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120 South Riverside Plaza, Suite 2000 Chicago, IL 60606-6995 800/877-1600 www.eatright.org Policy Initiatives and Advocacy 1120 Connecticut Avenue, Suite 480 Washington, DC 20036-3989 202/775-8277 FAX 202/775-8284

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

Comments of the American Dietetic Association on the Food and Drug Administration's request for comments as published in the February 20, 2003 Federal Register (68 FR 8163): Food Labeling; Nutrient Content Claims, Definition of Sodium Levels for the Term "Healthy"; (Extension of Comment Period).

FDA Docket Nos. 91N-384H and 96P-0500

Dear Sir or Madam:

The American Dietetic Association (ADA) represents nearly 70,000 food and nutrition professionals who serve the public promoting good health through diet and physical activity. ADA commends FDA for considering the term "healthy" and qualifying sodium levels for meals and individual foods.

ADA understands FDA's efforts to help consumers achieve the Dietary Guidelines for Americans and the focus on the relationship between sodium intake and high blood pressure in the general population. At this point in time, our comments on this issue are geared toward the need to examine thoroughly the effect this proposal would have on consumer options in the marketplace. In addition, there are several impending initiatives related to sodium and health that would add value to FDA's consideration of this issue. These include the upcoming Institute of Medicine report on electrolytes, possible revision of the Dietary Guidelines for Americans and Food Guide Pyramid, and the DASH-Sodium study (*Science*, 26 May 2000, p. 1319). The outcomes of these initiatives would afford FDA a better opportunity to understand the health implications of lowering the sodium level to the proposed amounts.

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In the current proposal, a "healthy" food must still be low in fat and saturated fat and contain limited amounts of cholesterol and sodium. In addition, if it's a single-item food, it must provide at least 10 percent of one or more of vitamins A or C, iron, calcium, protein, or fiber. The proposal specifies that the sodium content would be lowered to 360 mg per serving for individual foods and stay at 600 mg per serving for meal-type products. Some items, including certain raw, canned and frozen fruits and vegetables and certain cereal-grain products, are exempt from the "10 percent" rule. As an organization that relies on science to guide its recommendations and positions, ADA is not aware of studies that suggest there are improved health outcomes with a reduction of 120 mg sodium (from 480 mg to 360 mg for individual foods).

ADA is a member organization of the National High Blcod Pressure Education Program (NHBPEP) Coordinating Committee. The clinical trial known as Dietary Approaches to Stop Hypertension, or DASH, has demonstrated the critical role of nutrition in controlling blood pressure. Based on the results of DASH, the NHBPEP now recommends an eating plan that is rich in fruits, vegetables, and low-fat dairy products and that has limited saturated and total fat. In addition, it was recommended that limiting daily dietary sodium intake to less than 2,400 mg of sodium (about 1 teaspoon of salt) per day helps lower or control blood pressure. As ADA members translate science to improve consumers' understanding, we consider the consumer response to products meeting this new low sodium standard. If those products fall short of taste and food quality expectations, consumers are likely to purchase foods that will meet their expectations for taste, texture and other qualities. If consumers forego "healthy" options in favor of those with higher levels of fat, saturated fat, cholesterol and sodium, the rationale behind this proposal could be undermined.

ADA encourages FDA to carefully consider the evidence between reducing the sodium content of individual food products and the correlation with reduced coronary heart disease. Thank you for your careful consideration of this important public health issue.

Sincerely,

Marianne Smith Edge/jd

Marianne Smith Edge, MS, RD President