DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0575]

Draft Compliance Policy Guide Sec. 510.800 Beverages—Serving Size Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft "Compliance Policy Guide Sec. 510.800 Beverages—Serving Size Labeling" (the draft CPG). The draft CPG, when finalized, will provide guidance for FDA staff on FDA's exercise of enforcement discretion related to 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 front of the container.

DATES: Although you can comment on any CPG at any time (*see* 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft CPG before it begins work on the final version of the CPG, submit either electronic or written comments on the draft CPG by February 22, 2011.

ADDRESSES: Submit electronic comments on the draft CPG to *http://www.regulations.gov.* Submit written comments on the draft CPG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the draft CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request or fax your request to 240–632–6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG.

FOR FURTHER INFORMATION CONTACT: Jillonne Kevala, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

The draft CPG is intended to provide guidance for FDA staff on the labeling of certain beverages. In particular, the draft CPG sets forth a policy to typically consider not taking an enforcement action when a beverage container larger than 20 fluid ounces states the calories per 12 fluid ounces on the Principal Display Panel (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. FDA's labeling regulations require that the labeled serving size be based on Reference Amounts Customarily Consumed (RACC) (21 CFR 101.9(b) and § 101.12(b) (21 CFR 101.12(b))). The RACC for beverages is 240 milliliters (8 fluid ounces) (§ 101.12(b)). FDA's exercise of enforcement discretion is limited to the following beverages in containers that are larger than 20 fluid ounces and that display calories on the PDP of the label per 12 ounces: (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. The CPG reflects the Agency's recent response to the American Beverage Association's request that FDA exercise enforcement discretion for industry to label certain beverages based on a 12 fluid ounce serving size (Refs. 1, 2, and 3). The draft CPG also contains information that may be useful to the regulated industry and to the public. FDA is issuing the draft CPG as level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent FDA's current thinking on the exercise of enforcement discretion for serving size labeling for the applicable beverages. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft CPG from FDA's Office of Regulatory Affairs history page at *http://www.fda.gov/ora/compliance_ref/cpg/default.htm.*

IV. References

The following references have been placed on display in the Division of Dockets Management (*see* **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from Stuart M. Pape, Counsel to the American Beverage Association, May 27, 2010.

2. Letter from Stuart M. Pape, Counsel to the American Beverage Association, June 24, 2010.

3. Letter from Michael R. Taylor, Deputy Commissioner for Foods, FDA, July 12, 2010.

Dated: December 13, 2010.

Dara Corrigan,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 2010–32249 Filed 12–22–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The NIH–American Association for Retired Persons (AARP) interactive Comprehensive Lifestyle Interview by Computer Study (iCLIC) (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on October 18, 2010 (75 FR 63833) and allowed 60-days for public comment. There was one public comment received on October 18, 2010 which questioned the use of "spending American tax dollars on this study." A response was sent on December 14, 2010. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1,