discretion for the beverage industry to describe 12 fluid ounces as a 'serving' on products that display calorie information on the [PDP] of certain beverage containers larger than 20 fluid ounces." We also stated, "the agency intends to exercise enforcement discretion so that the change [in the serving size] is reflected in the Nutrition Facts panel." Finally, we specified that "the beverage products in question are as follows: (1) sports drinks (this term is used by industry and has not been defined by the agency); (2) bottled water and water beverages; (3) soft drinks and diet soft drinks; (4) energy drinks (this term is used by industry and has not been defined by the agency); and (5) ready-to-drink teas."

III. Policy:

FDA will typically consider not taking an enforcement action when a beverage container larger than 20 fluid ounces states the calories for 12 fluid ounces on the PDP and correspondingly provides the number of 12 fluid ounce servings in the container and the nutrition information is based on a 12 fluid ounce serving in the Nutrition Facts panel. This policy applies to the following beverages in containers larger than 20 fluid ounces that display calorie information per 12 fluid ounce serving on the PDP: (1) sports drinks (this term is used by industry and has not been defined by the agency); (2) bottled water and water beverages; (3) soft drinks and diet soft drinks; (4) energy drinks (this term is used by industry and has not been defined by the agency); and (5) ready-to-drink teas. This policy does not apply to any other beverages, including 100% juices, diluted juice beverages, alcoholic beverages, or 100% milks.

IV. Regulatory Action Guidance:

FDA staff typically should not submit a recommendation for an enforcement action when "12 fl oz (360 mL)" is stated as the labeled serving size on the following beverages in containers larger than 20 fluid ounces that display calorie information per 12 fluid ounce serving on the PDP: (1) sports drinks; (2) bottled water and water beverages; (3) soft drinks and diet soft drinks; (4) energy drinks; and (5) ready-to-drink teas.

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