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*Protect, Prevent, Live Well*

January 23, 2012

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

**RE: Docket Number: FDA-2011-N-0400**

To Division of Dockets Management:

The American Public Health Association (APHA) appreciates the opportunity to provide comments on the U.S. Food and Drug Administration's (FDA) request for comments, research and information on "Approaches to Reducing Sodium Consumption" (Federal Register, Vol. 76, No. 179, Thursday, September 15, 2011).

APHA is the oldest and most diverse organization of public health professionals in the world and has been working to improve public health since 1872. APHA and its state affiliates represent over 50,000 health professionals and others who work to promote health, prevent disease and ensure conditions in which we all can be safe and healthy.

APHA commends FDA for providing stakeholders with an opportunity to provide comments, data and information regarding the best approaches to reducing sodium consumption. APHA believes that overconsumption of sodium is a very pressing public health problem which significantly increases morbidity and mortality from heart disease, stroke and other diseases. We are fully in support of a comprehensive public health approach to reducing the level of sodium consumption for the population in the United States.

Based on the strong scientific data now available, APHA recommends that FDA take immediate action to protect the public from the harmful effects of exposure to the high levels of sodium currently present in our food supply. In addition, food and restaurant industries should take immediate steps to identify and reduce the amount of sodium on a voluntary basis prior to FDA regulations being formulated.

APHA recognizes the serious health threat created by high levels of sodium consumption. Cardiovascular diseases are responsible for 31 percent of all deaths in the United States. Each year, more than 600,000 Americans die of heart disease and more than 135,000 die of stroke.<sup>1</sup> Elevated blood pressure levels are a major cause of these diseases. The relationship between blood pressure levels and risk of developing cardiovascular diseases is strong, continuous, graded, consistent, independent, and etiologically significant.<sup>2-3</sup>

Almost 60 percent of adults in the United States have blood pressure levels which are higher than normal (defined as < 120 mm Hg systolic and < 80 mm Hg diastolic), thereby putting them at significantly increased risk of developing these diseases.<sup>4</sup> For example, the estimated 70 million persons with prehypertension (defined as 120-139 mm Hg systolic and/or 80-89 mm Hg diastolic) have a 1.5 to 2.5 times greater risk of having a heart attack, a stroke, or heart failure in 10 years than those with normal blood pressure levels.<sup>5</sup> Every 20 mm Hg increase in systolic blood pressure above the level of 115/75 leads to a doubling of risk of death from coronary heart disease and stroke.<sup>6</sup>

FDA has the power to make crucial changes in the food supply that will support the public health community's efforts to reduce hypertension, a largely preventable risk factor.<sup>9</sup> The National Heart, Lung, and Blood Institute guidelines recommend five nutritional/lifestyle approaches to prevent hypertension: (1) reduction of sodium intake, (2) weight reduction in the overweight, (3) regular physical activity, (4) moderation of alcohol intake, and (5) an eating plan that is rich in fruits, vegetables, and low-fat dairy products and reduced in saturated fat, total fat and cholesterol.<sup>9</sup> These same nutritional approaches are also highly effective in treating hypertension and can significantly reduce the amount or even need for medications.<sup>9</sup> Because of the high prevalence of elevated blood pressure levels and the associated mortality and morbidity in the United States, effective public health interventions that will lead to population-wide reductions in blood pressure are urgently needed. Reduction in sodium intake, the subject of this request for comments, represents one of the approaches most readily amenable to a public health solution.

In addition to reducing sodium in the food supply, sodium consumption can be reduced by measures increasing the consumption of the currently under-consumed healthy foods recommended by the U.S. Dietary Guidelines, such as fruits and vegetables. These measures include offering the public clearer health messaging and nutrition information on packaged and restaurant foods. As the lack of progress over three decades shows, much stronger measures are needed to meet Healthy People 2020 goals for nutrition.

APHA believes that FDA can take action to significantly reduce hypertension by reducing the consumption of sodium by lowering the amount of sodium in the food supply and by providing Americans with clear nutrient information on labels and menus that promote healthier choices. There is a relationship between habitual sodium intake and blood pressure levels.<sup>10</sup> The large amount of evidence is sufficiently strong to warrant recommendations for the public to substantially reduce dietary sodium intake. The World Health Organization now characterizes the evidence linking excess sodium intake to cardiovascular diseases as "conclusive."<sup>11</sup> Others refer to the evidence linking excess sodium consumption to hypertension as "overwhelming" and state that excess sodium is the primary cause of hypertension.<sup>12</sup>

By reducing the intake of sodium, FDA can also reduce coronary heart disease, strokes and other diseases. Higher sodium intake results in adverse effects beyond those of increasing blood pressure. An intake of sodium higher by 2,300 mg per day is associated with a 61 percent increase in coronary heart disease mortality, an 89 percent increase in stroke mortality, and a 39 percent increase in all-cause mortality over a 19-year period among adults who are overweight after adjusting for blood pressure, age, BMI, and other important variables.<sup>13</sup> Higher sodium consumption is also associated with an increased risk of developing urinary stones, osteoporosis, and gastric cancer.<sup>14-16</sup>

In response to the request for comments and research related to existing voluntary sodium reduction efforts, APHA is in agreement with the Institute of Medicine published 2010 report, *Strategies to Reduce Sodium Intake in the United States*, which noted that the voluntary approach to sodium reduction by the food industry had been totally unsuccessful over the past 40 years.<sup>17</sup> APHA agrees with the Institute of Medicine report which recommended that the GRAS status of sodium be modified and that FDA regulate the amount of sodium permitted in foods and progressively ratchet down the amount permitted.

The average American adult ingests roughly 3,600 mg of sodium daily, after accounting for discretionary salt.<sup>18</sup> This amount far exceeds current recommendations and physiologic need. The true amount of sodium intake may be even higher since current estimates are based on dietary recall, but more accurate biochemical assessments via 24 hour urine samples are not currently available for the population.

APHA believes that the evidence for the weak impact of voluntary standards is clear. Between 75 and 80 percent of the daily sodium intake of the U.S. population comes from salt added to processed and restaurant foods, the remainder coming from salt added while cooking or at the table.<sup>19-20</sup> Thus, in the United States and other Western societies, a high dietary salt intake is due to a large portion of daily calories consisting of processed and restaurant foods. These foods frequently contain large amounts of sodium. For example, some processed foods and some restaurant meals contain more than 4000 mg of sodium.<sup>21</sup> The exact amount across food processors or purveyors is not quantified or tracked in any existing surveillance system.

APHA recommendations regarding the request for comments on avoiding potential unintended consequences for food safety focuses on the need for a federal commitment to research. The U.S. Department of Agriculture should be provided with the resources necessary to conduct research on the best options for lowering sodium while maintaining food safety.

APHA offers the following recommendations in response to the request for comments related to (a) methods for establishing sodium reduction targets, including information on general target design and (b) step-wise approaches to achieve sustainable sodium reductions and timeframes for achieving such reductions.

- Based on the strong scientific data now available, APHA recommends that a uniform upper level for sodium consumption be advised to the American public and that FDA should take immediate steps to reduce the high levels of sodium currently present in our food supply, and to assure clear nutrient information on labels and menus that will allow consumers to easily identify and avoid high-sodium foods. These steps would create an environment that would greatly facilitate dietary sodium reduction by the American public and would substantially improve the cardiovascular health of the American public helping to reduce associated health care costs.
- Gradually reducing the amount of sodium added in the manufacturing and commercial preparation of food is a prudent and safe public health intervention, and the single most effective means of reducing the sodium intake of Americans. A 2010 analysis estimated that regulatory action would result in 20 times greater health benefits than voluntary action.<sup>22</sup> There is an urgent need for rapid, effective actions by the food industry and by FDA. Without a considerable decrease in the sodium content of processed and restaurant foods, it

will be exceedingly difficult, if not impossible, for most Americans to reduce intake to recommended levels.<sup>23</sup>

APHA recommends that FDA:

- Act within one year to 1) either remove or modify the GRAS status of sodium, 2) begin regulating the amount of sodium permitted in processed foods, and 3) establish a schedule for the progressive lowering of sodium in food products over the next ten years;
  - Require easily understandable front-of-package labels that identify whether products are high, medium, or low in sodium content;
  - Reduce the standard for DV for processed foods to 1,500 mg by 2017;
  - Urge the food and restaurant industries to take immediate steps to reduce and to identify the amount of sodium on a voluntary basis prior to FDA regulations being formulated; and
- Urge the food and restaurant industries to develop and promote low-sodium food and menu offerings to customers.

APHA appreciates the opportunity to provide the public health community's recommendations to FDA as it works to reduce sodium consumption. We look forward to continuing to work with the agency to reduce this preventable public health threat.

Sincerely,

A handwritten signature in black ink, appearing to read "Georges C. Benjamin". The signature is fluid and cursive, with the first name being the most prominent.

Georges C. Benjamin, MD, FACP, FACEP (E)  
Executive Director

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