

**CHAMBER OF COMMERCE  
OF THE  
UNITED STATES OF AMERICA**

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July 3, 2003

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

**Re: Docket No. 1991N-0384H: Proposed Rule, Food Labeling; Nutrient Content Claims, Define Sodium Levels - Term Healthy**

Dear Dockets Management Branch:

The U.S. Chamber of Commerce, the world's largest business federation representing more than three million businesses of every size, sector, and region, is pleased to provide the following comments on the Food and Drug Administration's (FDA) proposed rule entitled, "Food Labeling: Nutrient Content Claims, Definition of Sodium Levels for the Term 'Healthy.'"<sup>1</sup> As explained below, we recommend that FDA delay further consideration of the proposed rule until such time that the National Heart, Lung, and Blood Institute (NHLBI) fully resolves a relevant "data quality" petition recently filed by the Chamber.

On May 14, 2003, the Chamber, jointly with the Salt Institute, filed a petition with NHLBI pursuant to Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Data Quality Act) and related agency guidelines. In the petition, the Chamber asserts that NHLBI is in violation of the Data Quality Act by virtue of its failure to demonstrate the reproducibility of agency statements concerning an important study, commonly referred to as the DASH-Sodium study, on the relationship between dietary sodium and blood pressure. The "reproducibility" of influential agency pronouncements, such as these, is a requirement of data quality guidelines developed by both the Office of Management and Budget and the National Institutes of Health.

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<sup>1</sup> 68 FR 8163.

We have attached a copy of the Chamber's May 14, 2003, petition to NHLBI. In short, the central question raised by the petition is whether NHLBI has accurately and objectively portrayed the DASH-Sodium study results when making several public pronouncements that *all* individuals can lower their blood pressure by reducing dietary sodium. Despite the agency's many statements to this effect, NHLBI has failed to release all pertinent data from the DASH-Sodium study concerning the effects of sodium on various subpopulations (e.g., those based on age, race, sex, etc.). In the aforementioned petition, the Chamber requests that NHLBI release all such data so that the statements of the agency can either be confirmed or refuted.

As such, the NHLBI petition is directly relevant to FDA's presently proposed rule. The Dietary Guidelines for Americans developed by the U.S. Department of Agriculture and the U.S. Department of Health and Human Services is largely informed by the work of NHLBI. Additionally, as FDA states in the preamble to the proposed healthy labeling rule, the "fundamental purpose of a 'healthy' claim is to highlight those foods that, based on their nutrient levels, are particularly useful in constructing a diet that conforms to current dietary guidelines, which suggest that daily sodium intake not exceed 2,400 mg."<sup>2</sup>

NHLBI has presented DASH-Sodium as the seminal study addressing the relationship between dietary sodium and blood pressure. If a review of the previously withheld subpopulation data reveals that NHLBI has not objectively presented the data, it will be necessary – whether through NHLBI's own initiative or as a result of further actions taken by affected parties pursuant to the Data Quality Act – for NHLBI to revisit its public pronouncements. This process, in turn, could ultimately result in a reexamination of the guidelines for dietary sodium. Of course, it is also possible that newly released DASH-Sodium subpopulation data will support NHLBI's public pronouncements, in which case further regulation of sodium (including "healthy" labeling standards) can proceed with confidence.

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<sup>2</sup> 68 FR 8163, 8165.

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For these reasons, the Chamber strongly encourages FDA to delay any further action on the present rulemaking until such time that the NHLBI/DASH-Sodium data quality issue has been fully resolved. This should not result in a substantial delay. In a May 23, 2003, letter to the Chamber and the Salt Institute, the National Institutes of Health indicated that the agency's goal was to provide a response within 60 days (or by July 22, 2003). Even if further administrative or legal action is necessary, it should be completed in ample time to allow any necessary FDA sodium standards for healthy products to take effect as scheduled on January 1, 2006.

Regardless, the Chamber believes that FDA would be best served by ensuring a proper scientific foundation for its labeling standards, even if such consideration results in a slight delay in the rule's effective date. As FDA readily admits in the proposal, this rule, if implemented in its proposed form, will result in a number of currently "healthy" products being discontinued or, at a minimum, being substantially altered. Such a drastic step, with its attendant consequences on consumer choice, should not be taken while an important aspect of the validity of the science underlying the regulation remains in question.

The Chamber will update FDA as to NHLBI's response to our data quality petition and, in the meantime, will be pleased to provide you any further requested information regarding either the data quality petition or these comments. We thank FDA for considering the importance of sound science and the views of the American business community as it works toward a final rule.

Sincerely,

A handwritten signature in black ink, appearing to read "William L. Kovacs". The signature is written in a cursive style with a prominent initial "W".

William L. Kovacs

Attachment