July 22, 2014

Division of Dockets Management
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2012-N-1210

Dear Sir or Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million volunteers and supporters, we appreciate the opportunity to provide comments on the proposed revisions to the Nutrition and Supplement Facts Labels.

AHA is extremely pleased that the Food and Drug Administration (FDA) is working to update the Nutrition Facts label. It has been over 20 years since the Nutrition Facts label was first introduced, and diet and health information has evolved significantly during that time. To ensure that the label remains scientifically valid and easily understandable by consumers, it is appropriate for the Agency to update the list of nutrients, their reference values, and the label format. This is particularly important given the changes in dietary guidance that have occurred. Conveying this new information on the Nutrition Facts label is needed to help consumers make informed food purchase decisions that facilitate adhering to current dietary guidance.

Overall, AHA strongly supports the proposed revisions. We are very pleased that the revised label would emphasize the number of calories, include a line for added sugars, make potassium a mandatory declaration, and require dual column labeling for certain product sizes. However, we are disappointed that the FDA only lowered the Daily Value (DV) for sodium by 100mg to 2,300mg; we urge the FDA to revise the DV to 1,500mg. We also recommend that the Agency lower the DV for saturated fat to less than 6% of calories. These two changes will help protect cardiovascular health.

LABELING OF INDIVIDUAL NUTRIENTS

The proposed rule explains how the FDA determines whether mandatory or voluntary declaration is appropriate for a nutrient. Mandatory declaration is required for nutrients with a "public health significance", which is determined, in part, by examining the Dietary Guidelines for Americans. AHA supports this process; the Nutrition Facts label should harmonize with the Dietary Guidelines. Nutrients identified as "nutrients of concern" in the Dietary Guidelines should be listed on the Nutrition Facts label. However, we note that the nutrients of concern could change every five years as the Dietary Guidelines are updated. We recommend that the FDA clarify how frequently it intends to update the list of nutrients with public health significance. While it could be challenging to revise the label requirements as frequently as every five years, we believe it is important for the Nutrition Facts label to keep up-to-date with the latest Dietary Guidelines.

Calories

Calories
We strongly support the FDA's proposal to continue to require total calories to be declared on the label and to increase the prominence of the calorie declaration. With nearly 1 in 3 children and almost 70% of adults overweight or obese, it is clear that consumers need to be more aware of their calorie intake. The larger, bolder font should draw attention to the calorie content per serving, and encourage consumers to consider this information when selecting a food product or deciding how much to eat. Also, the presentation of the number of servings per container is prominently displayed so that consumers understand the total calorie content of the entire container.

Calories from Fat
We support removing "calories from fat" from the label. Current dietary recommendations no longer emphasize total fat. Research indicates that the quality of fat consumed is more important than the overall quantity. For example, lowering total fat intake (fat reduction alone) does not clearly have a benefit on cardiovascular events, while replacing some saturated fat with unsaturated fats (fat reduction and fat modification, or fat modification alone) may reduce the incidence of cardiovascular events.[1]

Calories from Saturated Fat
The FDA should require mandatory declaration of "calories from saturated fat". While many consumers are aware that saturated fats can increase the risk of cardiovascular disease, consumers still need help identifying foods that contain it. Consumers also need to be able to determine if a food is high or low in saturated fat. The Dietary Guidelines and AHA both recommend limiting the percent of calories from saturated fat, yet this information does not appear on the product label. Requiring the inclusion of "calories from saturated fat" will help consumers implement the Dietary Guidelines' recommendation and allow them to make healthy food choices.

2,000 Calories as the Reference Caloric Intake Level
We support continuing to use 2,000 calories as the reference calorie intake used to set Daily Reference Values (DRVs) for fats, carbohydrates, protein, and dietary fibers. The FDA should, however, include text in the label footnote that explains that 2,000 represents an average calorie intake and that more or less may be needed.

In addition, the Agency should explore other methods to provide consumers with calorie and nutrient information based on their individual needs. For example, the FDA could encourage food manufacturers to provide nutrition information on their websites using different reference calorie levels. Consumers could use their phone (or a handheld device provided by the food retailer) to scan the food product's bar code, QR code, or shelf tag to access the online version of the Nutrition Facts label. This method could also be used by consumers interested in specific nutrients, such as phosphorus, that do not require mandatory labeling.

[1] Hooper L, et al. Reduced or modified dietary fat for preventing cardiovascular disease. Cochrane Database of Systematic Reviews 2012, Issue 5. Art. No.: CD002137. DOI: 10.1002/14651858.CD002137.pub3.

Fat

Total Fat

As noted above, total fat consumption is no longer emphasized in dietary guidelines. Instead, consumers are advised to limit their consumption of saturated and *trans* fats, and replace them with monounsaturated and polyunsaturated fats. We therefore question if including "total fat" on the label may inadvertently discourage consumers from selecting foods that appear to be high in fat without regard to the source of fat. For example, consumers may avoid olive or corn oil because they list a high "total fat" content even though they are good sources of monounsaturated and polyunsaturated fats.

Rather than list "total fat" on the label, the FDA should require mandatory declaration of the amount of each type of fat: saturated fat, *trans* fat, polyunsaturated fat, and monounsaturated fat. Doing so would provide consumers with important information about polyunsaturated and monounsaturated fat content, which are currently voluntary declarations, and frequently omitted from the label. Consumers would be able to use this information to evaluate foods based on the quality, not just the quantity, of fat they contain, while still allowing consumers to calculate the total amount of fat.

However, if the FDA decides to keep "total fat" on the label, we support a level of 30% calories from fat.

Saturated Fat

Saturated fat should continue to be a mandatory declaration; however, we strongly disagree with the Agency's proposal to keep the DRV at 20g or 10% of calories; 10% of calories is too high for heart health. The FDA should lower the DRV to less than 6% of calories.

Scientific evidence shows that diets low in saturated and *trans* fatty acids reduce the risk of cardiovascular disease, in large part through their effects on LDL cholesterol levels, but data also show reductions in all-cause mortality among populations with lower saturated fat intake. Lowering the saturated fat recommendation is supported by the American College of Cardiology's and the American Heart Association's recently published guidelines on reducing cardiovascular risk through lifestyle management.[2] The guidelines were originally initiated by the National Heart, Lung and Blood Institute in 2008, which sponsored a systematic evidence review by an expert panel convened to develop critical questions, interpret the evidence, and develop recommendations. In 2013, ACC and AHA collaborated with the NHLBI to complete and publish the guidelines. The guidelines concluded that no more than 5 to 6% of calories should come from saturated fat.

A lower saturated fat recommendation is also consistent with the diets used in the OmniHeart and Dietary Effects of Lipoproteins and Thrombogenic Activity (DELTA) trials, as well as the 2010 Dietary Guidelines Advisory Committee Report, which advised that no more than 7% of calories should come from saturated fat. In addition, the 2010 Dietary Guidelines for Americans recommends that lowering saturated fat from <10% to <7% of calories can further reduce risk of cardiovascular disease.

[2] Eckel RH, et al. 2013 ACC/AHA Guideline on Lifestyle Management to Reduce Cardiovascular Risk. *Circulation.* 2013;00:000–000. See http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437740.48606.d1.full.pdf.

Trans Fat

AHA supports the mandatory declaration of *trans* fats.

However, we remain concerned that the FDA will continue to allow food products with less than 0.5g of *trans* fat per serving to list "zero" grams on the label. This policy can confuse and mislead consumers about the amount of *trans* fat they are actually consuming. And, if a consumer eats multiple servings of a food product(s) they believe to contain zero grams of *trans* fat, the total amount of *trans* fat they consume in a day will quickly add up, a problem the FDA has acknowledged.[3] To address this problem, the FDA should consider lowering the threshold for "*trans* fat free" claims to 0.2g per serving; this threshold should apply to foods that contain naturally-occurring *trans* fat and/or *trans* fat produced through the deodorization process of liquid vegetable oils.

In addition, the FDA should revise its regulations and clarify that foods cannot be labeled as "*trans* fat free" if they contain an industrially-produced *trans* fat or partially hydrogenated oil (PHO) of any amount. If the FDA continues to allow foods that contain PHOs to list zero grams of *trans* fat on the label, the Agency should require those foods to include the following statement on the label to alert consumers to its presence: This product contains partially hydrogenated oils. Expecting consumers to search the ingredient list to determine if a product contains PHOs when the label indicates "zero" grams is not reasonable.

Polyunsaturated Fat

AHA urges the FDA to mandate the inclusion of polyunsaturated fatty acids on the label. It is difficult for consumers to make choices regarding foods containing polyunsaturated fats if manufacturers are not required to include this information on the label. This is especially important since AHA, the 2010 Dietary Guidelines, and other dietary guidance recommend that consumers replace saturated and *trans* fats with polyunsaturated and monounsaturated fats; consumers must have a way to identify these better fats.

Not having this information on labels may also confuse consumers when a food product contains a health claim that references the quantity of polyunsaturated fats, but the quantity is not listed on the Nutrition Facts label. For example, the FDA requires products that bear the qualified health claim for omega-3 fatty acids and reduced risk of coronary heart disease[4] to include the number of grams of EPA and DHA fatty acids in the claim statement; however, this information does not have to be included in the Nutrition Facts label. The health claim and the Nutrition Facts label should be consistent.

We also encourage the FDA to work with the Institute of Medicine to develop a DRI for polyunsaturated fatty acids that can be used to establish a DV. We understand that this will take time and the FDA should not delay implementation of the updated label for this reason. Rather, the Agency should require

[3] Food and Drug Administration. Consumer Update: FDA Targets *Trans* Fat in Processed Foods. November 7, 2013. http://www.fda.gov/forconsumers/consumerupdates/ucm372915.htm

[4] Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]

manufacturers to list the quantitative amount of polyunsaturated fat now; the percent DV should be required when it is available in the future.

Monounsaturated Fat
As with polyunsaturated fats, we request that the FDA mandate the inclusion of monounsaturated fat on the Nutrition Facts label. Again, it is difficult for consumers to make choices regarding foods containing monounsaturated fats if this information is not on the label.

Carbohydrates

Total Carbohydrate
We support keeping the mandatory declaration for "total carbohydrate".

We also recommend that, as part of a broader education campaign on the new Nutrition Facts label, the FDA include messages designed to help consumers understand the differences between refined and complex carbohydrates. Consumers should be advised to eat complex carbohydrates.

Sugars
We support the FDA's proposal to use the term "total sugars" in lieu of "sugars" on the label.

Added Sugars
AHA strongly supports the FDA's proposal to require mandatory declaration of "added sugars". Added sugars are a significant source of excess calories and are associated with greater overall calorie intake and higher body weight. Excess sugar consumption has also been linked to several metabolic abnormalities, adverse health conditions, and a shortfall of essential nutrients.

Evidence from randomized trials suggests that drinking sugar-sweetened beverages, which are the primary source of added sugars in the American diet, leads to weight gain in both children and adults.[5] One study, for example, found that overweight and obese adolescents who received a one-year intervention designed to decrease consumption of sugar-sweetened beverages had a smaller increase in body mass index (BMI) than those in the control group.[6] Another study found that replacing sugar-sweetened beverages with sugar-free beverages reduced weight gain and fat accumulation in normal weight children.[7] In addition, a recent systematic review explored the relation between sugar-sweetened beverage consumption and blood pressure, and found that the consumption of sugar-sweetened beverages is associated with higher blood pressure, leading to increased incidence of hypertension.[8]

[5] Malik VS, et al. Sugar-sweetened beverages and weight gain in children and adults: a systemic review and meta-analysis. Am J Clin Nutr doi: 10.3945/ajcn.113.058362. 2013.
[6] Ebbeling CB, et al. A randomized trial of sugar-sweetened beverages and adolescent body weight. N Engl J Med. 2012 Oct 11;367(15):1407-16.
[7] De Ruyter JC, et al. A trial of sugar-free or sugar-sweetened beverages and body weight in children. N Engl J Med. 2012 Oct 11;367(15):1397-406.
[8] Malik AH, Akram Y, Shetty S, Malik SS, Yanchou Njike V. Impact of sugar-sweetened beverages on blood pressure. Am J Cardiol. 2014;113:1574-1580.

Because of the impact on weight and health, AHA, the 2010 Dietary Guidelines, MyPlate.gov, and countless other dietary guidelines recommend that consumers limit consumption of added sugars. Yet this can be difficult to do when added sugars are not included on the Nutrition Facts label. To identify added sugars, consumers must examine the product's ingredient list and look for the more than 25 ingredient names[9] that indicate the presence of added sugars.

Including added sugars on the Nutrition Facts label will give consumers an easy way to determine the amount of added sugars a product contains. We look forward to seeing this requirement implemented.

In addition, we support the Agency's proposed definition for "added sugars" and agree that fruit juice concentrates should be included.

We also recommend that FDA address added sugars in its consumer education campaign. Public education on the food sources and health consequences of excessive added sugar intake is needed. Consumers will also need guidance on an appropriate intake amount; consumers may not understand how much (or how little) they can consume while maintaining a healthy diet quality. AHA recommends that no more than one-half of discretionary calories should come from added sugars. The limit for most women would be no more than 100 calories (6 teaspoons) per day and no more than 150 calories (9 teaspoons) per day for most men.[10] The World Health Organization, which is in the process of updating its sugars guideline, has also tentatively identified 6 teaspoons (25 g), or less than 5% of energy as the appropriate free sugars limit for an adult with a healthy BMI for the greatest health benefit.[11]

To provide context for an acceptable intake of added sugars, we encourage the FDA to establish a DV for added sugars. A quantitative limit will help consumers reduce added sugars by giving them a specific target or goal to work toward. As with polyunsaturated and monounsaturated fats, we understand that establishing a DV for added sugars will take time. We encourage the FDA to begin work with the IOM to establish a DRI that can be used to set a DV, but do not want that work to delay release of the Nutrition Facts label final rule. The FDA should require mandatory declaration of added sugars now, and require the addition of the percent DV when the DRI is established.

Finally, we recommend that the FDA conduct consumer research to determine the best way to express "added sugars" content. Few Americans are familiar with the metric measures (grams) used for total sugars and other nutrients. It may be more appropriate to use a commonly understood measure such as number of teaspoons or number of calories. Providing both the number of grams and the number of calories may be most helpful since consumers are used to seeing calorie information on the Nutrition Facts label.

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[9] What are added sugars? Choosemyplate.gov. USDA. http://www.choosemyplate.gov/weight-management-calories/calories/added-sugars.html

[10] Johnson RK, et al. Dietary sugars intake and cardiovascular health: a scientific statement from the American Heart Association. Circulation. 2009 June; 120:1011-1020.

[11] World Health Organization. Draft Guideline: Sugars intake for adults and children. March 2014. The draft guidelines recommend a sugars limit of <10% of energy, but further suggests that a reduction to <5% of energy will have additional benefits.

Dietary Fiber
We support continuing to require "dietary fiber" to be declared on the label and we applaud the Agency's proposal to increase the DRV from 25g to 28g.

We are also very pleased that the FDA has proposed a definition for dietary fiber, which would allow declaration of only those forms of dietary fiber that the Agency has determined to have a physiological effect that is beneficial to human health. This definition would exclude soluble and insoluble non-digestible carbohydrates that do not have a demonstrated benefit for health. As we have seen fortification of foods with processed fiber that can make less healthful foods appear to be a healthier choice, such as ice cream bars fortified with inulin, the proposal's inclusion of a test for added fiber that measures its benefits for health represents a considerable advance.

However, both AHA and the Dietary Guidelines emphasize that consumers should eat unprocessed, natural forms of dietary fiber, which is often present as part of whole, healthy foods, such as vegetables and legumes. The Dietary Guidelines note that "fiber is sometimes added to foods and it is unclear if added fiber provides the same health benefits as naturally occurring sources."[12]

We therefore recommend that FDA consider requiring manufacturers to disclose the amount of "added fiber" as a subcategory under "total fiber", in a manner similar to the proposed requirements for disclosure of added sugars under the total sugars category. Consumers should be able to tell from reading the label how much fiber has been added during processing versus the amount that is naturally in foods such as whole fruits, vegetables, whole grains, and beans.

Other Carbohydrate
We support removing "other carbohydrate" from the label.

Protein

We disagree with the Agency's plan to leave the DRV for "protein" at 50g or 10% of calories. 10% is too low considering the IOM's Acceptable Macronutrient Distribution Range (AMDR) for protein is 10 to 35% of energy intake for adults. We are also concerned that this may lead to overconsumption of calories from other macronutrients such as carbohydrates or fats.

We recommend that the FDA consider raising the DV for protein to a minimum of 15% of calories.

Sodium

We are pleased that the FDA is considering lowering the DRV for sodium, but the proposed reduction from 2,400mg to 2,300mg does not go far enough. The DV for sodium should be lowered to 1,500mg.

According to the proposed rule, the FDA selected 2,300mg because it represents the Upper Limit and is consistent with the 2005 and 2010 Dietary Guidelines recommendations for the general population. We

[12] USDA and HHS. 2010 Dietary Guidelines for Americans. 7th Edition, Washington, DC: U.S. Government Printing Office, December 2010.

disagree with this rationale. The Upper Limit represents the highest "tolerable" intake level that is likely to pose no risk of adverse health effects; it is not intended to be a recommended intake. The Dietary Guidelines also caution that 2,300mg is too high, or intolerable, for individuals who are 51 and older, African-American, or have hypertension, diabetes, or chronic kidney disease – which is approximately one-half of the American population, including children, and the majority of adults.[13,14] The Guidelines advise these individuals to reduce intake to 1,500mg per day.

1,500mg is an appropriate target level for the general population. 1,500mg represents the Adequate Intake level or recommended average daily intake. As noted above, the Dietary Guidelines already recommend this amount for nearly half of all Americans. The 2010 Institute of Medicine report *Strategies to Reduce Sodium Intake in the United States* recommended that the FDA lower the DV for sodium to 1,500mg based on the Adequate Intake. 1,500mg is also consistent with recommendations from AHA, the 2010 Dietary Guidelines Advisory Committee, the Centers for Disease Control and Prevention, and others in the public health community.

There is ample evidence to support setting the DV for sodium at 1,500mg. A substantial number of studies show a direct relationship between sodium intake and blood pressure; as dietary salt intake rises, so does blood pressure. Excess sodium consumption is strongly associated with the development and worsening of high blood pressure and an increased risk for stroke, heart failure, kidney failure, gastric cancer, and osteoporosis.[15,16]

Studies have also found that reducing sodium consumption can have significant health benefits and reduce medical costs. A reduced sodium intake can prevent hypertension in non-hypertensive individuals, can lower blood pressure, and can facilitate hypertension control. A reduced sodium intake is also associated with a blunted age-related rise in systolic blood pressure and a reduced risk of atherosclerotic cardiovascular events, congestive heart failure, and stroke.[17] A long-term study published in 2014 documented a direct relationship between sodium intake and cardiovascular disease; lowering sodium intake lowered cardiovascular risk without any evidence of harm.[18]

One study, for example, found that reducing sodium intake by 1,200mg daily could result in 60,000 to 120,000 fewer coronary heart disease events, 32,000 to 66,000 fewer strokes, 54,000 to 99,000 fewer myocardial infarctions, and 44,000 to 92,000 fewer deaths from any cause, as well as save $10 to $24

[13] U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2005. 6th Edition, Washington, DC: U.S. Government Printing Office, January 2005.
[14] U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2010. 7th Edition, Washington, DC: U.S. Government Printing Office, December 2010.
[15] Appel LJ, et al. The importance of population-wide sodium reduction as a means to prevent cardiovascular disease and stroke: a call to action from the American Heart Association. *Circulation*. 2011;123:1138-1143.
[16] Whelton PK, et al. Sodium, blood pressure, and cardiovascular disease: Further evidence supporting the American Heart Association sodium reduction recommendations. *Circulation*. 2012;126:2880-2889.
[17] Lichtenstein A, et al. Diet and Lifestyle Recommendations Revision 2006: A Scientific Statement from the American Heart Association Nutrition Committee. 2006.
[18] Cook NR, et al. Lowers levels of sodium intake and reduced cardiovascular risk. *Circulation*. 2014;129(9):981-9.

billion in health care costs each year.[19] Another study suggested that if Americans moved to an average intake of 1,500mg a day, it could result in a 25.6% overall decrease in blood pressure and an estimated $26.2 billion in health care savings.[20] While another study projected that achieving a goal of 1,500mg would reduce deaths from cardiovascular disease by 500,000 to 1.2 million over the next 10 years.[21]

The benefits of sodium reduction have also been demonstrated in England, which launched a sodium reduction program in 2003. Between 2003 and 2011, the average population salt intake fell by 15% due to a gradual reduction in the sodium content of processed foods. During the same time period, the average population blood pressure also fell (3 mm Hg systolic / 1.4 mm Hg diastolic) and deaths from heart disease and stroke decreased 40 and 42%, respectively. The authors of the study believe that the reduction in blood pressure and the resulting decrease in mortality are likely due, at least in part, to the lower salt consumption across the population.[22]

The FDA, however, has expressed concern that decreasing the DV to 1,500mg may be inconsistent with the 2013 IOM report *Sodium Intake in Populations: Assessment of Evidence*. We caution the FDA against using this IOM report to set dietary policy because the IOM did not consider hypertension itself as a health outcome despite the indisputable relationship between blood pressure and cardiovascular disease. As stated in the IOM report itself, there are also methodological concerns with some of the studies the IOM considered, such as unreliable measures of sodium intake and results that are not generalizable to the general population. Also, the IOM based its conclusions, in part, on a study with suspect evidence that focused on people with heart failure who received an aggressive treatment that is not utilized in the U.S.[23] These methodological issues limit the usefulness of this IOM report in setting dietary recommendations that are applicable to the general population.

The FDA also raised concern that changing the DV for sodium to 1,500mg may confuse consumers, because 1,500mg represents a Reference Daily Intake (level to achieve) rather than a Daily Reference Value (level not to exceed). We do not believe this will be a serious issue. As the FDA points out, consumers are "generally aware that too much sodium is not healthy"[24] so they may continue to view the DV for sodium – whether it is 2,300mg or 1,500mg – as a level not to exceed. This, however, should cause little concern. Because of the high sodium content of the food supply and the fact that the average American consumes more than 3,400mg of sodium a day, it is unlikely that individuals will quickly reduce their sodium intake too much and fall short of the 1,500mg recommendation. In addition, there

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[19] Bibbins-Domingo K, et al. Projected effect of dietary salt reductions on future cardiovascular disease. *New England Journal of Medicine* 2010, vol. 362, pp. 590-599.

[20] Palar K, Sturm R. Potential societal savings from reduced sodium consumption in the U.S. Adult population. American Journal of Health Promotion. 2009;24:49-57.

[21] Coxson P, et al. Mortality benefits from US population-wide reduction in sodium consumption: projections from three modeling approaches." *Hypertension* 2013, vol. 61, pp. 564-570.

[22] He FJ, et al. Salt reduction in England from 2003 to 2011: its relationship to blood pressure, stroke and ischaemic heart disease mortality. *BMJ Open.* 2014;4:e004549. doi:10.1136/bmjopen-2013-004549.

[23] This Italian study randomly assigned patients with heart failure to normal or very-low-sodium diets. Researchers also restricted the patients' water intake and gave them high doses of diuretics, an aggressive treatment that can deplete blood volume and is not used in the U.S. In June 2013, the journal *Heart* retracted a meta-analysis from the same research group because two of the studies had duplicate data thus calling into question the researchers' findings.

[24] 79 FR at 11917.

is no reliable evidence that consuming less than 1,500mg a day of sodium poses a risk for the general population.

Finally, the FDA notes that it may be difficult for consumers to reduce their sodium consumption to 1,500mg because of the current food supply and taste preferences. We agree. However, lowering the DV for sodium could encourage manufacturers to reduce the sodium content of their foods. No manufacturer wants their food product's label to reflect an extremely high percentage of the DV for sodium, a scenario that would be increasingly more likely if the DV is lowered; thereby, encouraging reformulation. In addition, as the FDA acknowledges, "DVs are based on scientific data supporting healthy dietary practices, not on the levels of a nutrient present in the food supply."[25] Following this principle, the FDA's decision should not be influenced by the current amount of sodium in the food supply or consumer ability to achieve the recommended amount. The FDA's recommendation should be based on the science, which strongly supports a DV of 1,500mg for sodium.

We urge the FDA to follow the science and set the DV for sodium to 1,500mg in the final rule. Alternatively, if the Agency is uncomfortable making a significant change at one time, the FDA could lower the DV to 1,500mg over time. As we have recommended in the past, the Agency could set two targets for the DV, such as an interim DV of 2,000mg and then a final DV of 1,500mg. As the FDA acknowledges, this would provide food manufacturers with more time to reformulate, allow consumer taste preferences to adjust, and be consistent with the 2010 Dietary Guidelines Advisory Committee recommendation to reduce sodium intake to 1,500mg over time. This phased-in approach would also be consistent with the 2010 IOM report which recommended reducing sodium content in a stepwise manner.

Although the Agency feels there is "inadequate justification" to utilize a tiered option for sodium, we believe sodium provides a unique case where the high levels in the food supply, widespread overconsumption, and significant health-related consequences justify taking a novel approach. If the Agency is unable or unwilling to lower the DV for sodium to 1,500mg at this time, we recommend that a phased-in approach be considered.

ESSENTIAL VITAMINS AND MINERALS

Potassium

AHA strongly supports the FDA's proposal to require mandatory labeling for potassium. We also support basing the DV on the RDI of 4,700mg. 4,700mg is consistent with AHA's position described in *Dietary Approaches to Prevent and Treat Hypertension*, the 2010 Dietary Guidelines, and the adequate intake for potassium set by the IOM.

Increasing potassium consumption is an important public health goal. Potassium helps blunt the adverse effects of sodium on blood pressure – an important function since Americans consume, on average, 3,400mg of sodium per day, far exceeding the recommended amount. Yet less than 2% of American

[25] 79 FR at 11917.

adults get the recommended amount of potassium.[26] We hope that requiring mandatory labeling will increase consumers' awareness of the potassium content of foods.

We are, however, concerned that food manufacturers may start to fortify their foods with potassium in an attempt to offset the sodium content. The FDA should monitor how food manufacturers respond to this new requirement.

In addition, we recommend that the FDA, as part of its overall consumer education campaign, encourage consumers to obtain potassium through a diet high in fruits and vegetables and recommended amounts of low-fat/fat-free dairy products rather than supplements or foods fortified with potassium.

Phosphorus

We recommend that the FDA consider whether phosphorus should be changed from a voluntary to a mandatory declaration. Individuals with renal impairment or chronic kidney disease must monitor or limit their phosphorus intake; however, this can be difficult to do when phosphorus content does not appear on the food label. Requiring phosphorus on the label will help the 26 million American adults with chronic kidney disease control their phosphorus intake.

FOODS FOR CHILDREN 1-3 YEARS AND INFANTS 7-12 MONTHS

We understand that current FDA regulations do not include DRVs or RDIs for children one through three years of age or infants seven to 12 months old, except for a RDI for protein. The FDA, however, is considering establishing DRVs and RDIs for these subpopulations.

In general, the proposed DRVs and RDIs are consistent with AHA's Dietary Recommendations for Children and Adolescents.[27] But we note that the Agency's proposal does not include recommended intakes or limits for sugar. Sugar consumption is an important issue for children. To help parents understand how much – or how little sugar – their children should have, the FDA should work with the IOM to establish a DRV for sugar for these subpopulations.

NUTRITION FACTS LABEL FORMAT

AHA generally supports the proposed format changes for the Nutrition Facts label. As discussed above, AHA is very supportive of the proposal to prominently display "calories". We also agree with increasing the prominence of the number of servings per container and using the phrase "amount per _____ (cup, muffin, etc.)" instead of "amount per serving". These changes should focus the consumer's attention on this important information.

With respect to the other changes proposed by the Agency such as moving the DV to the left-hand column, changing "% Daily Value" to "% DV", or using "total carbs" instead of "total carbohydrate",

[26] Cogswell ME, et al. Sodium and potassium intakes among U.S. adults: NHANES 2003-2008. *Am J Clin Nutr* 2012, vol 96, pp. 647-57.

[27] Gidding SS, et al. Dietary recommendations for children and adolescents: A consensus statement from the American Heart Association. *Circulation.* 2005; 112:2061-2075.

we urge the FDA to conduct consumer research to evaluate the impact these changes would have and determine if presenting the information in this manner will facilitate greater use and understanding by consumers.

Consumer research will be particularly important when selecting between the proposed new label and the alternative format. Both labels appear to be an improvement over the current Nutrition Facts label, but the alternative "quick facts" format may be the better of the two.

The current Nutrition Facts label and the proposed label are both lists of information with many numbers and some nutrients that may not be familiar to consumers. For certain nutrients, we suspect that some consumers may not know whether they should consume more of less of them. The quick facts label, on the other hand, attempts to put the nutrition information into context by helping consumers understand which nutrients they should eat more of and which ones they should eat less of. Grouping nutrients into these categories that clearly indicate, in comprehensible language ("get enough" and "avoid too much"), which nutrients are more or less healthful may help to achieve the purposes underlying most of FDA's proposed changes to the label, as it would make clear that consumers should consume less sodium and added sugars, among other food product constituents/ingredients.

We look forward to learning the results of the Agency's field testing of these label revisions.

Dual Column Labeling

AHA strongly supports the FDA's proposal to require dual column labeling for food products that contain at least 200% and up to 400% of the applicable reference amount customarily consumed. Dual column labeling will help consumers understand how many calories and nutrients they will consume if they eat or drink a single serving *or* the entire container of food.

With regard to the format for dual column labeling, we believe the FDA should require manufacturers to list the calorie content and *all* of the nutrient content per serving and per container. This would allow consumers to base decisions on the food product's overall nutrient profile.

However, if the FDA decides to go forward with one of the alternative formats, we prefer option number one which would present calorie information per serving and per container, but would provide the remainder of the information by serving only. This option would emphasize the calorie content, one of the most important factors consumers should consider when deciding whether they will eat more than the serving size listed.

We do not support option number two which would present calories, saturated fat, and sodium per serving and per container, and would present the remainder of the nutrition information by serving size only. While AHA agrees that these factors are extremely important components to balance in a healthy diet, by focusing on calories, saturated fat, and sodium, this may falsely imply to consumers that these are the only nutrients they should consider.

Footnote

The FDA has indicated that it intends to develop a new footnote statement for the Nutrition Facts label, but does not provide any draft statements for public comment.

AHA recommends that the Agency include text in the footnote that explains that everyone's calories needs are different and may be more or less than the 2,000 calories included as the reference amount.

COMPLIANCE AND RECORDKEEPING

The proposed rule contains a discussion about how the Agency determines compliance with nutrition labeling requirements. Under current regulations, a food is considered misbranded if the nutrient content of a food varies by greater than 20% in excess of the value for that nutrient declared on the label. A tested food composite could, for example, contain 20% more calories, fat, saturated fat, *trans* fat, cholesterol, or sodium than the amount declared on the label without being considered misbranded by the FDA. Similarly, a food composite could contain up to 20% less of other nutrients such as protein, total carbohydrate, dietary fiber, polyunsaturated or monounsaturated fat, or potassium and still be considered in compliance with the law. AHA is concerned that this practice could result in the provision of inaccurate and misleading information to consumers; information that is intended to help consumers evaluate and select more nutritious foods to facilitate implementing a healthful dietary pattern that meets current dietary recommendations.

We recommend that the FDA review the need for the 20% variance for nutrient content declarations, particularly for those added nutrients of concern such as sodium, sugar, and saturated and *trans* fat. Consumers have a right to know what nutrients their food contains, and modern manufacturing and testing methods should allow food manufacturers to provide a more accurate representation of the nutrient content of their foods. The Agency should tighten the allowable variance to no more than 10%.

CONCLUSION

In closing, we reiterate our overall support for the updates to the Nutrition Facts label. The Nutrition Facts label is a valuable source of nutrition information for the public, and the proposed revisions should make it easier for consumers to evaluate and select more nutritious foods.

We support the proposed formatting changes, including increasing the prominence of calories and the number of serving sizes and requiring dual column labeling for food containers of a certain size. We also strongly support the addition of a line for added sugars, increasing the DRV and adding a new definition for dietary fiber, and making potassium a mandatory declaration.

However, as discussed above, we recommend that the FDA make a number of changes to the proposed revisions. Specifically, the Agency should:

- Clarify how often the nutrients of public health significance will be updated
- Lower the DV for saturated fat to less than 6% of calories
- Lower the threshold for *trans* fat free claims to 0.2g and prohibit foods that contain PHOs from using the *trans* fat free claim
- Make polyunsaturated and monounsaturated fats mandatory declarations
- Lower the DV for sodium to 1,500mg
- Increase the DRV for protein to at least 15%
- Lower the allowable nutrient content variance to 10%

We also recommend that the FDA work with the IOM to develop a DRI for polyunsaturated fatty acids and for monounsaturated fat, as well as a DRV for added sugars. The FDA should begin this work immediately, but we recognize that it will not be concluded before the label revisions are finalized. The Agency can require labels to include the percent DV for polyunsaturated and monounsaturated fats and added sugars at a later date.

Finally, we recommend that FDA conduct a comprehensive consumer education campaign when the new Nutrition Facts label begins appearing on food products. A well-funded, coordinated, multi-component education campaign to promote and explain the new label will be necessary to help consumers understand the information provided by the label and how they can use it to make healthier food and beverage choices. AHA would be pleased to partner with the Agency on this initiative.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop, AHA's senior regulatory affairs advisor, at (202) 785-7908 or susan.k.bishop@heart.org.

Thank you for your consideration of our comments.

Sincerely,

Elliott M. Antman, MD, FAHA
President, American Heart Association