Quaker Foods & Beverages
Law Department
P.O. Box 049001
Chicago, Illinois 60604-9001

Area Code 312
Telephone 821-1000

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

RE: Food Labeling; Nutrient Content Claims,
Definition of Sodium Levels for the Term "Healthy"
Docket No. 91N-384H and 96P-0500

This comment is submitted by The Quaker Oats Company ("Quaker") in response to the Food and Drug Administration's ("FDA") request for comments on the subject of FDA's proposal to amend the regulation for sodium levels for foods that use the nutrient content claim "healthy".

Quaker is a major manufacturer and distributor of processed foods and beverages in both retail and food service markets. The foods that Quaker processes include the oat-based products consumers traditionally associate with the company as well as other hot and ready-to-eat cereals, dry breakfast food mixes, pasta and rice side dishes, grain-based snacks and cakes, sports beverages and a number of other wholesome and nutritious foods. Quaker has, for some time, been in the forefront of food manufacturers advocating the development and marketing of healthier and more nutritious food products and has been an active participant in recent years in the debate over food labeling and health claims. In fact, Quaker's petition for a health claim regarding the relationship between oats and coronary heart disease was the first food-specific health claim approved by the FDA. Quaker continues to share with the FDA the goal that food labeling should ensure that consumers are fully informed and not misled about the nutritional properties of their foods, while fostering an environment in which manufacturers are encouraged to innovate and develop safe, nutritious, and healthy food products.

Quaker appreciates the opportunity to provide comments to the FDA on this important matter.

96P-0500 C41

Quaker Supports FDA's Effort To Incent The Creation of "Healthy" Foods; For The Reasons Enumerated Below, Quaker Recommends That FDA Delay Implementation of This Proposal Pending Receipt and Review of the Institute of Medicine Report on Electrolytes and Water.

On February 20, 2003, FDA proposed to amend 21 CFR 101.65(d)(2), and move forward with a more restrictive sodium level for single foods to qualify for the implied nutrient content claim "healthy", while retaining more generous sodium criteria for meal and main dish foods to qualify for the claim. The proposed sodium level for the "healthy" claim is 360 mg sodium for single foods and 600 mg sodium for meal and main dish products.

The original definition of "healthy" was published as a final rule on May 10, 1994. At that time, a two-tier sodium level was specified, with the step-down to the lower tier scheduled to occur January 1, 1998. The sodium step-down would have required that sodium levels drop from 480 mg per serving to 360 mg, for single foods, and from 600 mg per serving to 480 mg, for meal and main dish foods. The sodium step-down has been the focus of a series of administrative stays of action. The most recent FDA stay was published on May 8, 2002 (67 FR 30795), delaying the change in sodium criteria until January 1, 2006.

On December 30, 1997, FDA published an Advance Notice of Proposed Rulemaking (ANPR) to address levels of sodium to qualify for the "healthy" claim on food labels. FDA solicited comments on the technological feasibility of reducing sodium levels while producing "healthy" products that are acceptable to consumers. FDA also was interested in the food safety aspects of reduced sodium levels in "healthy" foods. FDA tentatively concluded that, in some cases, the lower-tier sodium levels might be overly restrictive. FDA noted that comments on the 1997 ANPR presented "strong and opposing views" on the sodium step-down for the "healthy" claim, along with a significant amount of data relating to use of the term "healthy."

Since that time, Quaker is aware of no scientific research that has increased concerns about sodium levels in the foods that consumers consume. Nor is Quaker aware of any scientific research that compels the conclusion that for a single-serve food item a 25% reduction from the current 480 mg level is necessary to insure consumer health. If anything, more recent research suggests that sodium's role may not be as significant as regards health problems than was once believed. While FDA has previously

acknowledged the significant costs that will be incurred by the food industry should this change be implemented, corresponding benefit to the population has not been demonstrated. In addition, as has been extensively documented, consumer acceptance of food products that are compliant with the proposed second-tier sodium level has not been encouraging.

The food industry is just now starting to undertake its compliance efforts with FDA's Trans Fatty Acids labeling initiative -- an initiative that has been supported by Quaker and a broad spectrum of the food industry. By imposing another labeling mandate, FDA will not only burden the food industry in general without clear evidence of benefit, but will disproportionately impose that burden on exactly those manufacturers who have attempted to create healthier products - products that comply with the current "healthy" definition.

Even more importantly, Quaker believes that implementing this proposal will be counterproductive to FDA's goal of encouraging the creation of more foods that qualify for the claim "healthy". As noted above, hedonic issues have been identified as regards many otherwise "good-for-you" foods when they are reformulated to meet the 360mg level. If consumers will not eat these foods they are unlikely to turn to even less appealing alternatives. Furthermore, recent focus on the rising problem of obesity places even more emphasis on the need to send clear and achievable messages to consumers. By revising the definition of healthy in the direction of disqualifying many good-for-you foods from that claim, FDA puts at risk the development and commercialization of more products that consumers should be eating.

Equally significant is the anomaly that is created for some products that currently qualify for FDA-approved cancer and heart-health claims. Some leading ready-to-eat cereal products, to take one example, which qualify for the soluble fiber/cardiovascular disease health claim would, ironically, be disqualified from making a "healthy" claim. Similarly, some of the products that qualify for and display the American Heart Association's "Heart Check" would not be considered "healthy" under this proposal. Surely these are not results that FDA intended.

There also appears to be an inconsistency in application of the second-tier requirement: single serve foods are being held to it yet main dish items will be exempted from it, even though both were originally obligated to meet this standard. While the cost of reformulating main dish items appears to have been taken into consideration by FDA in its proposal, no such consideration appears evident as regards single-serve items.

For all of the above reasons, Quaker believes that FDA should give careful consideration to the imposition of the second-tier sodium requirement for single-serve foods at this time. This is not to say that Quaker does not share in FDA's goal to encourage manufacturers to create healthier food products. Certainly our track record proves that Quaker is willing to invest in achieving exactly that result. Fortunately, the timing is fortuitous in that more data regarding the role that sodium plays in the U.S. population will soon be available. The Institute of Medicine ("IOM") is in the process of preparing a report on Dietary Reference Intakes for Electrolytes and Water. This report is expected to be finalized in the fall of 2003.

The IOM Committee for Dietary Reference Intakes for Electrolytes and Water is charged with reviewing the scientific literature about sodium, potassium, chloride, sulfate, and water and other components of foods that may influence risk of cardiovascular disease, asthma, osteoporosis, hypertension, gastric cancer, and renal stones. Dietary Reference Intakes (DRIs) are expected to be established for these substances where there are sufficient data available to do so, including consideration of levels of intake that are compatible with good nutrition throughout the lifespan and that may decrease risk of developmental abnormalities and chronic disease. The Committee is expected to provide guidance on the use of these recommendations and reference intakes for individuals in addressing questions of applicability to assessing intakes of populations and in formulation of appropriate dietary standards.

Given the importance of the work of this Committee and the likelihood that its output will shed important light on this subject, Quaker recommends that FDA postpone its decision to implement the more restrictive second-tier sodium level for individual foods until the agency can review IOM's report on Dietary Reference Intakes for Electrolytes and Water. Once that report is available for review by the agency and all interested parties, there will be time for a fully informed debate and satisfactory resolution of this important matter.

Sincerely,

Mark L. McGowan
Chief Counsel – Foods Division

Dr. Steven Ink
Director- Nutrition Services