Rec'd 7-9-03
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July 5, 2003

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

Re: Dockets No. 91N-384H; 96P-0500

Dear Sir or Madam:

The Salt Institute submits these comments to the Food and Drug Administration's ("FDA") proposed rule to lower the sodium levels for use of the nutrient content claim "healthy," 68 Federal Register 8163 (February 20, 2003) ("Definition of Sodium Levels for the Term "healthy"). Pursuant to a notice dated May 6, 2003, the comment period for this proposed rule was extended to July 5, 2003.

The Salt Institute is the trade association representing virtually all United States food salt producers. The Salt Institute has, for many years, closely monitored the scientific literature concerning the alleged relationship between sodium, hypertension, and adverse health outcomes and participated in funding research and symposia concerning this alleged relationship. The relationship between sodium hypertension, and cardiovascular health has become increasingly complex and unclear over the last two decades. Notwithstanding this increasing scientific complexity, however, FDA has continued to advocate a now-simplistic and -incomplete sodium/hypertension message,

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which has been shown to be unrelated to positive cardiovascular health outcomes. The Salt Institute therefore strongly recommends for the reasons discussed below that FDA recognize this current scientific uncertainty, not adopt the proposed rule and reconsider the need for any definition of sodium for use of the term "healthy."

The Salt Institute believes that FDA should take this course of action in recognition of recent Supreme Court decisions that clarify that speech that contains elements of commercial and non-commercial (public-issue-oriented) speech, such as nutrition labels, should be afforded the highest level of speech protection possible. The Salt Institute further objects to the proposed rule because it violates the First Amendment protection for commercial speech by improperly restricting the use of the nutrient content claim "healthy" on foods containing more than 360 mg. of sodium per serving. The agency has not demonstrated through scientific or other evidence that it is either appropriate or necessary to further its public health goals to reduce the amount of sodium that can be present to use the term healthy, which thereby would further restrict the number of products that can use this claim. In fact, based on recent current science on the sodium-health relationship, FDA instead should delete sodium as a criterion for use of the term "healthy."

Moreover, by reducing the sodium definition to 360 mg. per serving without a re-assessment of the new science on the role of sodium in cardiovascular health which has been developed since the last rulemaking on this issue in 1994, over nine years ago, FDA's action will be arbitrary and capricious, in violation of the Administrative Procedure Act ("APA"). In addition, promulgation of the proposed rule will cause the Agency to facilitate the use of a food label which is false and misleading to consumers in violation of the Federal Food, Drug, and Cosmetic Act, and FDA's own

regulations. That is, FDA will be promoting a concept of "healthy" as it relates to sodium consumption that is false – that foods containing only 360 mg. sodium per serving are somehow healthier than those foods containing more than 360 mg. or more sodium per serving.

Finally, the Salt Institute believes that FDA has improperly relied on dietary recommendations and studies from NIH and other agencies which do not meet the requirements of the Data Quality Act. The Salt Institute has recently filed a joint petition with the U.S. Chamber of Commerce to challenge NIH's refusal to release data relating to the DASH-sodium study in view of its pronouncements on the findings of the study. To the extent that FDA is relying on NIH's findings and recommendations to substantiate the Agency's decision to further reduce the definition of sodium for healthy, the rule is further vulnerable to challenge.

LABELS CONTAINING NUTRITION AND HEALTH INFORMATION SHOULD RECEIVE HIGHER LEVEL FIRST AMENDMENT PROTECTION AFFORDED TO NON-COMMERCIAL SPEECH

Congress passed the Nutrition Labeling and Education Act ("NLEA") to prohibit "unfounded," "inaccurate," or "insupportable health claims" that have "great potential for defrauding consumers" and at the same time, to "permit health claims based on scientifically valid information."[1] Congressional intent thus was to provide consumers with access to information about the nutritional value of food products. As a result of NLEA, FDA identified nutrient content claims, such as use of the term "healthy," "low sodium" and others, to assist consumers to make scientifically informed decisions about their food choices and their diet.

Consistent with and in parallel with the increase in nutritional information available in food labeling, the courts have also clarified, beginning in 1999 with the decision in *Pearson v. Shalala*[2] (*Pearson I*), that food labeling, in particular health claims, is commercial speech and is protected under the First Amendment.[3] The courts have agreed that food labeling is entitled to the limited protection afforded commercial speech. The Salt Institute urges the Agency also to recognize that labels containing nutrition and health information – whether it is in the form of a health claim or a nutrient content claim (i.e., "healthy") – are entitled to the highest level of First Amendment speech protection possible and that any restrictions on this constitutional protection receive heightened scrutiny.

Labels containing nutrition and health information, by their very nature, are hybrids of commercial and non-commercial (public-issue-oriented) speech. Just as Justice Breyer noted in his recent opinion dissenting from dismissal of *Nike v. Kasky*[4], certain speech may have "predominant non-commercial characteristics with which the commercial characteristics are 'inextricably intertwined.'"[5] The Salt Institute believes that labels containing nutrition and health information fall in this category. For example, the non-commercial characteristics of nutrition labels are apparent by the fact that the nutritional content of foods and the diet-health relationship is of significant public

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1 See 136 CONG. REC. H12953 (daily ed. Oct. 26, 1990) (remarks of Rep. Waxman); See also, H.R. Rep. No. 538, 101st Cong., 2d Sess. 7, *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337.

2 See *Pearson v. Shalala*, 164 F3d. 650 (D.C. Cir. 1999) ("*Pearson I*").

3 See *Pearson v. Thompson*, 141 F. Supp. 2d 105, 112 (D.D.C. 2001) (*Pearson III*) (". . . the philosophy underlying *Pearson I* is perfectly clear: that . . . First Amendment analysis . . . . applies in this case, and that if a health claim is not inherently misleading, the balance tilts in favor of disclaimers rather than suppression").

4 See *Nike, Inc. v. Kasky*, 2003 WL 2146758 (U.S.).

5 , *Id* at 13. (citing *Riley v. National Federation of the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988).

interest, active controversy, and existing public debate. Consider, for example, recent announcements by Kraft that it is capping its serving size and limiting the types of foods it sells in schools because of the juvenile obesity problem and the perceived need for marketing of "healthier" foods to children.[6] Further, health and nutrient content claims contained on food labels are aimed at assisting consumers to make important choices concerning their diet on the basis of physical effects of consumption, rather than on ephemeral aspects of the product (e.g., taste, appearance). Therefore, to facilitate consumer access to obtaining the best information possible in order to make an informed decision regarding the amount and type of foods in their diet, it is incumbent upon FDA and the courts to ensure that nutritional labeling is afforded the highest level of speech protection possible. Under this proper and heightened standard, the proposed healthy rule on sodium cannot be adopted.

FDA'S PROPOSAL TO RESTRICT FURTHER THE USE OF THE "HEALTHY" CLAIM BASED ON SODIUM CONTENT CONSTITUTES AN IMPERMISSIBLE BAN ON COMMERCIAL SPEECH

Numerous court decisions have recognized that food labeling, in particular health claims, is commercial speech that has a substantial level of protection under the First Amendment, and have rejected FDA's attempts to improperly restrict the use of health claims in food labeling for dietary supplements. *See*, e.g., *Pearson v. Thompson,*[7] (rejection of FDA effort to restrict use of folic acid health claim) and *Whitaker v. Thompson* (rejection of FDA effort to restrict use of antioxidant claim

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[6] See Christina Berk, *Kraft Plan a Sign of Growing Attention to Obesity Issue*, The Wall Street Journal Online, July 1, 2003, *at* http://online.wsj.com/article/0,,BT_CO_20030701_006403-search,00.html?collection=autowire%2F30day&vql_string=kraft%3Cin%3E%28article%2Dbody%29.

[7] See *Pearson v. Thompson*, 141 F. Supp. 2d 105 (D.D.C. 2001).

on dietary supplements).[8] Any attempt by FDA to restrict commercial speech must be analyzed at a minimum consistent with the Supreme Court's decision in *Central Hudson Gas and Electric Corp. v. Public Service Commission,* if not as non-commercial speech.[9]

Under *Central Hudson* and *Pearson I*, it is necessary to conduct a four-step analysis of the proposed regulation/restriction on commercial speech to determine if it is constitutionally valid. First, it is necessary to decide whether the expression is protected under the First Amendment by considering whether "the speech concerns lawful activity and is not misleading."[10] A complete ban on commercial speech can only be approved where the government proves that "the expression itself was flawed in some way, either because it was deceptive or related to unlawful activity."[11] Second, if the speech is protected, it is necessary to decide "whether the asserted government interest is substantial."[12] If the governmental interest is substantial, it is necessary to determine "whether the regulation directly advances the governmental interest asserted."[13] Finally, it is necessary to determine "whether [the regulation] is not more extensive than is necessary to serve that interest."[14]

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8 See *Whitaker v Thompson,* 248 F. Supp. 2d 1 (D.D.C. 2002).

9 See *Central Hudson Gas & Electric Corp v Public Service Commission,* 447 U.S. 557 (1980); *Whitaker v Thompson,* 248 F. Supp. 2d at 8 (D.D.C. 2002).

10 See *Thompson v. Western States Med. Ctr*, 122 S.Ct. 1497, 1504 (U.S. 2002).

11 See *Central Hudson Gas & Electric Corp v Public Service Commission,* 447 U.S. at 566 n. 9 (1980).

12 See *Thompson v Western States Med. Ctr*, 122 S.Ct. at 1504. (citing *Central Hudson Gas & Electric Corp v. Public Service Commission,* 447 U.S. at 566 (1980)).

13 See *Pearson I,* 164 F.3d. at 657 (emphasis in original) (citing *Central Hudson Gas & Electric Corp v. Public Service Commission,* 447 U.S. at 566 (1980)).

14 See *Thompson v. Western States Med Ctr*, 122 S.Ct. at 1504 (U.S. 2002) (citing *Central Hudson Gas & Electric Corp v Public Service Commission,* 447 U.S. at 566 (1980)).

This fourth step requires an evaluation of "whether the fit between the government's ends and the means chosen to accomplish those ends is . . . reasonable."[15]

Not only has FDA completely failed to conduct the analysis mandated by *Central Hudson* and *Pearson I*, but even if it does, it must conclude that there is no basis to further reduce the sodium definition for healthy and preclude additional foods from using the claim. Consequently, the proposed rule is unconstitutional and cannot be adopted.

Under the *Central Hudson* analysis, the affected speech (the "healthy" claim) is protected. The use of the "healthy" claim with foods containing more than 360 mg of sodium is not inherently misleading,[16] based on current scientific research regarding the sodium – health relationship.[17] Also, FDA's interest in public health and food labeling is substantial and the Salt Institute agrees that scientific-supported regulation of health claims directly advances public health. FDA's proper regulation of health claims furthers lawful activity – the sale of wholesome food and the dissemination of nutritional information to consumers. Therefore, under the *Central Hudson* analysis, the only genuine controversy is whether the proposed regulation to further reduce sodium level is more extensive than necessary.

While examining this issue and the "reasonable" fit between the government's goals and the means chosen to advance those goals in the health claims context, the *Pearson I* court noted that the

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15 See *Pearson I*, 164 F.3d at 656 (D.C. Cir. 1999) (internal citations and quotations omitted).

16 The Supreme Court has held that inherently misleading information may be banned in its entirety. Inherently misleading should be differentiated from potentially misleading. The Supreme Court has reasoned that so long as information can be presented in a way that is not deceptive, such information is only potentially misleading.

Supreme Court, in *Bates v. State Bar of Arizona, 433 U.S. 350 (1997)*, refused to credit the notion that "the public is not sophisticated enough to realize the limitations of advertising and that the public is better kept in ignorance than trusted with correct but complete information."[18] In examining restrictions on commercial speech under the First Amendment, the Supreme Court has consistently "rejected the 'highly paternalistic' view that government has complete power to suppress or regulate commercial speech" in order to protect the public.[19]

This same thesis was the basis for the recent decision in *Whitaker v. Thompson.*[20] There the court examined FDA's refusal to authorize a vitamin seller's proposed health claim on a dietary supplement for the beneficial health effects of antioxidants. The *Whitaker* court found that FDA's decision to ban the claim was not compatible under the *Central Hudson* analysis with the clear preference for disclosure over suppression of commercial speech. The court found that FDA could have chosen a less restrictive means of protecting its interest in safeguarding the public health through the approval of an accompanying disclaimer for the health claim rather than an outright ban on its use. The court stated that in finding that speech is misleading, the government must consider

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17 See *Whitaker v. Thompson*, 248 F. Supp. 2d at 9-10 (D.D.C. 2002)

18 See *Pearson I*, 164 F.3d. at 657 (D.C. Cir. 1999) (commenting on *Bates v. State Bar of Arizona*, 433 U.S. at 374-75 (1997)).

19 See *Whitaker v. Thompson*, 248 F. Supp. 2d at 9 (citing *Central Hudson Gas & Electric Corp v Public Service Commission*, 447 U.S. at 562 (1980)).

20 See *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002).

that "people will perceive their own best interests if only they are well enough informed, and . . . the best means to that end is to open the channels of communication rather than to close them."[21]

Indeed, consumers today are highly sophisticated and have access to more information regarding products, nutrition, and health claims than ever before. This is especially the case with respect to sodium which has been on the front burner of nutritional health issues since the late 1970s. Consumers are well-informed and capable of making informed decisions concerning their own dietary choices.

Here there is no doubt that the proposed regulation to further reduce by 25% the sodium content definition for use of the term healthy is more extensive than necessary and will not aid consumers to maintain a healthy diet. In fact, as discussed below, any restriction on sodium content in determining whether an individual food product is healthy is not scientifically or medically supportable.

FOODS WITH ABOVE 360 MG OF SODIUM ARE HEALTHY AND CAN BE PART OF A HEALTHY DIET.

The effort to reduce sodium consumption by the general population has been encouraged under the assumption that it will provide positive cardiovascular profile benefits. However, there is no evidence that restricting sodium consumption results in improved cardiovascular health outcomes. In fact, the rulemaking in which FDA decided what makes a food healthy with respect to dietary

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[21] See *Whitaker v. Thompson*, 248 F. Supp. 2d at 9 (D.D.C. 2002) (citing *Virginia Pharmacy Board v. Virginia Citizens Consumer Council*, 425 U.S. 748, 770 (1976)).

sodium intake was completed before the first published "health outcomes" study in 1995 examined the question of whether low-sodium diets reduce cardiovascular risk.

Instead, FDA has relied on studies that have examined the relationship between intermediate variables, such as salt intake and blood pressure, rather than focusing on the relationship between intake levels of dietary sodium and improved cardiovascular health outcomes. Since 1995, nine different studies have now examined the health outcomes of reducing dietary sodium. As briefly summarized below, none of them show a benefit to the general population in terms of health outcomes such as reduced incidence of heart attacks or strokes. In fact, as noted, some of the studies found that low sodium diets actually cause adverse health outcomes (*i.e.*, greater incidence of heart attacks). They are the following:

- H. Tunstall-Pedoe *et al.*, 1997. Comparison of the Prediction by 27 Different Factors of Coronary Heart Disease and Death in Men and Women of the Scottish Heart Health Study: Cohort Study. *BMJ* 315:722-729. (This ten-year follow-up study to the Scottish Heart Health Study found no improved health outcomes for those on low-salt diets, and specifically, no association between sodium intake and cardiovascular or all-cause mortality).
- An analysis of the MRFIT database by Dr. J. Cohen examined data over fourteen years and suggested that there was no improved health benefit from low-sodium diets. The author noted that there is "no relationship observed between dietary sodium and mortality." [Cohen, J.D. presentation to NHLBI Workshop on Sodium and Blood Pressure, January 28, 1999, Bethesda, MD (unpublished)].

- An analysis by Dr. J. Cutler of the National Institutes of Health, National Heart Lung and Blood Institute, of the first six years' data from the MRFIT database documented no health outcomes benefits of lower-sodium diets. (1997). [Cutler, J.R., Presented May 30, 1997, at American Society of Hypertension annual meeting, San Francisco, CA. (unpublished)].

- M. Alderman *et al.* 1998. Dietary Sodium Intake and Mortality: the National Health and Nutrition Examination Survey (NHANES I). Lancet 351:781-785. (An analysis of the health outcomes over twenty years from those in the NHANES I documented a 20% greater incidence of heart attacks among those on low-salt diets compared to normal-salt diets).

- M. Alderman *et al.*, 1995. Low Urinary Sodium Is Associated With Greater Risk of Myocardial Infarction Among Treated Hypertensive Men. *Hypertension* 25:1144-1152. (An eight-year study of a New York City hypertensive population stratified for sodium intake levels finding that patients on low-salt diets had more than four times as many heart attacks as those on normal-sodium diets).

- A health outcomes study in Finland, reported to the American Heart Association that no health benefits could be identified and concluded "...our results do not support the recommendations for entire populations to reduce dietary sodium intake to prevent coronary heart disease." [Valkonen, V-P. "Sodium and potassium excretion and the risk of acute myocardial infarction" Presented October 15, 1998 to the American Heart Association Scientific Sessions, Dallas, TX (unpublished)].

- He, J. et al.1999. "Dietary sodium intake and subsequent risk of cardiovascular disease in overweight adults." *Journal of the American Medical Association*, 282:2027-2034. (A study of Americans found that less sodium-dense diets did reduce the cardiovascular mortality of one population sub-set, overweight men, but not the general population. The article reporting the findings did not explain why this obese group actually consumed less sodium than normal-weight individuals in the study).

- Tuomilehto J. et al. 2001. "Urinary sodium excretion and cardiovascular mortality in Finland: a prospective study." *Lancet* 357:848-51. (This Finnish study reported an increase in cardiovascular events for obese men, but not women or normal-weight individuals of either gender. The article, however, failed to adjust for potassium intake levels which many researchers consider a key associated variable).

- Hooper, L. et al. 2002. "Systematic review of long term effects of advice to reduce dietary salt in adults." *British Medical Journal* 325:628-636. (This study by the prestigious Cochrane Collaboration is the latest and highest-quality meta-analysis of clinical trials. It confirmed earlier meta-analyses' conclusions that significant salt reduction would lead to very small blood pressure changes in sensitive populations and no health benefits).

Because these studies represent updated and state-of-the-art research regarding the relationship of sodium intake and cardiovascular health outcomes, not only must FDA evaluate these studies in determining what amount of sodium is healthy for an individual serving of food, but FDA will also find that these studies confirm that there is no basis on which to conclude that there is a need for any

further restriction on sodium content in order to consider a food item healthy. In fact, these studies will demonstrate that the sodium content of foods contained in a normal American diet is irrelevant to cardiovascular health outcomes of healthy Americans and thus foods with 500, 700 or 900 mg. sodium per serving are just as healthy as foods with 480 mg. sodium per serving.

Moreover, the courts have made it clear that FDA should not ignore studies that examine the relationship of salt intake to health outcomes, and should not give undue emphasis to studies which address health issues that are not relevant to the general population. Importantly, in *Whitaker*, the court noted that approximately one-third of the more than 150 intervention and observational studies considered by FDA actually supported the antioxidant vitamin/cancer relationship.[22] Of the antioxidant vitamin/cancer studies reviewed by FDA: a) five of seventeen intervention studies supported the relationship, and one study produced mixed reports both for and against the relationship; b) two of the six post-hoc intervention studies supported the relationship; and c) sixty-five of 191 observational studies supported the relationship as did the one observational meta-analysis reviewed by FDA. However, FDA discounted many of the studies supporting the relationship for study errors or design limitations.[23] The *Whitaker* court found that, contrary to its own protocols, FDA gave undue emphasis to many intervention studies that did not focus on the general population, but rather focused on specific populations that were at a higher risk for cancer (i.e., smokers at risk for lung cancer). FDA banned the plaintiff's antioxidant claim by concluding that the evidence in support of it was weaker than evidence against it. The *Whitaker* court noted that

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[22] See *Whitaker v. Thompson*, 248 F. Supp. 2d at 11 (D.D.C. 2002).

[23] *Id.* at 12 n. 12.

it was clear that *more than 60 recent studies* reviewed by FDA supported the claim. The court noted that this number "hardly constitutes the 'one or two old studies' that the Court of Appeals contemplated might support a total ban."[24] Here, the most recent credible science has shown that it is irrelevant to focus on the sodium/hypertension relationship; rather, it is only appropriate to focus on the sodium/health relationship and determine if reducing sodium reduces the number of heart attacks and strokes. If it does not, as the recent studies show, then there is no basis for restricting sodium consumption at all. In any event, there is no credible medical basis whatsoever to further reduce sodium levels in an effort to produce health outcomes which have not been shown to exist.

Moreover, the public interest will not be served by further restricting salt content in individual healthy foods. As noted in the above-cited scientific studies, dietary sodium restriction for most adults does not affect health outcomes. Although dietary sodium restriction is associated with some decrease in blood pressure (an intermediate variable), recent studies indicate that the effect that sodium intake has on blood pressure is related to deficiencies of minerals and other key nutrients. Moreover, although it is well accepted that a substantial variation in dietary salt intake (75 to 100 mmol/day) can produce measurable but modest changes in blood pressure, this effect is heterogeneous. For example, the amount of sodium intake effect on blood pressure appears to be more substantial in older and hypertensive subjects.[25] Thus, certain subjects can be classified as salt-sensitive and salt-resistant, indicating their blood pressure response to dietary sodium.

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[24] *Id* at 13

[25] See M. Alderman, *et al.*, "Salt, Blood Pressure, and Human Health," Hypertension (2000): Vol. 36, 890-893.

In addition, several studies have suggested that reducing dietary sodium produces other effects that may negatively affect health outcomes. The Alderman studies suggest that many hypertensive persons on reduced sodium diets actually experience a greater increase in heart attacks. Similarly, mandating reduced sodium content in healthy foods may cause consumers to reduce their intake of foods with high levels of calcium, potassium and magnesium, minerals which are now known to be critical in maintaining cardiovascular health. Consequently, the use of a more restrictive "healthy" claim may result in consumers making dietary choices adverse to their health (e.g., not eating low fat dairy products) based on the misperception that even low levels of dietary sodium should be avoided.

THERE IS NO EVIDENCE THAT THE EXISTING DEFINITION FOR HEALTHY HAS NEGATIVELY AFFECTED OR INTERFERES WITH HEALTH OUTCOMES

There is no evidence that FDA's existing rule, allowing a maximum of 600 mg of sodium per serving size for individual foods, has adversely affected public health. Likewise, there is no evidence that it is more important or effective to restrict sodium in individual food sources than in meals and main dish products. Consumers typically have a wide variety of food choices available to them and do not necessarily make a distinction regarding individual food sources and main dish choices.

Further, neither maintaining FDA's existing sodium criteria of 600 mg per serving for individual foods nor removing sodium completely as a determinant of "healthy" foods would prevent FDA from achieving its goal of allowing consumers to make informed choices concerning their daily sodium intake. Either course is also more consistent with the new FDA health claims guidelines

which acknowledge that consumers are active partners in their own health care, and will behave in health promoting ways when given accurate health information.[26] As the majority of food products contain label statements regarding the sodium content and the percentage of the recommended sodium daily allowances, and as many foods also contain a sodium health claim,[27] consumers are provided ample opportunities to monitor and make choices regarding their salt intake.

Moreover, a more expansive interpretation of "healthy" foods would be consistent with the Federal Trade Commission ("FTC") position that there are a spectrum of food choices that in the aggregate can help a consumer eat a healthy diet.[28] This view is more reflective of the recent science that there are a myriad of foods from which informed consumers can properly choose to balance their diet in order to achieve health.

THE POTENTIAL HARM TO THE SALT INSTITUTE'S MEMBERS AND THEIR CUSTOMERS FIRST AMENDMENT RIGHTS OUTWEIGHS ANY POTENTIAL HARM FROM MAINTAINING THE CURRENT SODIUM DEFINITION

The potential harm to the Salt Institute's and its members' First Amendment rights outweighs any potential injury to the public from maintaining the existing sodium definition for healthy foods. Under the governing analysis set forth in *Pearson I* and similar cases reviewing FDA restrictions on labeling,[29] even if a health claim is in some respects "potentially" misleading because there is scientific controversy about the health effects of dietary sodium, the resulting injury that could flow

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[26] FDA, Center for Food Safety and Applied Nutrition, "Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements," (Dec. 18, 2002).

[27] The Salt Institute objects to the current sodium health claim but understands it is not the subject of this rulemaking.

[28] See FTC Comments to FDA Docket No. 02N-0209, (Sept. 13, 2002).

to consumers cannot compare, as a matter of law, with the First Amendment injury that results.[30] The Salt Institute and its members will suffer irreparable harm by FDA's proposed regulation. The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.[31] This injury is compounded by the adverse economic effect that will accrue to those food manufacturers who can no longer market healthy foods because of the reduced sodium content definition or which are required to reformulate, in both cases adversely affecting the economic interests of Salt Institute members. Therefore the burden is on FDA to prove that further restriction of sodium levels in foods labeled as "healthy" is a critical, rather than merely convenient, means of achieving its interests.[32] No such showing has been or can be made here.

THE SALT INSTITUTE REQUESTS FDA TO REMOVE SODIUM AS A DETERMINANT FOR THE DEFINITION OF "HEALTHY"

For the reasons stated above, the Salt Institute requests FDA to revise its food labeling regulations consistent with current nutritional science and remove sodium content as a factor in determining whether a product can be labeled "healthy." As noted in the above scientific studies, current nutritional science confirms that reducing dietary sodium consumption in the general population does not result in beneficial health outcomes such as reduced cardiovascular events. Therefore, it is misleading to consumers in the general population to suggest that a food, or an entire diet, with reduced sodium content is healthier than a comparable food or diet with higher sodium

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[29] See *Thompson v Western States Med Ctr*, 122 S.Ct. 1497 (U.S. 2002).

[30] See *Whitaker* v. *Thompson*, 248 F. Supp. 2d at 15 (D.D.C. 2002).

[31] See *id.*

[32] See *Whitaker v. Thompson*, 248 F. Supp. 2d at 14-15 (D.D.C. 2002); See also *Thompson v. Western States Med Ctr*, 535 U.S. 357 (2002).

content. Not only are such conclusions not substantiated, but they are refuted by current science. As a result, FDA should not endorse or facilitate the use of misleading labels on food products by adopting this proposed rule. Consequently, FDA should remove sodium as a determinant for foods that use the "healthy" claim until such time when significant randomized clinical trials, examining the relationship between the effect of dietary sodium intake on health outcome factors such as cardiovascular morbidity and mortality, can be performed.

THE PROPOSED RULE IS ARBITRARY AND CAPRICIOUS AND VIOLATES THE APA

In addition to being unconstitutional, for all of the above reasons, the proposed rule for the 25% reduction in sodium for individual foods is arbitrary and capricious, in violation of the APA.[33] The need for any level of reduction is not only unsupported by the scientific literature but is refuted by the existing evidence that further reducing dietary sodium consumption will result in positive health outcomes for consumers. Therefore, FDA should abandon this rulemaking.

USE OF DISSEMINATED INFORMATION RELEASED AFTER OCTOBER 1, 2002, REGARDING THE RELATIONSHIP BETWEEN LOWERED SODIUM CONTENT IN FOODS AND REDUCTION OF HYPERTENSION, VIOLATES THE DATA QUALITY ACT ("DQA") AND NIH GUIDELINES REGARDING PRE-DISSEMINATION REVIEW

As FDA is aware, the Data Quality Act mandates that agencies "ensur[e] and maximiz[e] the quality, objectivity, utility, and integrity" of all disseminated information.[34] Under the Act, OMB developed government-wide guidelines and each agency has created its own agency-specific guidelines, allowing affected parties to seek correction of disseminated information that does not

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[33] 5 U.S.C. § 706(2)(A).

[34] Section 515, Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554; See also 44 U.S.C. Section 3516 (other provisions).

comply with OMB's Guidelines. The OMB Guidelines provide that the administrative mechanism must also allow correction of information that is inconsistent with the disseminating agency's own guidelines.[35] Accordingly, information disseminated by an agency must be corrected if it is determined to be inconsistent with either the OMB Guidelines or the agency specific guidelines.

The Salt Institute and the U.S. Chamber of Commerce have jointly filed a petition to the National Heart, Lung, and Blood Institute ("NHLBI") seeking correction of information disseminated[36] by it which states or suggests that reduced sodium consumption will result in lower blood pressure in all individuals.[37] Specifically, NHLBI continues to disseminate information suggesting that "all Americans" can experience a reduction in blood pressure by reducing daily sodium intake to no more than 100 mmol/day, which equates to approximately six grams of sodium chloride or 2.4 grams of sodium per day. Following the initial publication of the DASH-Sodium study in January 2001, NHLBI made multiple statements in various forms (i.e., News Releases, NHLBI website documents, published documents, etc.) concerning the purported effect of salt intake on human blood pressure. In contravention of the DQA, the data that have been released from the DASH-Sodium study do not support the continuing statements or messages made by NHLBI in connection with the study. The data released by the authors did not address study results specific to subpopulations within the 412 participants, such as race, existing (or lack of existing) hypertension, sex, age, body-mass index, education level and other parameters. Especially noteworthy was the lack

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[35] OMB Guidelines, Section III.3, 67 Fed. Reg. 8451, 8459 (Feb. 22, 2002).

[36] The term "dissemination" is broadly defined in HHS Guidelines (Section D.2h.) as meaning "agency initiated or sponsored distribution of information to the public."

of data concerning the mean blood pressures with standard deviations and sample size for each individual subgroup studied.

Without this information, an objective determination of the accuracy, reliability and unbiased nature of the study cannot be made by independent reviewers. Therefore, the Salt Institute requests that FDA, in its consideration of this proposed rule, not take into account any interpretation of the results related to the DASH-Sodium Trial or any other studies subject to DQA, until such time that they are in accord with the DQA.

CONCLUSION

The Salt Institute submits that there exists no well-documented scientific data supporting any clear relationship between dietary sodium, hypertension, and cardiovascular health outcomes applicable to the general population. Further, recent scientific evidence shows that a reduced sodium diet does not reduce the risk of hypertension in healthy individuals, and may, in fact, contribute to serious health outcomes such as heart disease and additional health risks. Consequently, FDA should conclude that further restriction of sodium levels to meet the definition of "healthy" is unwarranted. Further, because the proposed rule is not necessary and is certainly not the least restrictive means of achieving FDA's goals, the proposed regulation violates the First Amendment and cannot withstand constitutional challenge.

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[37] Joint Petition to NHLBI filed by The Chamber of Commerce of the United States and the Salt Institute, May 14, 2003.

Consequently, the Salt Institute requests that the Agency not amend the regulation to lower the sodium content for foods bearing the nutrient content claim "healthy." Instead, the Salt Institute believes that FDA should revise its food labeling regulations consistent with current nutritional science and remove sodium content as a factor in determining whether a product can be labeled "healthy." Current nutritional science confirms that reducing dietary sodium consumption in the general population does not result in beneficial health outcomes such as reduced cardiovascular events. Therefore, it is misleading to consumers in the general population to suggest that a food with a low sodium content is healthier than a comparable food with a higher sodium content. Promulgation of a rule on this basis would be arbitrary and capricious. It would also result in the endorsement and facilitation by the FDA of the use of false and misleading labels on food products in violation of the FFDCA § 403 (21 U.S.C. 343) and FDA's own food labeling regulations at 21 C.F.R. Part 101.

The Salt Institute appreciates the opportunity to submit these comments.

Sincerely,

Richard L. Hanneman

Richard L. Hanneman
President

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