June 20, 2005

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

Re: Comments to the Advance Notices of Proposed Rulemakings on Food Labeling (Docket Nos. 2004N-0456 and 2004N-0463)

Dear Sir or Madam:

The American Beverage Association ("the Beverage Association") is pleased to submit these comments to the Food and Drug Administration ("FDA" or the "Agency") on the two Advance Notices of Proposed Rulemakings ("ANPRs") on food labeling. Specifically, on April 4, 2005, FDA published ANPRs on: (1) the Prominence of Calories[1] (hereinafter referred to as the "Prominence of Calories ANPR"); and (2) Serving Sizes of Products that Can Reasonably Be Consumed at One Eating Occasion; Updating Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes[2] (hereinafter referred to as "Serving Size ANPR"). These comments respond to the Agency's requests for additional information on the issues identified in the ANPRs.

The Beverage Association is the national trade organization of the beverage industry. The Association's member companies produce 95% of all soft drinks consumed annually in the United States. They also produce and distribute purified water, ready-to-drink teas, sports drinks, juice and juice-based beverages, and all other carbonated and non-carbonated products. In addition, the vast majority of the beverage licensors who manufacture

[1] 70 Fed. Reg. 17008 (April 4, 2005).

[2] 70 Fed. Reg. 17010 (April 4, 2005).

concentrates and/or syrups from which soft drinks and other beverages are made belong to the Association. These comments are submitted on behalf of these members.

Summary of Association's Views

The Association believes that the current reference amount of 8-fluid ounces for all beverages is appropriate.[3] A standard quantity that is not influenced by various container sizes serves the important function of allowing consumers to compare nutrient content for all types of beverages across the entire product category and thus facilitates informed decision making by consumers in their beverage selection.

As for calorie declarations, the Association believes that it is unnecessary and unwise to require manufacturers to declare caloric content information on the Principal Display Panel ("PDP") of food labels. Data are not conclusive regarding whether this information aids or benefits consumers in any meaningful way. In addition, manufacturers are already permitted to declare the calorie content (or other nutrient information) on the PDP either as a nutrient content claim[4] or nonmisleading factual statement.[5]

Although the Beverage Association believes that allowing comparison claims for different portion sizes would be useful to consumers, the Association submits that the goal of increasing consumers' awareness of calorie content of foods can best be achieved by making changes within the existing Nutrition Facts Panel ("NFP") -- the location which consumers are accustomed to looking for nutrition information -- to give calories greater prominence rather than requiring the declaration on the PDP.

Furthermore, the Beverage Association fully supports NFP dual column labeling and developed criteria for its use on food products, which are described in these comments. Dual column labeling advises consumers of

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[3] 21 C.F.R. § 101.12.

[4] 21 C.F.R. § 101.60.

[5] 21 C.F.R. § 101.13(i)(3).

not only total calorie content but also other valuable nutrients contained in packages that can be consumed on one occasion. It also preserves the presentation of information on the basis of the Reference Amount Customarily Consumed ("RACC"), thus fulfilling a fundamental goal of the Nutrition Labeling and Education Act of 1990 ("NLEA"),[6] which is to allow consumers to readily compare nutrient content of different foods in the same category even when packaged in different size containers. More radical changes to the NFP, which have been advocated by some, have not been convincingly shown to be of value to consumers in making informed food choices.

I. Background on the ANPRs

A. FDA Obesity Working Group

On March 12, 2004, the FDA published "Calories Count," the report developed by the Agency's Obesity Working Group ("OWG"). The OWG was established on August 11, 2003, by the Commissioner of Food and Drugs to outline an action plan covering critical dimensions of the obesity problem and help consumers lead healthier lives through better nutrition.

FDA determined that the rise of obesity necessitated consideration of changes to its food labeling regulations to the extent that these changes would assist consumers in making sound food choices. FDA concluded that the problem of obesity has no single cause. Rather, obesity is the result of multiple factors acting together over time. Therefore, the OWG determined that there could be no single solution to the problem of obesity, and it will only be brought under control as a result of coordinated, complementary efforts from a variety of societal sectors.

B. Summary of the ANPRs

As part of its report, the OWG recommended that FDA develop an approach for enhancing and improving the food label to assist consumers in preventing weight gain and reducing obesity. Accordingly, FDA published the Serving Size and Prominence of Calories ANPRs to gather information on:

[6] Public Law No. 101-535.

Serving Size ANPR

- Whether consumers use the information contained in the NFP and its practical implications;
- Whether it is necessary to update the RACC and, if so, how to update the RACCs;
- Appropriate criteria and labeling for single serving containers;
- Claims about comparison of calories in foods of different portion sizes; and

Prominence of Calories ANPR

- How to distinguish calorie information on the food label such as a "starburst" with the calorie information on the PDP, increasing font size for calories, providing a percent Daily Value ("%DV") and eliminating the "calories from fat" listing.

Accordingly, the Beverage Association submits these comments to respond to the issues identified above.

II. RACC for Beverages is Appropriate

A. Development of Current RACC

After enactment of the NLEA,[7] FDA re-proposed the serving size rule in 1991 to outline the methodology used to develop the reference amounts and the specific RACCs for certain food categories.[8] FDA proposed 8-fl.oz. as the RACC for all beverages although food consumption data could support a reference amount of 12-fl.oz. for carbonated beverages.

[7] Public Law No. 101-535.

[8] 56 Fed. Reg. 60394 (Nov. 27, 1991).

The Agency determined that the 12-fl.oz. reference amount for carbonated beverages inaccurately reflected the prevalence of 12-fl.oz. containers. Also, during the rulemaking, FDA considered other factors including: (1) the applicability of reference amounts for all other beverages including fruit and vegetables juices; (2) consumer complaints about the 6-fl.oz serving size, which resulted in multiple serving declarations on a 12-fl.oz. container; and (3) the ability for consumers to make nutritional comparisons across all beverage categories with a single consistent 8-fl.oz reference amount. Based on this information, FDA concluded that consumers are best served with a consistent and uniform RACC for all beverages, which is currently reflected in the regulations as 8-fl.oz.

B. 8-fl.oz. RACC Continues to Assist Consumers in Making Valuable Product Comparisons

The rationale that FDA applied during the 1991 rulemaking stands true today, particularly as the nation attempts to address the rise of obesity. Consumers are encouraged to eat healthy and monitor calorie intake. To achieve this goal, consumers must have access to and be able to compare nutrient information among products within a specific food category on the basis of a standard serving, even when those foods are repackaged in different sized containers.

Therefore, it is unnecessary to revise the RACC for all beverages. The ability of consumers to compare readily nutritional content among numerous beverage choices – which the 8-fl.oz. common RACC permits – is by far the most important factor in assessing whether to change the RACC for beverages. A consistent and uniform RACC thus fulfills the fundamental purpose of the NLEA, which is to assist consumers in making healthier food choices through education. Food choices are not made in isolation and, without a common RACC, it is doubtful that consumers will be able to routinely "do the math" necessary to convert disparate RACCs or serving sizes into common units.

III. Requiring Disclosure of Calories on the PDP of Food Labels is Unnecessary

The Agency suggests that modifications of the rules governing the PDP may be a means to emphasize calorie content on food labels. Some food manufacturers believe this approach will enhance food labels, and, under the current regulations, they are permitted to include such information on their food labels as either a factual statement[9] or nutrient content claim.[10] The Beverage Association, however, strongly disagrees.

As evidenced by FDA's own studies as well as independent evaluations, consumers do not respond consistently or in a positive manner to calorie information on the PDP. Without reliable evidence that consumers will benefit from this significant change, FDA should not mandate that such information appear on the PDP. Rather, manufacturers should be allowed to continue to declare the information voluntarily as prescribed in the regulations.

A. Studies Do not Demonstrate that Calorie Declarations on the PDP Benefit Consumers

In the ANPR, FDA explained that focus groups were assembled to determine receptivity to various calorie declarations on food labels.[11] In particular, focus group participants were shown two designs that highlighted the calories on the PDP. A "starburst" and "white box" with the amount of calories per serving was placed on the front of the label. The focus groups felt that the "starburst" design was misleading, while the "white box" had mixed reviews.

Other studies corroborate FDA's findings that consumers are confused or react negatively to calorie declarations that appear on the PDP. The IFIC Focus Group Studies reviewed food labeling variations including "calorie flags" on the PDP.[12] Although there were some favorable comments,

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[9] 21 C.F.R. § 101.13(i)(3).

[10] 21 C.F.R. § 101.60.

[11] 70 Fed. Reg. at 17009 (April 4, 2005).

[12] IFIC, Food Label & Calorie Research: Qualitative Research Findings (Aug. 30, 2004).

particularly among consumers who were counting calories, participants also responded with negative remarks, such as the "calorie flags":

- Resembled marketing techniques such as those used for lower fat or carbohydrate messages;
- Are redundant for smaller products because calorie information was already declared on the NFP; and
- Made consumers feel guilty for eating foods they liked.

Further, calorie declaration on the PDP may have the unintended effect of dissuading consumers from drinking nutrient-dense beverages, such as milk or certain juices, or be perceived as a warning label. As discussed later in these comments, calories are merely one component of a good diet and maintaining healthy body weight. "Starbursts" and other mechanisms that highlight the calorie content of the food product overemphasize the importance of calories in an overall balanced diet, and neglect the importance of vitamins, minerals, and other nutrients. Additionally, there is evidence to support the view that the focus on fat in the current nutrition labeling scheme is partially responsible for consumers' apparent inattention to calories. Requiring PDP declarations of calories would be repeating this same mistake.

Finally, another concern is the potential adverse impact calorie statements on the PDP may have on consumers,[13] which may be counterproductive to weight control efforts and may disrupt more appropriate food choice behaviors.

The American Beverage Association believes that the currently available evidence calls into question the value of "starburst" or "calorie flags" on the

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[13] Some participants in the IFIC Focus Group Studies "felt somewhat threatened by the [calorie flags and]… made to feel guilty for what they [ate]." (*See*, IFIC, Food Label & Calorie Research: Qualitative Research Findings (Aug. 30, 2004)). See also, Westenhoefer, J., et al., "Validation of the flexible and rigid control dimensions of dietary restraint," *Int. J. Eat. Disord.* 26(1):53-64 (1999); and Mela, D.J., "Determinants of food choice: relationships with obesity and weight control" *Obesity Research* 9:S249-S255 (2001).

PDP and may undermine consumers' effective use of the NFP. Dividing nutrition information (i.e., on the PDP and NFP) creates the risk that consumers may not pay attention to the information on the PDP or fail to read the NFP. Without reasonably conclusive evidence of the benefit to consumers, manufacturers should not be required to declare calorie content on the PDP. Moreover, manufacturers are currently permitted the flexibility to include truthful statements about the nutrient level of a food so long as it does not directly or by implication characterize that level. Therefore, manufacturers should not be required to declare calorie content of the product on the PDP and nutrition information should remain in one, readily recognizable location -- the NFP.

IV. Labeling Changes, if any, Should be Limited to Only Minor Modifications to the NFP

Among its purposes, the NLEA was intended to help consumers make healthier food choices through improved access to nutrition information.[14] To achieve this goal, FDA developed the NFP as a tool for consumers to readily understand the nutritional content of food products.

The Agency also conducted numerous educational and outreach activities to advance the public's understanding of the nutrition labeling information.[15] The Beverage Association believes that allowing food marketers to make calorie claims comparing foods of different portion sizes is a valuable tool that may assist consumers in understanding that calorie intake is directly linked to food choices and serving sizes. However, any changes to the NFP should be guided by the principle that informed and sensible food choices require consideration of more than just caloric content. For example, the Beverage Association supports changes to the food label that highlight calorie content in the NFP and dual column labeling (as discussed later in these comments) as these modifications educate consumers about the usefulness of the NFP

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[14] Public Law No. 101-535.

[15] *See, e.g.*, FDA, The Food Label: How to Understand and Use the Nutrition Fact Label (Nov. 2004); FDA, Food Labeling Education Video (1996); FDA, The Power of Choice: Helping Youth Make Healthy Eating and Fitness Decisions (Sept. 2003); and FDA, Food Labeling Education Program for High School Teacher, "High School Kit", (July 1994).

and the entire nutrient profile of the food product. A balanced and healthful diet cannot be formulated without regard for protein, vitamins, minerals, and fiber. To suggest to consumers that only calories matter is far too narrow a view of the nutrition information of which consumers should be aware.

A. NFP Provides Consumers with Essential Information about the Nutrient Content of the Food

By concentrating the nutrient information within the NFP, FDA is supporting its previous efforts in educating consumers on nutrition labeling and identifying the NFP as a vital tool to assist in healthy dietary choices. The NFP provides consumers with ready access to the entire nutrient profile of the food product. Nutrient density is equally, if not more, important than calorie content of the food, particularly for certain populations with health conditions such as hypercholesterolemia, hypertension, and diabetes.

In the Prominence of Calories ANPR, the Agency notes that during its focus group participants stated that they were interested in not only calories but other nutrients such as saturated fat, total fat, cholesterol, carbohydrates, and sodium.[16] In addition, an FDA study confirmed that consumers who use the NFP for total fat, saturated fat and cholesterol information were less likely to consume those nutrients.[17] Other studies support FDA's findings that use of food nutrition labels is associated with positive dietary practices.[18]

Further, the U.S. Department of Agriculture ("USDA") and Department of Health and Human Services ("DHHS") recently published the 2005 Dietary Guidelines for Americans.[19] The Dietary Guidelines underscored the importance of maintaining a balanced diet with proportionality, variety and

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[16] 70 Fed. Reg. at 17009.

[17] Lin, C.T., et al., "Do dietary intakes affect search for nutrient information on food labels?" *Soc. Sci. Med.* 59(9):1955-67 (2004).

[18] Neuhouser, M.L., et al., "Use of food nutrition labels is associated with lower fat intake" J. Am. Diet. Assoc. 99(1):45-53 (1999); and Kreuter, M.W., et al., "Do nutrition label readers eat healthier diets? Behavioral correlates of adults' use of food labels" Am. J. Prev. Med. 13(4):277-83 (1997).

[19] USDA/DHHS, Dietary Guidelines for Americans, 2005. 6th Edition, Washington, D.C.: U.S. Government Printing Office, January 2005.

moderation. The Guidelines also encouraged consumers to eat nutrient-dense foods that contain calcium, potassium, fiber, magnesium, and Vitamin A, C, and E.

B. Increasing the Prominence of Calorie Declaration on NFP is Consistent with NLEA Educational Efforts and Consumers' Understanding of Food Labels

By limiting changes to minor modifications to the NFP, FDA can enhance consumers' awareness of calories within the context of the familiar information tool while maintaining a consistent message that the NFP as a whole can be used to understand the nutrient content in foods and develop healthy eating patterns.

In the IFIC Focus Group Study, respondents liked the presentation of the larger calories line in bold with comments such as "easier to read in bold' and "calories jump out at you".[20] These responses are consistent with general findings by IFIC that consumers generally want food labels that are easy to understand and use.

Therefore, modifying the calorie declaration in the NFP by increasing its prominence is consistent with FDA's efforts to concentrate nutrition information in one easy to find area of the food label and strengthen consumers' understanding of how to use food labeling information to develop healthy eating habits and good food choices.

C. FDA Should Explore the Benefits of Declaring %DV for Calories in the NFP Before Mandating Such Change

Although the Beverage Association believes that consumers may benefit from added attention to the calorie line in the NFP, other changes, such as %DV for calories, should be adequately evaluated before being instituted as a requirement on the NFP. For example, %DV for calories may be potentially misleading as it could have the anomalous effect of causing consumers to

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[20] IFIC, Food Label & Calorie Research: Qualitative Research Findings (Aug. 30, 2004).

exclude necessary nutrients from their daily intake for fear of exceeding the daily value of 2000 calories.

Studies have shown that consumers do not understand the meaning and relevance of %DV. Specifically, a study conducted by the Fred Hutchinson Cancer Research Center in Seattle, Washington discovered that only about 29% of 104 adults correctly selected the definition of %DV for fat.[21] Similarly, many participants of the IFIC Focus Group Study did not understand or were confused about the %DV on food labels although some preferred the information to appear on the NFP.[22] For example, many consumers did not know who set the %DV level, what it means, and how to apply the information to their daily diet.

The concept of a %DV for calories is also inconsistent with the structure and purposes of the new "MyPyramid" released by USDA. The " MyPyramid" was developed to create a system of tools that would provide more specific advice tailored to individual needs. A 2,000 calorie diet may not suit all people, particularly those that are overweight or obese. It does not appear that adding a %DV for calories to the NFP will assist consumers. FDA should evaluate further the value of such information on the NFP before instituting a change.

Although obesity is a multifactorial and complex issue, the Beverage Association believes that educating consumers about calorie content and nutrient density through the NFP builds on the educational programs developed by FDA as well as the Dietary Guidelines and will help address the obesity problem. In addition, the Association's proposed dual column nutrition labeling (discussed in the next section) maintains the information within the readily recognizable location and format of the NFP. It also provides consumers with information and flexibility for single serving containers as well as entire packages of food products.

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[21] Levy, L., et al., "How well do consumers understand percentage daily value on food labels?" Am. J. Health Promot. 14(3):157-60, ii (2000).

[22] IFIC, Food Label & Calorie Research: Qualitative Research Findings (Aug. 30, 2004).

V. Proposed Dual Column Nutrition Labeling for Single Serving Containers Provides Consumers with Important Nutrition Information and Flexibility to Suit Their Dietary Needs

After the publication of the OWG's report and recommendations, FDA began encouraging food manufacturers to take advantage of the flexibility in the serving size regulations and begin modifying their labels with dual columns.[23] The Beverage Association has taken seriously the FDA's recommendations and many of its member companies have already begun a transition to this type of labeling. In addition, the Association has developed criteria for the consistent use of dual column labeling based on the amount of food (i.e., %RACC) in the product container, which is outlined below.

A. Proposed Dual Column Nutrition Labeling Plan

To ensure consistency, the Beverage Association developed the following criteria for dual column labeling on the NFP based on the quantity of the food in the container. Specifically, dual column labeling on the NFP would be required for products that contain 200-300% of the RACC, unless the NFP for the product provides a single column for the entire packaged amount. Of course, claims for products that contain single column NFP declarations for the entire package must be based on the RACC and not the entire package size.[24]

For products that contain more than 150% but less than 200% of the RACC, dual column labeling is optional, which is similar to the existing requirement for NFP declaration for single serving containers. Finally, dual column labeling is not required for products that: (1) contain up to150% of the RACC; or (2) contain five calories or less per RACC and that are not fortified. These criteria are summarized in the table below.

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[23] *See*, Speech by Lester Crawford, D.V.M., Ph.D. before the Health Care Research and Innovations Congress (Dec. 1, 2004).

[24] *See*, 21 C.F.R. §§ 101.13 and 101.14.

Product Criteria for Including Dual Column Labeling

Dual Column Requirement	% RACC
Mandatory (unless the NFP provides a single column for the entire package)	1. Products that contain 200-300% of the RACC
Optional	1. Products that contain more than 150% but less than 200% (with RACCs of 100 grams or milliliters or larger)
Not Required	1. Products that contain up to 150% ; or 2. Products that have five (5) calories or less per RACC and are not fortified

In fact, FDA may implement immediately this dual column labeling plan by issuing a guidance document setting forth the above-identified criteria. The regulations currently permit flexibility of declaring dual columns in the NFP,[25] and a guidance document would provide the additional criteria for when such labeling is necessary. In addition, guidance documents require significantly less resources than issuing regulations or other rulemaking mechanisms. Lastly, FDA may use its enforcement discretion to ensure that

[25] 21 C.F.R. § 101.9(e).

the food industry is in compliance and properly declaring the dual column information.

B. Dual Column Nutrition Labeling is Beneficial to Consumers

As recognized by FDA, the dual column labeling provides consumers with meaningful and flexible nutrition information about the food product. For example, with dual column labeling, consumers will have access to information whether they eat a single serving or the entire package.

Indeed, consumers recognized the benefit of dual column labeling by responding favorably to this format during the IFIC Focus Group Studies. Specifically, comments consisted of:[26]

- "This is the best. It makes it easy."
- "This makes the calculations for me. I have more choices with this one."
- "They are giving you the information so you don't have to guesstimate."
- "It's good because it reminds people of what single serving should be."

These remarks clearly indicate a positive response to the availability of information and the knowledge it imparts to the consumer. The dual columns also reduce the burden to perform the math to determine calorie or other nutrient intakes for multiple servings, which is a constant complaint among consumers. Moreover, the dual column approach is consistent with FDA's educational efforts of maintaining the NFP as the primary tool used by consumers to understand the nutrient profile of the food product.

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[26] IFIC, Food Label & Calorie Research: Qualitative Research Findings (Aug. 30, 2004).

Although there were some less favorable observations, some of these statements were from consumers that do not commonly use the NFP.[27] This misunderstanding could be addressed by providing additional education tools and assisting consumers in understanding the new format, as FDA has done in the past.

Further, the dual column labeling avoids the problem noted in the Serving Size ANPR that consumers may wrongly interpret single column nutrient content information based on the entire package as a single recommended serving size. As FDA explained, consumers confuse the RACC with recommended serving sizes.[28] Consumer confusion may be prevented through the use of the dual column NFP approach. Dual column labeling provides consumer with additional assistance in understanding the relationship between the size of the serving they choose to consume and the number of calories associated with that portion size.

Finally, dual column labeling is unlikely to affect the packaging sizes of food products. Decisions on the type, shape and size of food packages are driven by consumer demand and not labeling requirements. For example, there are a number of extremely popular package sizes between 100-300% of the RACC, such as 12-fl.oz cans and 8-fl.oz, 16.9-fl.oz and 24-fl.oz. bottles. Dual labeling will assist the market place by providing a mechanism for consumers to readily understand the nutrient content of the food product without limiting the variety of food packages.

Therefore, FDA should focus on providing consumers more and flexible information through the proposed dual column labeling plan as outlined above. Dual column labeling continues to educate consumers about the usefulness of NFP, provides the nutrient profile of the individual food whether eaten as a single or multiple serving, and simplifies the information.

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[27] IFIC, Food Label & Calorie Research: Qualitative Research Findings (Aug. 30, 2004).

[28] 70 Fed. Reg. at 17012.

VI. Conclusion

Based on the foregoing, the American Beverage Association concludes that the RACC for beverages should not be revised and that calorie declarations should not be required on the PDP of food labels. To the extent labeling changes are made, it should be limited to increasing the prominence of calories within the NFP and dual column labeling as outlined herein.

If you have any questions or require additional information, please do not hesitate to contact us.

Sincerely,

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