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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
21 CFR Part 15  
[Docket No. 2005P-0450]

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**Salt and Sodium; Petition to Revise the Regulatory Status of Salt and Establish Food Labeling Requirements Regarding Salt and Sodium; Public Hearing; Request for Comments**

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attorney  
10/19/07

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public hearing; notice of availability of citizen petition; request for comments.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public hearing concerning FDA's policies regarding salt (sodium chloride) and sodium in food. FDA also is announcing the availability for comment of a citizen petition, submitted by the Center for Science in the Public Interest (CSPI), requesting that FDA make changes to the regulatory status of salt, require limits on salt in processed foods, and require health messages related to salt and sodium. The purpose of the hearing is for FDA to share its current framework of policies regarding salt and sodium and to solicit information and comments from interested persons on this current framework and on potential future approaches, including approaches described in the citizen petition.

**DATES:** The public hearing will be held on November 29, 2007, from 9 a.m. to 4:30 p.m. Registration begins on October 22, 2007. See section V of this document for other dates associated with participation in the hearing. Submit written or electronic comments (i.e., submissions other than notices of participation and written material associated with an oral presentation) by

March 28, 2008. The administrative record of the hearing will remain open until March 28, 2008.

**ADDRESSES:** *Public hearing.* The public hearing will be held at the Harvey W. Wiley Federal Building, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD, 20740–3835 (Metro stop: College Park on the Green Line).

*Registration.* Submit electronic notices of participation for the hearing to <http://www.cfsan.fda.gov/register.html>. We encourage you to use this method of registration, if possible. Submit written notices of participation by mail, fax, or e-mail to Isabelle Howes, U.S. Department of Agriculture Graduate School, 600 Maryland Ave., SW, suite 270, Washington, DC 20024–2520, FAX: 202–479–6801, or e-mail: [Isabelle\\_Howes@grad.usda.gov](mailto:Isabelle_Howes@grad.usda.gov). You may also submit oral notices of participation by phone to Isabelle Howes, U.S. Department of Agriculture Graduate School (see **FOR FURTHER INFORMATION CONTACT**).

*Written material associated with an oral presentation.* Submit written material associated with an oral presentation by mail, fax or e-mail to Isabelle Howes.

*Comments.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. For additional information on submitting comments, see section VI in this document.

**FOR FURTHER INFORMATION CONTACT:**

*For questions about registration or written material associated with an oral presentation, or to register orally:* Isabelle Howes, 202–314–4713.

*For all other questions about the hearing or if you need parking or special*

*accommodations due to a disability:* Juanita Yates, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 301–436–1731, e-mail: *Juanita.Yates@fda.hhs.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

#### *A. Salt*

##### 1. Salt in the Human Diet

Salt (sodium chloride) is an essential part of the diet. Both the sodium and chloride ions are required, for example, to maintain extracellular volume and serum osmolality (Ref. 1). Salt is found naturally in foods such as milk and shellfish (Ref. 1). Salt also is added intentionally as a food ingredient for multiple technical effects in foods, e.g., as a seasoning agent and flavor enhancer, a preservative and curing agent, a formulating and processing aid, and a dough conditioner (47 FR 26590, June 18, 1982 (the 1982 policy notice)).

The Dietary Guidelines for Americans, 2005 (Dietary Guidelines) (Ref. 2), a joint publication of the Department of Health and Human Services and the U.S. Department of Agriculture (USDA), forms the basis for the Federal Government's nutrition programs and policies. Chapter 8 of the Dietary Guidelines reports that, on average, the natural salt content of food accounts for only about 10 percent of total intake, while discretionary salt use (i.e., salt added at the table or while cooking) provides another 5 to 10 percent of total intake. Chapter 8 of the Dietary Guidelines also reports that approximately 75 percent of total salt intake is derived from salt added to processed food by manufacturers.

## 2. Adverse Health Effects of Salt

Excessive sodium has been cited by the scientific community as a contributory factor in the development of hypertension and cardiovascular disease (47 FR 26580). In general, there is a dose-dependent relationship between sodium intake and blood pressure that has been observed to occur throughout the range of levels of sodium intake (Ref. 1). Blood pressures among individuals in certain populations (e.g., persons with hypertension, diabetes, kidney disease, older persons, and African Americans) are more responsive to dietary sodium than blood pressures among the general population (Ref. 1). The Dietary Guidelines recommend that the general population consume no more than 2,300 milligrams/day (mg/d) and that persons with hypertension, blacks, and middle-aged and older adults consume no more than 1,500 mg/d (Ref. 2).

## 3. Regulatory Status of Salt (1959–1982)

The definition of “food additive” in section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)) is a multistep definition that first broadly includes any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food. However, the definition then excludes substances that are generally recognized, among experts qualified by scientific training and experience to evaluate their safety as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or through experience based on common use in food) to be safe under the conditions of their intended use. The definition also excludes certain other substances from the definition of food additive. In particular, under

section 201(s)(4) of the act, any substance used in accordance with a sanction or approval granted prior to September 6, 1958, under the act, the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*) or the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) is excluded from the definition of food additive. Under the act, substances that are not food additives are not subject to the requirements in section 409 of the act (21 U.S.C. 348) for premarket review. Prior-sanctioned substances remain subject, however, to the general adulteration provisions in section 402 of the act (21 U.S.C. 342). These provisions prohibit, among other things, the use of added deleterious substances that “may render [the food] injurious to health.”

In the **Federal Register** of November 20, 1959 (24 FR 9368), FDA clarified the regulatory status of a multitude of food substances that were used in food prior to 1958 and amended its regulations to include an initial list of food substances that, when used for the purposes indicated and in accordance with current good manufacturing practice, are generally recognized as safe (GRAS). This initial list (the “GRAS list”) is currently published in part 182 (21 CFR part 182). Section 182.1(a) provides in part:

“[I]t is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, vinegar, baking powder, and monosodium glutamate as safe for their intended use.”

In the early 1970s, FDA announced that the agency was conducting a comprehensive study of substances presumed to be GRAS (35 FR 18623, December 8, 1970; and 36 FR 20546; October 23, 1971). FDA also issued several regulations regarding GRAS substances and procedures associated with its comprehensive review of GRAS substances. These regulations are currently

in part 170 (21 CFR part 170) and include: (1) Criteria that could be used to establish whether substances presumed to be GRAS should be listed as GRAS, become the subject of a food additive regulation, or be listed in an interim food additive regulation pending completion of additional studies (§ 170.30) (36 FR 12093, June 25, 1971); (2) procedures that the agency could use, on its own initiative, to affirm the GRAS status of substances that were the subject of its comprehensive review and were found to satisfy the established criteria (§ 170.35(a) and (b)) (37 FR 25705, December 2, 1972); and (3) the general process that the agency would use to review ingredients included in the original GRAS list (§ 170.30(e)) (41 FR 53600, December 7, 1976). Under § 170.30(e):

“[f]ood ingredients were listed as GRAS [in 21 CFR part 182] during 1958–1962 without a detailed scientific review of all available data and information relating to their safety. Beginning in 1969, [FDA] has undertaken a systematic review of the status of all ingredients used in food on the determination that they are GRAS or subject to a prior sanction. All determinations of GRAS status or food additive status or prior sanction status pursuant to this review shall be handled pursuant to [21 CFR 170.35, 170.38, and 180.1] \* \* \*”

As part of FDA’s approach to the comprehensive review of GRAS substances, FDA contracted with the Federation of American Societies for Experimental Biology (FASEB) for a committee of scientific experts to summarize the available scientific literature regarding substances presumed to be GRAS, including salt. FASEB provided FDA with a tentative report containing its findings and recommendations, held public hearings to provide an opportunity for interested persons to submit additional information and to express their views about the tentative report, and then submitted a final report (47 FR 26590).

In the 1982 policy notice, FDA described the uses of salt in food, reviewed the statutory framework for food ingredients, and described its comprehensive review of GRAS substances. FDA also discussed the findings and conclusions in FASEB's final report on salt. The FASEB report recognized that there are many variables and uncertainties in determining an individual's healthy salt intake. However, the FASEB report also raised concerns about salt consumption levels and concluded that:

“The evidence on sodium chloride is insufficient to determine that the adverse effects reported are not deleterious to the health of a significant proportion of the public when it is used at levels that are now current and in the manner now practiced.”

The FASEB report recommended the development of guidelines for restricting the amount of salt in processed foods and adequate labeling of the salt content of foods.

In the 1982 policy notice, FDA encouraged food manufacturers to reduce voluntarily the amount of added salt and other sodium-containing substances in processed foods and requested comment on this approach. FDA also announced its tentative decision to defer any revision in the regulatory status of salt until the agency could assess the impact in light of proposed sodium labeling regulations that would respond to health concerns about the levels of use of salt in the food supply. We discuss the proposed labeling regulations in section I.A.5 of this document.

In the 1982 policy notice, FDA described evidence that some uses of salt were granted sanction or approval prior to September 6, 1958, and therefore would be excluded from the definition of a food additive under section 201(s)(4) of the act (47 FR 26590). In part, this evidence relates to the inclusion

of salt as an ingredient in several food standards issued before September 6, 1958. We discuss food standards in section I.A.4 of this document.

#### 4. Food standards

Section 401 of the act (21 U.S.C. 341) gives FDA the authority to issue regulations fixing and establishing food standards, whenever it is the judgment of the Secretary of Health and Human Services that such action will promote honesty and fair dealing in the interest of consumers. Food standards are established to define the basic nature, and describe the essential characteristics, of a food consistent with consumer beliefs and expectations, and to establish its common or usual name. The process to amend existing standards requires either notice and comment rulemaking or formal rulemaking, depending on the specific standard.

Among other things, food standards establish the name of the food and the ingredients that are mandatory (i.e., required ingredients) or permitted (i.e., optional ingredients) in the manufacture of the food. Foods that are marketed under the standardized name must conform to all the requirements of the relevant standard(s) of identity. Conversely, foods that do not meet the requirements of the relevant standard(s) of identity cannot be marketed under the standardized name. Rather, such foods must be named using descriptors that accurately and adequately describe the food and that sufficiently distinguish it from the standardized food. Examples of foods subject to standards of identity include cheeses and related cheese products (part 133 (21 CFR part 133)); bakery products (part 136 (21 CFR part 136)); and cereal flours and related products (part 137 (21 CFR part 137)).

Salt is a required or optional ingredient in many standardized foods. For example, salt is a required ingredient in “self rising flour” (§ 137.180), “self

rising white corn meal,” (§ 137.270) and “cheddar cheese” (§ 133.113). In addition, salt is an optional ingredient in bakery products such as “bread, rolls and buns” (§ 136.110) and “dry curd cottage cheese” (§ 133.129). However, such standardized foods do not require a specific amount of salt and, thus, there is flexibility for food companies to lower salt concentrations by adjusting their formulations regarding the amount of salt added in the preparation of these standardized foods. The primary consideration for lowering salt concentrations in standardized foods where it is required is to ensure that the intended technical effect of the salt ingredient is accomplished.

The provisions in § 130.10 (21 CFR 130.10) allow standardized foods to deviate from certain requirements of a standard of identity to make the food eligible to bear a FDA-defined nutrient content claim. (A “nutrient content claim” (defined in section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A))) is a claim that characterizes the level of a nutrient in a food. We have established regulations implementing section 403(r)(1)(A) of the act with respect to nutrient content claims (§ 101.13 (21 CFR 101.13 and subpart D)).) Under § 130.10, the levels of sodium or salt in standardized foods can be altered to make the food eligible to bear a FDA-defined sodium- or salt-related claim such as “sodium free,” “low sodium,” “reduced sodium,” “salt free,” and “unsalted” (See § 101.61 (21 CFR 101.61)). For example, although the standard of identity for “self rising flour” in § 137.180 requires the addition of salt in the manufacture of a food named “self rising flour,” manufacturers may deviate from this requirement for the specific purpose of making the food eligible for the “unsalted” claim in accordance with the provisions of § 101.61(c)(2). Similarly, other standardized foods can be modified to eliminate or reduce the sodium content of the food to manufacture sodium-free or lower sodium

versions of the standardized food, such as “low sodium bread” or “salt free cottage cheese.”

## 5. Sodium Labeling

In 1984, as a followup to the 1982 policy notice, FDA established in § 101.13 definitions for terms related to sodium content, e.g., “sodium free,” “low sodium,” and “no added salt” and required that information about sodium be included with other nutritional information wherever it appears on food labels (49 FR 15510, April 18, 1984). FDA later revised and redesignated § 101.13 as nutrient content regulations at §§ 101.56 (21 CFR 101.56) (Nutrient content claims for “light” and “lite”) and 101.61 (Nutrient content claims for the sodium content of food) (58 FR 2302 at 2414 and 2417; January 6, 1993) in response to the Nutrition Labeling and Education Act of 1990 (NLEA). Section 101.61 addresses the use of terms such as “sodium free,” “low sodium,” “reduced sodium,” and “no added salt” (58 FR 2302 at 2417) and § 101.56 addresses the use of the terms “light” and “lite,” including the use of those terms in relation to sodium content (58 FR 2302 at 2414).

FDA also published a number of other labeling regulations in the January 6, 1993 **Federal Register** in response to NLEA, which bears on how sodium is declared on the label; namely, the agency’s revised nutrition labeling regulations that required nutrition labeling of sodium content on virtually all processed food products (§ 101.9(c)(4) (21 CFR 101.9(c)(4))) (58 FR 2079 at 2176) and established a reference value or “Daily Value” (DV) for sodium (§ 101.9(c)(9)) (58 FR 2206 at 2227), and the agency’s new regulation (§ 101.74 (21 CFR 101.74)) establishing a health claim regarding low sodium diets and reduced risk of hypertension (58 FR 2820). FDA subsequently established regulations (§ 101.65 (21 CFR 101.65)) requiring that foods labeled as “healthy”

contain less than specified amounts of certain food components, including sodium (59 FR 24232, May 10, 1994; amended at 70 FR 56828, September 29, 2005).

*B. CSPI's Prior Challenges to the GRAS Status of Salt*

In 1978, CSPI submitted a citizen petition requesting that FDA establish limits for sodium in processed foods and reclassify salt as a food additive. In a letter dated August 18, 1982 (Ref. 3), FDA denied the petition, stating that the agency had decided to leave salt in part 182. In 1984, CSPI sought review of FDA's actions in the United States District Court of the District of Columbia. (See *Center for Science in the Pub. Interest v. Novitch*, Food, Drug, and Cosm. L. Rep. (CCH) 38,275 (No. 83-801) (D.D.C. June 11, 1984)). CSPI argued that FDA's denial of its petition was arbitrary and capricious because it violated FDA's procedures for reviewing substances on the initial GRAS list. CSPI also argued that FDA's decision to defer any change to the GRAS status of salt constituted unreasonable delay in violation of the Administrative Procedures Act (5 U.S.C. 706(1)). The district court concluded that FDA's decision was consistent with its regulations and the act and rejected the argument that FDA had unreasonably delayed reconsideration of the GRAS status of salt. CSPI did not appeal.

In 2005, CSPI sought a writ of mandamus, in the United States Court of Appeals for the District of Columbia, compelling FDA to publish in the **Federal Register** a proposed rule either affirming or denying the GRAS status of salt and providing an opportunity for comment on the proposal. The court dismissed CSPI's petition for lack of jurisdiction, explaining that CSPI had not sought a remedy from FDA or initiated any proceeding in FDA before resorting

to the court. (See *In re Center for Science in the Public Interest*, 2005 U.S. App. (No. 05–1057) (D.C. Cir. 2005)).

*C. CSPI's Prior Citizen Petitions Regarding Label Requirements for Salt*

The 1978 CSPI citizen petition also requested that FDA require sodium content labeling on packaged foods and require a special symbol on the labels of high-sodium foods. FDA denied the petition in a letter dated August 18, 1982 (Ref. 3). In that denial letter, FDA considered that mandatory labeling for all processed foods was not justified and noted that the 1982 sodium labeling proposed rule would affect approximately one third of all processed food at that time. In addition, FDA considered a decision regarding special symbols for sodium-containing products to be premature because FDA was researching the utility of such symbols and vignettes.

In 1981, CSPI submitted a citizen petition requesting that FDA require warning labels on packages of salt weighing half an ounce or more. FDA denied that petition in a letter dated October 7, 1982 (Ref. 4). In that denial letter, FDA considered an isolated warning appearing on the label of one class of food products to be inappropriate given that many foods contribute to an individual's sodium intake.

*D. Citizen Petition Submitted by CSPI in 2005 (Docket No. 2005P–0450)*

In a citizen petition dated November 8, 2005, CSPI requested that the agency take certain regulatory actions regarding salt. Specifically, CSPI requested that FDA initiate rulemaking to revoke the GRAS status for salt, amend prior sanctions for the use of salt, require food manufacturers to reduce the amount of sodium in all processed foods, require a health message on retail packages of salt one-half ounce or larger, and reduce the DV for sodium from its current level of 2,400 mg/d to 1,500 mg/d. CSPI also requested that FDA

take regulatory action to reduce the amount of sodium in processed foods sold directly to restaurants, e.g., by regulating salt in precooked French fries that are purchased by restaurants who then add more salt.

In its petition, CSPI acknowledges that FDA has implemented several labeling requirements related to the sodium content of food through the NLEA as well as other labeling provisions, but asserts that these measures have not done enough to reduce sodium consumption.

CSPI summarizes several published clinical and population-based studies regarding the effect of sodium on blood pressure to support its view that the link between cardiovascular disease and excessive sodium intake has been clearly defined in the scientific community (Refs. 5 to 8). CSPI discusses the potential impact on public health of reductions in blood pressure, citing published estimates that reductions in blood pressure and resultant reductions in the incidence of hypertension would reduce the risk of stroke and heart disease significantly, resulting in fewer deaths from cardiovascular disease (Refs. 9 to 13).

CSPI provides a table summarizing estimates of the average consumption of sodium in time periods ranging from 1971-1974 to 1999-2000 and argues that these estimates show that per capita sodium consumption has increased from 2,800 mg/d in the years 1976-1980 to 3,400 mg/d in the years 1999-2000. (CSPI reports that it derived these estimates from dietary recall surveys conducted by the Centers for Disease Control and Prevention (i.e., the National Health and Nutrition Examination Surveys) and USDA (i.e., the Continuing Survey of Food Intakes of Individuals)). CSPI also cites a clinical study, based on urinary sodium excretion, estimating an average sodium intake of 4,000 mg/d in the United States (Ref. 14). CSPI compares these estimates to the current

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DV for sodium (i.e., 2,400 mg/d) and to recommendations in the Dietary Guidelines (Ref. 2) for the general population (i.e., no more than 2,300 mg/d) and for persons with hypertension, blacks, and middle-aged and older adults (i.e., no more than 1,500 mg/d). CSPI concludes that the available data demonstrate current intake of sodium is significantly higher than the intake recommended by governmental and scientific organizations around the world.

CSPI discusses the sources of sodium in the food supply, noting that some of the salt in the diet occurs naturally as an inherent component of foods, such as in milk. CSPI acknowledges that one reason for the increased consumption of sodium by the U.S. population in recent years is increased consumption of food in general. However, CSPI notes that the Dietary Guidelines estimate that 75 percent of the sodium in the diet is derived from processed foods. CSPI states that regulatory action to reduce the sodium content of the diet should therefore focus on these foods. CSPI discusses the feasibility of reducing salt levels in foods, stating that reductions can be made without adversely affecting public health or taste. CSPI also describes the activities of the British government's Food Standards Agency, which has introduced voluntary goals for the reduction of sodium in processed foods by food category (Ref. 15).

Based on the health effects of salt cited in its petition, CSPI asserts that salt should no longer be considered "safe." As a result, CSPI argues that salt should not be considered as a GRAS food ingredient and that prior sanctions for certain uses of salt should be revoked.

CSPI also asserts that FDA has authority to require its requested labeling under several provisions of the act and FDA's regulations in Title 21 of the Code of Federal Regulations. These include the misbranding provisions of section 403(a) of the act (together with the associated definition in section

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201(n) of the act and the associated regulation in 21 CFR 1.21) and the premarket approval provisions of section 409 of the act.

In August 2006, FDA issued a tentative response to CSPI's citizen petition, indicating the need for additional information before a final response could be rendered (Ref. 16).

## **II. Purpose and Scope of the Hearing**

The purpose of the hearing is for the agency to solicit comment, information and discussion from interested persons on the regulatory status of salt, and food labeling requirements regarding salt and sodium, particularly with respect to the feasibility and potential effectiveness of the regulatory actions requested in CSPI's citizen petition. FDA is aware that other organizations are in general agreement with some of the recommendations in CSPI's petition. For example, at the July 2006 annual meeting of the American Medical Association (AMA), the AMA announced recommendations, in the form of a report issued by the AMA's Council on Science and Health, to the agency echoing many of the regulatory actions suggested by CSPI (Ref. 17). The agency is very much interested in hearing the views of other interested parties, including the AMA.

The agency also is interested in discussions regarding other potential approaches for reducing salt intake. Because FDA has separate plans to issue an advanced notice of proposed rulemaking that would address DVs, including the DV for sodium (Ref. 18), comments regarding the DV for sodium are outside the scope of the public hearing announced in this document.

The scope of this hearing is determined by this notice. FDA invites general comments on the citizen petition (other than the requested actions regarding

DVs) as well as comments on the issues and questions listed in section III of this document.

### **III. Issues and Questions for Discussion**

The following issues and questions will be discussed at the public hearing:

*Issue 1:* FDA considered revoking the GRAS status of salt and declaring it to be a food additive in 1982, but rejected this approach for several reasons, including the following: (1) The agency would have to establish a limitation for each technical effect for which salt is used in each food category, and it would be extremely difficult to prescribe and enforce “fair use” limitations for salt that would be safe and effective for all consumers (including those hypertensive patients on severe sodium restrictions) given the fact that salt has numerous technical functions in a wide variety of processed foods and may often be used for several different technical effects in a single food and (2) many uses of salt are prior sanctioned and the agency would have to show that salt in food is a “poisonous or deleterious substance” for it to take regulatory action against a prior sanctioned ingredient. Failing to do this, the practical effect of regulating those remaining uses of salt not authorized by prior sanction might be quite small and the issuance and enforcement of limitations for uses of salt would therefore constitute an extraordinary regulatory burden for FDA. These facts and the uncertainty about the precise role of salt as a basic causative factor in essential hypertension left unclear whether the use of salt in a particular food would render that food uniformly injurious to health. Therefore, FDA concluded in 1982 that informative labeling would be more responsive to the health concerns about sodium (47 FR 26590). FDA is not aware of any fundamental changes to these considerations since it published the 1982 policy notice.

Question 1. Could a food additive regulation be constructed to prescribe limitations for uses of salt? If so, how might the regulation be constructed?

Question 2. Would reducing the salt content of food, even in a modest way, impact the safety or quality of various foods given the wide variety of technical functions for which salt is used in food? How feasible would it be to mitigate this impact if true? Could it be mitigated by, for example, the addition of other ingredients?

Question 3. If you agree with the underlying premise of CSPI's petition (i.e., that the sodium content of processed foods should be reduced), but disagree with one or more of the specific actions requested by CSPI, what other actions would you recommend?

Question 4. How could FDA partner with interested stakeholders regarding the development of appropriate recommendations or other information to reduce the salt content of processed foods?

*Issue 2:* Food labeling initiatives introduced by FDA during the last 25 years have been designed to provide consumers with more information about the sodium content of foods. For example, our regulations currently require declarative statements on the label about the sodium content of processed food (§ 101.9(c)(4)), define nutrient content claims for foods based on their salt content (§§ 101.61 and 101.56), provide for a health claim regarding low sodium diets and reduced risk of hypertension (§ 101.74), and stipulate maximum sodium concentrations for foods that are to be labeled as “healthy” (§ 101.65(d)(2)). In addition to the goal of providing information to consumers, these labeling initiatives are also intended to encourage food manufacturers to reduce the salt content of foods and to provide incentives to manufacturers to produce lower sodium foods. CSPI argues that these measures have not

ultimately served to reduce salt intake and that further, more aggressive regulatory action is needed.

Question 5. How would you describe the effectiveness of the following FDA regulations in reducing salt intake by the public? (1) Declaration of sodium content in the Nutrition Facts panel (§ 101.9(c)); (2) sodium content claims (§§ 101.61 and 101.56); health claims (§ 101.74); and (4) “healthy” claims (§ 101.65(d)(2))? How would you change these labeling requirements to make them more effective?

Question 6. What, if any, data, such as consumer studies, are available regarding the potential for label statements about the health effects of salt to reduce salt intake?

Question 7. To what extent could FDA’s labeling policies provide incentives to manufacturers to reduce the salt content of processed foods? For example, would there be an incentive to manufacturers to reduce the salt content of processed foods if FDA used enforcement discretion to permit a claim about a reduction in salt or sodium when that claim does not satisfy the criteria for a defined nutrient content claim? Would there be an incentive to manufacturers to reduce the salt content of processed foods if FDA encouraged the use of health messages to identify products with reduced salt? How would such incentives differ from the incentives provided by currently authorized label statements?

#### **IV. Notice of Hearing Under 21 CFR Part 15**

By delegation from the Commissioner of Food and Drugs (the Commissioner) (Staff Manual Guide 1410.21 paragraph 1.f.(5)), the Assistant Commissioner for Policy finds that it is in the public interest to permit persons to present information and views at a public hearing regarding the regulatory

framework for salt and sodium, particularly with respect to CSPI's petition to revise the regulatory status of salt and establish food labeling requirements regarding salt and sodium and is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The presiding officer will be the Commissioner or his designee. The presiding officer will be accompanied by a panel of FDA employees with relevant expertise.

Persons who wish to participate in the hearing (either by making a presentation or as a member of the audience) must file a notice of participation (see **DATES, ADDRESSES, FOR FURTHER INFORMATION CONTACT**, and section V of this document). By delegation from the Commissioner (Staff Manual Guide 1410.21 paragraph 1.f.(5)), the Assistant Commissioner for Policy has determined under § 15.20(c) that advance submissions of oral presentations are necessary for the panel to formulate useful questions to be posed at the hearing under § 15.30(e), and that the submission of a comprehensive outline or summary is an acceptable alternative to the submission of the full text of the oral presentation. For efficiency, we request that individuals and organizations with common interests consolidate their requests for oral presentation and request time for a joint presentation through a single representative. After reviewing the notices of participation and accompanying information, we will schedule each oral presentation and notify each participant of the time allotted to the presenter and the approximate time that the presentation is scheduled to begin. If time permits, we may allow interested persons who attend the hearing but did not submit a notice of participation in advance to make an oral presentation at the conclusion of the hearing. The hearing schedule will be available at the hearing.

After the hearing, the schedule and a list of participants will be placed on file in the Division of Dockets Management (see **ADDRESSES**) under the docket number listed in brackets in the heading of this notice.

To ensure timely handling of any mailed notices of participation, written material associated with presentations, or comments, any outer envelope should be clearly marked with the docket number listed in brackets in the heading of this notice along with the statement “Salt and Sodium; Petition to Revise the Regulatory Status of Salt and Establish Food Labeling Requirements Regarding Salt and Sodium; Public Hearing.”

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA’s policy and procedures for electronic media coverage of FDA’s public administrative proceedings (part 10 (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to the procedures and limitations in § 10.206, to videotape, film, or otherwise record FDA’s public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). For additional information about transcripts, see section VII in this document.

Any handicapped persons requiring special accommodations to attend the hearing should direct those needs to the appropriate contact person (see **FOR FURTHER INFORMATION CONTACT**).

To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a

waiver of these provisions as specified in §§ 10.19 and 15.30(h). In particular, § 15.21(a) states that the notice of hearing will provide persons an opportunity to file a written notice of participation with the Division of Dockets Management within a specified period of time. If the public interest requires, e.g., if a hearing is to be conducted within a short period of time, the notice may name a specific FDA employee and telephone number to whom an oral notice of participation may be given. If the public interest requires, the notice may also provide for submitting notices of participation at the time of the hearing. In this document, the conditions for the hearing specify that notices of participation be submitted electronically to an agency Web site, to a contact person who will accept notices of participation by mail, telephone, fax, or e-mail, or in person on the day of the hearing (as space permits). In addition, the conditions for the hearing specify that written material associated with an oral presentation be provided to a contact person who will accept it by mail, fax, or e-mail rather than to the Division of Dockets Management. We are using these procedures to facilitate the exchange of information between participants and the agency. By delegation from the Commissioner (Staff Manual Guide 1410.21 paragraph 1.f.(5)), the Assistant Commissioner for Policy finds under § 10.19 that no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with law if notices of participation are submitted by any of the procedures listed in this notice.

#### **V. How to Participate in the Hearing**

Registration by submission of a notice of participation is necessary to ensure participation and will be accepted on a first-come, first-served basis. Registration begins on October 22, 2007. The notice of participation may be submitted electronically, orally, or by fax, mail, or e-mail (see **ADDRESSES** and

**FOR FURTHER INFORMATION CONTACT**). We encourage you to submit your notice of participation electronically. A single copy of any notice of participation is sufficient.

The notice of participation must include your name, title, business affiliation (if applicable), address, telephone number, fax number (if available), and e-mail address (if available). If you wish to request an opportunity to make an oral presentation during the open public comment period of the hearing, your notice of participation also must include the title of your presentation, the sponsor of the oral presentation (e.g., the organization paying travel expenses or fees), if any; and the approximate amount of time requested for the presentation. Presentations will be limited to the questions and subject matter identified in section III of this document and, depending on the number of requests received, we may be obliged to limit the time allotted for each presentation (e.g., 5 minutes each).

Under § 15.20(c), if you request an opportunity to make an oral presentation you must submit your presentation (either as the full text of the presentation, or as a comprehensive outline or summary). You may submit your presentation by e-mail, fax, or mail. A single copy of your presentation is sufficient. See **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT** for information on where to send your presentation.

Persons who wish to request an opportunity to make an oral presentation must submit a notice of participation by November 8, 2007, and also must submit either the full text of the oral presentation, or a comprehensive outline or summary of the oral presentation, by November 21, 2007. All other persons wishing to attend the hearing must submit a notice of participation by November 21, 2007. Persons requiring special accommodations due to a

disability must submit a notice of participation by November 21, 2007, and should inform the contact person of their request (see **FOR FURTHER INFORMATION CONTACT**). Persons wishing to park onsite should inform the contact person of their request by November 26, 2007. Individuals who request an opportunity to make an oral presentation will be notified of the scheduled time for their presentation prior to the hearing.

We will also accept notices of participation onsite on a first-come, first served basis; however, space is limited and registration will be closed when the maximum seating capacity is reached. Requests for an opportunity to make a presentation from individuals or organizations that did not make such a request in advance may be granted if time permits.

Persons who submit a notice of participation in advance of the hearing should check in at the onsite registration desk between 8 a.m. and 9 a.m. Persons who wish to submit a notice of participation onsite on the day of the hearing may do so at the registration desk between 8 a.m. and 9 a.m. We encourage all participants to attend the entire hearing. Because the hearing will be held in a Federal building, hearing participants must present photo identification and plan adequate time to pass through the security system.

All submissions and comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided.

## **VI. Request for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments for consideration at or after the hearing in addition to, or in place of, a request for an opportunity to make an oral presentation (see section V of this document). Submit two paper copies

of any written comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## VII. Transcripts

Transcripts of the hearing will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at <http://www.fda.gov/ohrms/dockets> approximately 30 days after the hearing. You may place orders for copies of the transcript through the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, at a cost of 10 cents per page.

## VIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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3. Letter from Joseph P. Hile, Associate Commissioner for Regulatory Affairs, FDA to Michael F. Jacobson, August 18, 1982.

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13. Havas, S., Roccella E.J., Lenfant C., "Reducing the Public Health Burden From Elevated Blood Pressure Levels in the United States by Lowering Intake of Dietary Sodium," *American Journal of Public Health*, 94: 19–22, 2004.

14. Zhou, B.F., Stamler J., Dennis B., et al., “Nutrient Intakes of Middle-Aged Men and Women in China, Japan, United Kingdom, and United States in the Late 1990s: The INTERMAP Study,” *Journal of Human Hypertension*, 17:623–630, 2003.

15. “Salt in Processed Foods” Food Standards Authority (UK), 2005 (Available at <http://www.food.gov.uk/healthiereating/salt/saltmodel>, accessed and printed on June 21, 2007.)

16. Letter from Laura M. Tarantino, Director of the Office of Food Additive Safety, FDA, to Michael F. Jacobson, June 5, 2006.

17. American Medical Association, Report 10 of the Council on Science and Public Health (A-06), Promotion of Healthy Lifestyles I: Reducing the Population Burden of Cardiovascular Disease by Reducing Sodium Intake, Action of the AMA House of Delegates 2006 Annual Meeting, 2006.

18. Food and Drug Administration, Center for Food Safety and Applied Nutrition, CFSAN FY 2007 Report to Stakeholders, June 2007, available at <http://www.cfsan.fda.gov/~dms/cfsan607.html#fy07pp>.

Dated: 10/17/07  
October 17, 2007.

Jeffrey Shuren

Jeffrey Shuren,  
Assistant Commissioner for Policy.

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Dezette Rose