dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: Aug 31 2011.

Carolyn M. Cancy,

Director.

[FR Doc. 2011–23539 Filed 9–14–11; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0400]

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2011–0014]

Approaches to Reducing Sodium Consumption; Establishment of Dockets; Request for Comments, Data, and Information

AGENCY: Food and Drug Administration, HHS; Food Safety and Inspection Service, USDA.

ACTION: Notice; establishment of dockets; request for comments, data, and information.

SUMMARY: The Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) are announcing the establishment of dockets to obtain comments, data, and evidence relevant to the dietary intake of sodium as well as current and emerging approaches designed to promote sodium reduction. FDA and FSIS are particularly interested in research that will help both organizations understand current and emerging practices by industry in sodium reduction in foods; current consumer understanding of the role of sodium in hypertension and other chronic illnesses, sodium consumption practices; motivation and barriers in reducing sodium in their food intakes; and issues associated with the development of targets for sodium reduction in foods to promote reduction of excess sodium intake. Excess sodium intake is linked to increased risk of heart disease and stroke. FDA and FSIS recognize ongoing efforts by a number of members of the restaurant and packaged food industries to reduce sodium and appreciate the complexities of reducing sodium in foods. Continued input and support from industry and other stakeholders are important to support further progress on this significant public health issue.

DATES: Submit either electronic or written comments and data and information by November 29, 2011.

ADDRESSES: *FDA:* Submit electronic comments and data and information to *http://www.regulations.gov.* Submit written comments and data and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All submissions must include the Agency name and docket number FDA–2011–N–0400.

FSIS: Submit electronic comments and data and information to *http://www.regulations.gov.* Submit written comments and data and information to the Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, FSIS Docket Room, 1400 Independence Avenue, SW., Patriots Plaza 3, Mailstop 3782, Room 163A, Washington, DC 20250–3700. All submissions must include the Agency name and docket number FSIS–2011–0014.

FOR FURTHER INFORMATION CONTACT: *FDA:* Richard E. Bonnette, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1235.

FSIS: Rosalyn Murphy-Jenkins, Director, Labeling and Program Delivery Division, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, USDA, FSIS, OPPD, LPDD Stop Code 3784, Patriots Plaza III, 8–161A, 1400 Independence Avenue, SW., Washington, DC 20250–3700.

SUPPLEMENTARY INFORMATION:

I. Background

Research shows that excess sodium consumption is a contributory factor in the development of hypertension, which is a leading cause of heart disease and stroke (Ref. 1), the first and fourth leading causes of death in the United States, respectively (Ref. 2). Research also shows that the increase in blood pressure seen with aging, common to most Western countries, is not observed in populations that consume low sodium diets (Refs. 3 and 4) and that the U.S. population consumes far more sodium than recommended (Ref. 5 and 7). Moreover, dietary reduction of sodium can lower blood pressure as has been demonstrated in the Dietary Approaches to Stop Hypertension (DASH)-Sodium trial (Ref. 6). Because over three-quarters of sodium in the diet of the U.S. population is added during manufacturing of foods and preparation of restaurant foods, reduction in sodium consumption in the United States involves reduction in the sodium content of food in the U.S. marketplace (Refs. 5 and 7).

In this document, we refer primarily to ''sodium,'' a component of sodium chloride, commonly known as ''salt.'' Most but not all sodium is added to food in the form of salt and we are interested in all sources of sodium added to foods. The comments, data, and evidence regarding sodium reduction obtained by the establishment of these dockets will provide important information about current and emerging practices and approaches designed to reduce excess sodium intake, primarily coming from salt.

A. Sodium: Current and Recommended Intake

According to national food survey data from the ''What We Eat in America, National Health and Nutrition Examination Survey (NHANES) 2007–2008,'' estimated average sodium intake from foods among persons in the United States aged 2 years or older is approximately 3,300 milligrams per day (mg/d) (excluding salt added at the table) (Ref. 8). Most of this sodium comes from salt used in the manufacture or preparation of foods (Ref. 9). In 2005, the IOM set a Tolerable Upper Intake Level (UL) for sodium at 2,300 mg/d and an Adequate Intake (AI) at 1,500 mg/d for those 9 to 50 years of age, including pregnant and lactating women (AIs are lower for those 0–8 years of age and for those over 50 years of age) (Ref. 1). The 2010 Dietary Guidelines for Americans recommendations are to ''reduce daily sodium intake to less than 2,300 milligrams (mg) and further reduce intake to 1,500 mg among persons who are 51 and older and those of any age who are African American or have hypertension, diabetes, or chronic kidney disease.'' The 1,500 mg recommendation applies to about half of the U.S. population (Ref. 7). Current sodium intake is substantially higher

than what has been recommended by scientific and public health agencies and organizations in recent years. The Centers for Disease Control and Prevention (CDC) reported in 2010 that over 80 percent of adults (≥20 years) recommended to consume less than 2,300 mg/d of sodium in fact consumed more than 2,300 mg/d (Ref. 10).

The 2010 Dietary Guidelines for Americans also stated that ''Given the current U.S. marketplace and the resulting excessive high sodium intake, it is challenging to meet even the less than 2,300 mg recommendation'' and that a concerted effort is needed to reduce sodium in foods to help consumers meet the levels recommended (Ref. 7).

An analysis of the potential savings from reduced sodium consumption in the U.S. adult population found that reducing average dietary sodium intake to 2,300 mg/d among adults 18 years or older could have substantial health and financial benefits. Estimates showed potential reduction of 11 million hypertension cases and an annual savings of $18 billion health care costs (Ref. 11). Another assessment on the cost-effectiveness of reducing sodium intake found that an intervention achieving a reduction of 1,200 mg/d would save $10 to $24 billion in health care costs annually, comparable to benefits of population-wide reductions in tobacco use, obesity, and cholesterol levels (Ref. 12). Furthermore, this analysis found that a modest reduction over 10 years of about 400 mg sodium/d would be more cost-effective than using medications to lower blood pressure in all persons with hypertension (Ref. 12).

B. Public and Industry Initiatives to Reduce Sodium Intake

Since 1980, the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (HHS) have made recommendations in the Dietary Guidelines for Americans, including ''avoid too much sodium,'' ''use salt and sodium only in moderation,'' and ''choose and prepare foods with less salt'' (Refs. 7 and 13 through 17).

FDA has supported these recommendations with a variety of initiatives designed to promote informed choices on the part of consumers. In 1984, FDA required that information on sodium be included on the label whenever nutrition information appeared on food labels (49 FR 15510, April 18, 1984). In 1990, Congress enacted the Nutrition Labeling and Education Act (NLEA), which mandated nutrition labeling of food. In response to the NLEA, in 1993 FDA issued regulations requiring the declaration of sodium in absolute amounts and as a percentage of the Daily Value (58 FR 2206, January 6, 1993). FDA has also established standards for sodium-related nutrient content and health claims (*e.g.,* 21 CFR 101.13; 21 CFR 101.14; 21 CFR 101.61; 21 CFR 101.74). Furthermore, under section 403(q)(5)(H)(ii)(III) of the Federal Food, Drug, and Cosmetic Act, as amended by the Patient Protection and Affordable Care Act of 2010, certain restaurants and similar retail food establishments must provide, upon request, written nutrition information, which includes sodium content, for standard menu items. Additional efforts by FDA have included consumer education initiatives such as a joint sodium education initiative in 1981 with the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH) as part of the National High Blood Pressure Education Program (Ref. 18), and a November 29, 2007, public hearing concerning policies regarding salt and sodium in food (72 FR 59973, October 23, 2007). At the hearing, there was general agreement that the levels of sodium in food are too high, but there was no consensus regarding approaches for reducing the levels of sodium in food (Ref. 19).

FSIS, the agency responsible for nutrition labeling requirements for meat and poultry products, also coordinates and collaborates with FDA on nutrition labeling issues. In 1993, FSIS issued regulations establishing nutrition labeling requirements for meat and poultry products (9 CFR 317, part 381, subpart Y). These regulations, similar to FDA's nutrition labeling regulations, required the declaration of sodium in absolute amounts and as a percentage of the Daily Value on the labeling of nonexempted meat and poultry products. In December 2010, FSIS issued regulations to ensure nutrition labeling of the major cuts of single-ingredient, raw meat and poultry products on labels or at point-of-purchase, unless an exemption applies (75 FR 82148, December 29, 2010). These regulations also require nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies. Thus, these regulations increase the type of meat and poultry products that must declare sodium in absolute amounts and as a percentage of the Daily Value in their labeling.

Other U.S. public health agencies and organizations have also sought to inform consumers and encourage reduced sodium intake. In addition to conveying the benefits of reducing sodium related to hypertension through professional and consumer education activities, the NHLBI published guidelines recommending a sodium intake of no more than 2,400 mg/d dating back to 1993 (Refs. 20 through 26). More recently, the CDC has provided funding to various states and communities across the country in support of sodium reduction efforts to help create healthier food environments and reduce sodium intake by the population (Ref. 27). In addition, USDA, through the nutrition programs of the Center for Nutrition Policy and Promotion, promotes consumer messages related to sodium reductions via the interactive, web-based dietary assessment and weight management resources at ChooseMyPlate.gov, as well as through its MyPlate 2010 Dietary Guidelines for Americans consumer communications initiative and Consumer Brochure.

In 2008, the New York City Department of Health and Mental Hygiene initiated the National Sodium Reduction Initiative (NSRI), a partnership of 70 local and state health departments and health organizations, which has set targets to reduce sodium in restaurant and processed foods (Ref. 28). The goal of NSRI is to decrease average sodium intake by 20 percent over 5 years (2009 through 2014) by developing stepwise reductions from 2009 base levels to those desired by 2014. To-date, 28 companies have responded to NSRI, committing to reductions in the sodium content of some of their products.

These initiatives have been accompanied by efforts by industry, where a number of companies have played, and continue to play, a leadership role. Many food companies recognize that reduction of sodium in the American diet is an important public health issue. Some major food manufacturers have publicly committed to reducing the sodium content of their products over time. Certain companies have voluntarily identified specific product goals for sodium reduction. Many have demonstrated that substantial reductions in sodium can be achieved in certain food products and have established research programs to address key issues such as taste preference, technological advances, safety, and consumer acceptance in working through challenges and gaps in knowledge.

Other countries are also engaged in sodium reduction activities (Refs. 29 and 30).

C. Institute of Medicine of the National Academies—Report on Strategies To Reduce Sodium

In April 2010, the IOM released a report entitled ''Strategies to Reduce Sodium Intake in the United States.'' The report concluded that sodium intake, with the greatest contribution from salt, remains well above recommended levels despite several decades of education, labeling, and outreach efforts to reduce sodium consumption in the United States (Ref. 5). In the report, the committee considered past and current sodium reduction initiatives, consumer preference, the functional roles of sodium in food, research needs, regulatory options, and nutrition labeling in developing its recommendations. The IOM report acknowledged a number of complicating factors in reducing sodium in food. Although sodium primarily plays a role in altering taste, the IOM report noted that sodium chloride and other sodium-containing ingredients play a critical role in food safety by reducing the growth of pathogens thereby improving safety and shelf-life. In addition, these compounds provide functional and physical properties such as improving texture, controlling stickiness, and improving meltability. Among other things, the IOM report noted that more research is needed to develop and implement new technologies for sodium reduction and discussed the role of voluntary action by industry.

D. Sources and Function of Sodium in the Typical Diet

According to data presented to the IOM committee during the March 2009 public information gathering workshop (see Appendix L of the IOM Sodium Report), approximately 75 percent of the total sodium intake for most individuals is attributed to salt added as an ingredient or processing aid to processed and restaurant foods (Ref. 5). Sodium in the form of salt is added to food for many reasons. For example, salt functions as a seasoning agent and flavor-enhancer, a preservative and curing agent, a formulating and processing aid, and a dough conditioner (Ref. 5). Salt added at the table and in cooking provides only a small proportion of the total sodium that Americans consume (Ref. 9). A number of other sodium-containing ingredients contribute to sodium intake in lesser amounts (<1 percent) (Ref. 31). Some examples include sodium alginate, which alters viscosity; sodium phosphates, which bind liquid to reduce purge, in particular for solution-enhanced meat and poultry products; sodium sulfite, sodium nitrite, and sodium benzoate, which preserve food and inhibit microbial growth; and sodium lactate, diacetate, and acetate, which are dual purpose for flavoring and antimicrobial (pathogen reduction) purposes (Ref. 32). Non-sodium forms of these ingredients, which replace sodium with compounds such as potassium, calcium, and magnesium, are also available for some of these applications (Ref. 31).

According to the National Cancer Institute (NCI), individual and mixed foods contributing the highest proportion of sodium to the U.S. diet include yeast breads (250 mg/d), chicken and chicken mixed dishes (233 mg/d), pizza (217 mg/d), pasta and pasta dishes (174 mg/d), and cold cuts (155 mg/d) (Ref. 33). The CDC reported that close to 40 percent of daily sodium intake comes from grain-based products, such as breads, cakes, cookies, and crackers, and that almost 30 percent comes from processed meat products, such as bacon, sausage, lunch meat, poultry, and fish mixtures (Ref. 10). Sodium occurs naturally in nearly all foods; however this intrinsic sodium is not a significant dietary contributor for most Americans. Essentially, any single-ingredient food is low in sodium.

E. Sodium Reduction Opportunities

FDA and FSIS are considering potential ways to promote gradual, achievable and sustainable reduction of sodium intake over time. Research on a variety of issues, including the development of possible targets for the reduction of the sodium content of foods, is needed to assist FDA and FSIS in this effort. Sodium-containing food ingredients are used for multiple purposes at variable levels in diverse foods. The sodium intake of the U.S. population reflects both the sodium levels of individual foods and the amounts of foods consumed. As such, there are a variety of factors that may inform judgments about appropriate opportunities for sodium reduction. These factors include:

1. The important role that sodium has in food safety with respect to limiting microbial growth and maintaining the shelf-life of some foods;

2. The effect of sodium reduction on the physical attributes (*e.g.,* consistency, texture, shape, form) of some foods in ways that may impact consumer acceptance or food processing and manufacturing practices;

3. The feasibility, practicality, and cost of reducing sodium in various food categories;

4. The magnitude (time and percent sodium reduction) of any gradual or stepwise reduction effort;

5. The need to act gradually in a manner that is acceptable to consumers, while also achieving significant sodium reduction, because taste preference for sodium is acquired and can be modified (Refs. 34 and 35).

II. Establishment of a Docket and Request for Specific Input on Certain Topics

FDA and FSIS are establishing dockets to provide an opportunity for interested persons to submit comments, research, data, and other information that will better inform them about current and emerging practices by the private sector in sodium reduction; current consumer understanding of the role of sodium in hypertension and other chronic illnesses; sodium consumption practices; motivation and barriers in reducing sodium in their food intakes; and issues associated with the development of targets for sodium reduction in foods to promote reduction in excess sodium intake. In particular, both agencies welcome input on the following matters:

1. Comments and research related to recent sodium reduction initiatives by industry and the effects of those initiatives;

2. Comments and research related to consumer understanding of the role of sodium in hypertension and other chronic illnesses, sodium consumption practices, and motivation and barriers in reducing sodium in their food intakes;

3. Comments and research related to effective strategies for sustainable and meaningful reduction of sodium in foods sold in packaged or prepared form across the food supply, including and in particular foods with a high sales volume;

4. Comments and research related to existing or potential positive incentives for innovation in reformulating packaged and restaurant foods to reduce added sodium;

5. Comments and research related to the recommendations from the April 2010 IOM Sodium report on ''Strategies to Reduce Sodium Intake in the United States,'' including research related to information gaps identified in the IOM report (taste preferences for sodium, technological role of sodium/salt, role of food matrix, food safety, *etc.*);

6. Comments and research related to the following: (a) Methods for establishing sodium reduction targets, including information on general target design (*e.g.,* setting sodium reduction targets based on food categories, serving size, or formulations), (b) step-wise

approaches to achieve sustainable sodium reductions and timeframes for achieving such reductions, and (c) methods for evaluating the impact of a sodium reduction strategy;

7. Comments and research related to avoiding potential unintended consequences for food safety, nutrition (including effects on added sugars or solid fats), or food manufacturing technologies that could result from interventions to reduce sodium;

8. Comments and research related to existing voluntary sodium reduction efforts, including the voluntary sodium reduction targets set by the New York City-initiated NSRI partnership, and their applicability to a potentential federal sodium reduction initiative;

9. Comments and research related to food formulation, processing, production, and other technology that could lead to meaningful and sustainable reductions in the amount of sodium in food, including specific food categories, targets, and methods to monitor;

10. Comments and research on the role that food standards of identity play in promoting or limiting the feasibility of sodium reduction of foods (among other things, standards of identity for certain foods define the nature of those foods, generally in terms of how those foods are prepared, the types of ingredients that they must contain (*i.e.,* mandatory ingredients) and that they may contain (*i.e.,* optional ingredients), and how those foods must be labeled (Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341); the Federal Meat Inspection Act (21 U.S.C. 607(c)); and the Poultry Products Inspection Act (21 U.S.C. 457(b)));

11. Comments and research on any advantages of sodium to consumers, including but not limited to, food safety, nutrition, and palatability;

12. Comments and research on the economic impacts of reducing sodium, including but not limited to, the cost of food, agricultural production, small businesses, jobs, and the health care system;

13. Comments and research on the impact of sodium reduction initiatives on consumer food choices and compliance with 2010 Dietary Guidelines for Americans recommendations;

14. Comments and research related to how consumers respond to sodium reductions (*i.e.,* adding back salt to foods, consumption of reformulated products); and

15. Comments and research related to effective methods for communicating to the public the health benefits associated with the sodium intake levels recommended by the 2010 Dietary Guidelines for Americans.

We anticipate that some interested persons may wish to provide FDA and FSIS with certain comments, research, data, and information that they consider to be trade secret or confidential commercial information (CCI) that would be exempt under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552). You may claim information that you submit to FDA and FSIS as CCI or trade secret by clearly marking both the document and the specific information as ''confidential.'' Information so marked will not be disclosed except in accordance with the Freedom of Information Act (5 U.S.C. 552) and the specific agency's disclosure regulations (FDA's regulations under 21 CFR part 20; FSIS's regulations under 9 CFR part 390). For electronic submissions to *http://www.regulations.gov*, indicate in the ''comments'' box of the appropriate docket that your submission contains confidential information. You must also submit a copy of the comment that does not contain the information claimed as confidential for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice.

III. Public Meeting

A **Federal Register** notice will be published in the near future announcing a public meeting to discuss the topics set forth in this notice.

IV. Comments

FDA: Interested persons may submit to FDA's Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

FSIS: Interested persons may submit to FSIS's Docket Clerk (see **ADDRESSES**) either electronic or written comments regarding this document. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the FSIS Docket Room between 8:30 a.m. and 4:30 p.m., Monday through Friday.

Because two docket numbers are associated with this document, please include with your comments the docket number that corresponds with the appropriate agency. Comments submitted for inclusion in both dockets should be separately submitted to each identified docket number to ensure consideration.

V. References

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

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Dated: September 12, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy, Food and Drug Administration.

Dated: September 12, 2011.

Alfred V. Almanza,

Administrator, Food Safety and Inspection Service.

[FR Doc. 2011–23753 Filed 9–13–11; 11:15 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0163]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Guidance for Industry on Studies To Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Metabolism Study To Determine the Quantity and Identify the Nature of Residues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#205) entitled ''Guidance for Industry on Studies To Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Metabolism Study To Determine the Quantity and Identify the Nature of Residues (MRK),'' (VICH GL46). This guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document is intended to provide recommendations for internationally harmonized test procedures to study the quantity and nature of residues of veterinary drugs in food-producing animals.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Julia Oriani, Center for Veterinary Medicine (HFV–151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8204, *julia.oriani@fda.hhs.gov.*