



July 5, 2003

Dockets Management Branch (HFA-305) 0 2 9 '03 JUL -2 12:29
Food and Drug Administration
5630 Fishers Lane, Room 1061
12420 Parklawn Drive
Rockville, MD 20852

Re: Docket Nos. 91N-384H and 96P-0500
Food Labeling: Nutrient Content Claims, Definition of Sodium Levels for the
Term "Healthy"
68 Fed. Reg. 8163 (February 20, 2003)

AARP appreciates this opportunity to comment on the appropriate sodium limits for foods that make "healthy" claims. FDA has grappled with this issue for more than a decade, seeking to strike the right balance between assisting consumers in their efforts to eat more healthful diets and recognizing the realities of the marketplace and of people's palates.

It has been clearly established that a high sodium intake is associated with higher blood pressure. The National Heart, Lung, and Blood Institute estimates more than 50 million Americans (one in four) suffer from hypertension (high blood pressure).¹ However, according to a recent study, an additional 45 million Americans have blood pressure levels that are "prehypertensive" – levels high enough to increase the risk of stroke, heart failure and kidney disease.² Limiting sodium intake, therefore, is important for more than just those people who have been diagnosed with hypertension.

The average American adult consumes about 4,000 milligrams of sodium a day.³ By contrast, the Nutrition Facts Panel recommends limiting daily sodium intake to 2,400 mg. It is particularly challenging to try to significantly lower sodium intake when up to 75 percent of that intake comes from salt in processed foods.⁴

One way to encourage companies to limit the sodium content of their products is to allow them to make "low sodium" and "reduced sodium" claims on their labels. Another way is to permit them to make "healthy" claims – which require, among other things, that a food have lower sodium content. In trying to determine this "lower" sodium value, FDA has faced two realities: 1) below a certain sodium content, many products are just not palatable; and 2) certain product lines that were marketed as "healthy" before adoption of the nutrition labeling rules may be eliminated from the marketplace if the sodium level is set too low.

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¹ Marian Uhlman, "So bad we can taste it," Philadelphia Inquirer, May 5, 2003, available at <<http://philly.com/mld/inquirer/5786709.htm?template=contentModules/printstory.jsp>>

² Sally Squires, "U.S. Expands Warning on Blood Pressure Risk, Washington Post, May 15, 2003 at A3.

³ Uhlman, *supra* note 1.

⁴ *Id.*

This last point is an important one. As we noted in our May 1998 comments in this proceeding, requirements for use of the term "healthy" on product labels should promote the development of food products that legitimately offer a more healthful alternative to conventional processed foods. We would amend our statement by noting the importance not only of developing new products but also of continuing established "healthy" brands. The reality is that, to date, food companies have not developed as many "healthy" products as had been anticipated and, while not "perfect," the healthy products that are currently on the market do provide consumers with more healthful alternatives to standard processed foods.

For these reasons, we support FDA's decision to keep the first-tier sodium levels for meal and main dish products that display the "healthy" claim, but recommend that the agency *not* adopt the second-tier sodium level (360 mg) for all individual foods. Rather, FDA should make this determination on a case-by-case basis. We are concerned that the second-tier sodium level could result in the elimination of more healthful alternatives in many food categories, such as soup. A healthy product that consumers just won't buy is of questionable value. While the agency noted in the proposal that at least one company said that it has met the second tier-level for some of its soups, we urge the FDA to consider the success of these particular products, as well as the market share of this company's line of "healthy soups," before relying too heavily on this assertion.

It is our understanding that soup products can have their sodium content reduced to 430 - 450 mg/serving and still retain their palatability. For this reason, we believe that the agency should not simply retain the first-tier sodium level for soups but, instead, should consider lowering their sodium level another 30-50 mg/serving. The agency should also consider setting appropriate sodium levels (higher than the current second-tier level, but below the first-tier level) for other product categories. We are concerned that, if required only to meet the first-tier level of 480 mg/serving, companies may not have the incentive to lower sodium levels even further. While the reduction suggested above for soups might seem relatively insignificant, the impact of similar changes across a wide range of individual processed foods in the total diet could be much greater.

If you have any additional questions, please contact Larry White on our Federal Affairs staff at (202) 434-3800.

Sincerely,

A handwritten signature in black ink, appearing to read "David Certner", with a long horizontal flourish extending to the right.

David Certner
Director
Federal Affairs