restriction, the extension will be effective on September 29, 2005.

To assist us in our ongoing consideration of Section 404 of the Sarbanes-Oxley Act in the context of smaller public companies, we are including a list of questions below to solicit public comment on some substantive issues regarding the application of our internal control over financial reporting requirements to these companies. We also are soliciting public comment on the amount of time and expense that companies that are not accelerated filers have incurred to date to prepare for compliance with the internal control reporting requirements. These comments will assist us in any future proposals regarding our rules under Section 404. We would expect to provide formal notice and an additional opportunity for public comment on any such proposals.

In this regard, we note that the Advisory Committee recently also has solicited public input on a range of issues related to the current securities regulatory system for smaller companies, including the impact on smaller public companies of the internal control reporting requirements mandated by Section 404 of the Sarbanes-Oxley Act of 2002. In formulating any possible proposed revisions to the internal control reporting requirements that would affect smaller reporting companies, we intend to consider relevant recommendations made to the Commission by the Advisory Committee.

Request for Comment

- Should there be a different set of internal control over financial reporting requirements that applies to smaller companies than applies to larger companies? Would it be appropriate to apply a different set of substantive requirements to non-accelerated filers, or for management of non-accelerated filers to make a different kind of assessment? Why or why not? If you think that there should be a different set of requirements for companies that are not accelerated filers, what should those requirements be? What would be the impact of any such differences in the requirements on investors?
- Would a public float threshold that is higher or lower than the $75 million threshold that we use to distinguish accelerated filers from non-accelerated filers be more appropriate for this purpose? If so, what should the threshold be and why? Would it be better to use a test other than public float for this purpose, such as annual revenues, number of segments or number of locations or operations? If so, why?
- Should the independent auditor attestation requirements be different for smaller public companies? If so, how should the requirements differ?
- Should the same standard for auditing internal control over financial reporting apply to auditors of all public companies, or should there be different standards based on the size of the public company whose internal control is being audited? If the latter, how should the standards differ?
- How can we best assure that the costs of the internal control over financial reporting requirements imposed on smaller public companies are commensurate with the benefits?
- We solicit comment describing the actions that non-accelerated filers already have taken to prepare for compliance with the internal control over financial reporting requirements. Specific time and cost estimates would be particularly helpful. We also would be interested in receiving additional information about the compliance burdens incurred this year by smaller accelerated filers that included internal control reports in their Form 10–K annual reports.

Dated: September 22, 2005.

By the Commission.

Jonathan G. Katz,

Secretary.

[FR Doc. 05–19426 Filed 9–28–05; 8:45 am]

BILLING CODE 8010–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 1991N–0384H and 1996P–0500] (formerly 91N–384H and 96P–0500)

RIN 910–AC49

Food Labeling; Nutrient Content Claims, Definition of Sodium Levels for the Term ''Healthy''

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations concerning the maximum sodium levels permitted for foods that bear the implied nutrient content claim ''healthy.'' The agency is retaining the currently effective, less restrictive, ''first-tier'' sodium level requirements for all food categories, including individual foods (480 milligrams (mg)) and meals and main dishes (600 mg), and is dropping the ''second-tier'' (more restrictive) sodium level requirements for all food categories. Based on the comments received about technological barriers to reducing sodium in processed foods and poor sales of products that meet the second-tier sodium level, the agency has determined that requiring the more restrictive sodium levels would likely inhibit the development of new ''healthy'' food products and risk substantially eliminating existing ''healthy'' products from the marketplace. After reviewing the comments and evaluating the data from various sources, FDA has become convinced that retaining the higher first-tier sodium level requirements for all food products bearing the term ''healthy'' will encourage the manufacture of a greater number of products that are consistent with dietary guidelines for a variety of nutrients. The agency has also revised the regulatory text of the ''healthy'' regulation to clarify the scope and meaning of the regulation and to reformat the nutrient content requirements for ''healthy'' into a more readable set of tables, consistent with the Presidential Memorandum instructing that regulations be written in plain language.

DATES: This final rule is effective September 29, 2005.

FOR FURTHER INFORMATION CONTACT: Constance Henry, Center for Food Safety and Applied Nutrition (HFS–832), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 10, 1994 (59 FR 24232), FDA published a final rule amending § 101.65 (21 CFR 101.65) to define the term ''healthy'' as an implied nutrient content claim under section 403(r) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)). The 1994 final rule defined criteria for use of the implied nutrient content claim ''healthy'' and its derivatives (e.g., ''health'' and ''healthful'') on individual foods, including raw, single-ingredient seafood and game meat, and on meal and main dish products. It also established two separate timeframes in which different criteria for sodium content would be effective for foods bearing a ''healthy'' claim (i.e., before January 1, 1998, and after January 1, 1998).

According to the 1994 final rule, before January 1, 1998, individual foods

could bear the term ''healthy'' or a related term if the food contained no more than 480 mg of sodium (first-tier sodium level) per reference amount customarily consumed (RACC or reference amount), per labeled serving (LS) (serving size listed in the nutrition information panel of the packaged product), and if the reference amount was small (i.e., 30 grams (g) or less or 2 tablespoons or less), per 50 g (§ 101.65(d)(2)(ii)(A) and (d)(2)(ii)(B) and (d)(3)(ii)(A) and (d)(3)(ii)(B)). After January 1, 1998, an individual food could bear the term ''healthy'' or a related term if it contained 360 mg or less of sodium (second-tier sodium level) per reference amount, per labeled serving and per 50 g if the reference amount was small (§ 101.65(d)(2)(ii)(C) and (d)(3)(ii)(C)). The agency derived this 360 mg sodium level by applying a 25 percent reduction to the original sodium disclosure level of 480 mg for individual foods (59 FR 24232 at 24240).[1]

Similarly, before January 1, 1998, meal and main dish products could bear the term ''healthy'' or a related term if they contained no more than 600 mg of sodium (first-tier sodium level) per labeled serving (§ 101.65(d)(4)(ii)(A)), and after January 1, 1998, no more than 480 mg of sodium per labeled serving (second-tier sodium level) (§ 101.65(d)(4)(ii)(B)). The agency selected the 480 mg sodium level because it was low enough to assist consumers in meeting dietary goals, while simultaneously giving consumers who eat such foods the flexibility to consume other foods whose sodium content is not restricted; because there were many individual foods and meal-type products on the market that contained less than 600 mg of sodium; and because comments suggesting other levels did not provide supporting data (59 FR 24232 at 24240). Higher levels of sodium were rejected in the 1994 final rule (59 FR 24232 at 24239) because the agency determined that higher levels would not be useful to consumers wanting to use foods labeled as ''healthy'' to limit their sodium intake in order to achieve current dietary recommendations.

On December 13, 1996, FDA received a petition from ConAgra, Inc., (the petitioner) requesting that the agency amend § 101.65(d) to ''eliminate the sliding scale sodium requirement for foods labeled 'healthy' by eliminating the entire second tier levels of 360 mg sodium for individual foods and 480 mg sodium for meals and main dishes'' (FDA Docket No. 96P–0500/CP1, p. 3). As an alternative, the petitioner requested that the January 1, 1998, effective date for the second-tier sodium levels be delayed until such time as food technology ''catches up'' with FDA's goal of reducing the sodium content of foods and there is a better understanding of the relationship between sodium and hypertension.

FDA responded to ConAgra's petition in the **Federal Register** of April 1, 1997 (62 FR 15390), by announcing a partial stay of the second-tier sodium levels in § 101.65(d)(2)(ii)(C) and (d)(4)(ii)(B) until January 1, 2000. The stay was intended to allow time for FDA to reevaluate the second-tier sodium levels based on the data contained in the petition and any additional data that the agency might receive; to conduct any necessary rulemaking; and to give industry an opportunity to respond to the rule or to any changes in the rule that might result from the agency's reevaluation.

On December 30, 1997 (62 FR 67771), FDA published an advance notice of proposed rulemaking (ANPRM) announcing that it was considering whether to initiate rulemaking to reevaluate and possibly amend the implied nutrient content claims regulations pertaining to the use of the term ''healthy'' (the 1997 AMPRM).

In the **Federal Register** of March 16, 1999 (64 FR 12886), FDA published a final rule extending the partial stay of the second-tier sodium requirements in § 101.65 until January 1, 2003. The agency noted that it took this action to provide time for the following: (1) FDA to reevaluate the supporting and opposing information received in response to the ConAgra petition, (2) the agency to conduct any necessary rulemaking on the sodium limits for the term ''healthy,'' and (3) companies to respond to any changes that may result from agency rulemaking. On May 8, 2002 (67 FR 30795), FDA issued another final rule to extend the partial stay of the second tier sodium requirements in § 101.65 until January 1, 2006.

While the partial stay was pending, the U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (HHS) jointly published the ''Dietary Guidelines for Americans 2000'' (Ref. 1). This report provides recommendations for nutrition and dietary guidelines for the general public and suggests a diet with moderate sodium intake, not exceeding 2,400 mg per day. The health concerns relating to high salt intake are high blood pressure and loss of calcium from bones, which may lead to risk of osteoporosis and bone fractures (Ref. 1).

On February 20, 2003, FDA published a proposed rule (68 FR 8163) to amend the ''healthy'' regulation by retaining the current, less restrictive first-tier sodium level of 600 mg for meals and main dish products while permitting the more restrictive second-tier level of 360 mg for individual foods to take effect when the partial stay expired (the 2003 proposed rule). The agency also proposed to revise the regulatory text for the definition of ''healthy'' to clarify the scope and meaning of the regulation and to convert the nutrient content requirements for ''healthy'' to a more readable table-based format, consistent with the Presidential Memorandum instructing Federal agencies to use plain language.

II. Summary of the Final Rule

As proposed, this final rule amends the ''healthy'' definition in § 101.65(d) by eliminating the second-tier, more restrictive sodium requirement (480 mg) for meal and main dish products, which had been stayed until January 1, 2006. The final rule also eliminates the second-tier sodium requirement for individual foods instead of allowing it to go into effect on January 1, 2006, as proposed. Consequently, neither second-tier sodium requirement will take effect when the stay expires on January 1, 2006, and the sodium requirements for products labeled as ''healthy'' will remain at the current first-tier levels of 600 mg of sodium for meal and main dish products and 480 mg of sodium for individual food products. As proposed, the final rule also revises the regulatory text for the definition of ''healthy'' to clarify the scope and meaning of the regulation and to convert the nutrient content requirements for ''healthy'' to a more readable table-based format.

As discussed in section III of this document, this action is being taken as a result of comments from a variety of stakeholders urging FDA to eliminate the more restrictive sodium requirements for individual foods as well as for meal and main dish products. The comments documented substantial technical difficulties in

[1] Under § 101.13(h)(1) (21 CFR 101.13(h)(1)), individual foods bearing a nutrient content claim and containing more than 480 mg sodium per reference amount, per labeled serving or per 50 g (if the reference amount is small—i.e., 30 g or less or 2 tablespoons or less), must bear a label statement referring consumers to information about the amount of sodium in the food. Such disclosure statements are required when a food contains more than a certain amount of total fat, saturated fat, sodium, or cholesterol and that food bears a nutrient content claim. (See section 403(r)(2)(B) of the act.) The agency developed disclosure levels based on dietary guidelines, and taking into account the significance of the food in the total daily diet, based on daily reference values for total fat, saturated fat, cholesterol, and sodium (58 FR 2302 at 2307, January 6, 1993).

finding suitable alternatives for sodium and demonstrated the lack of consumer acceptance of certain ''healthy'' products made with salt substitutes and/or lower sodium. Comments from both industry and consumer advocates support the conclusion that implementing the second-tier sodium requirements would risk substantially eliminating existing ''healthy'' products from the marketplace because of unattainable nutrient requirements or undesirable and, thus, unmarketable flavor profiles. As a result of these comments, FDA has concluded that it can best serve the public health by continuing to permit products that meet the first-tier sodium level to be labeled as ''healthy,'' and thereby ensure the continued availability of foods that consumers can rely on to help them follow dietary guidelines not only for controlling sodium but also for limiting total fat, saturated fat, and cholesterol and consuming adequate amounts of important nutrients such as fiber, protein, and key vitamins and minerals.

III. Summary of Comments from the Proposed Rule

FDA received a total of 18 responses, each containing one or more comments, to the 2003 proposed rule. Of these comments, 5 were about topics other than the nutrient content claim ''healthy'' and are not considered here because they are outside the scope of this rulemaking. The remaining comments were from consumers, industry, a trade association, health and nutrition scientists and organizations, and consumer groups. The majority of the comments took the view that the more restrictive second-tier requirements for both the meal and main dish category and individual foods category should be revoked. The comments are discussed in detail in this section of the document.

To make it easier to identify comments and FDA's responses to the comments, the word ''Comment'' will appear in parentheses before the description of the comment, and the word ''Response'' will appear in parentheses before FDA's response. FDA has also numbered each comment to make it easier to identify a particular comment. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted.

A. Sodium and Hypertension

(Comment 1) Several comments agreed that there is a problem with high blood pressure in the United States, citing statistics showing that 40 million people in this country are hypertensive and that an additional 45 million people are prehypertensive. Most of these comments further agreed that excess sodium in the diet is a primary cause of the incidence of high blood pressure in the United States. Comments pointed out that for two decades the National Institutes of Health's (NIH) National Heart Lung and Blood Institute (NHLBI) has recommended that Americans cut back on their sodium consumption while eating a diet high in fruits and vegetables, low-fat dairy products and limited in saturated and total fat (the DASH diet). Some comments, including comments from a consumer advocacy group and health advocacy groups, stated that it was indisputable that reducing sodium would lower blood pressure.

One comment maintained that there was no evidence that restricting sodium consumption will result in improved cardiovascular health outcomes. This comment criticized FDA's reliance on studies examining the intermediate variables associated with salt intake, such as changes in blood pressure, maintaining that the agency should instead focus on whether restricting sodium consumption will result in improved cardiovascular health outcomes. According to this comment, none of the nine studies reported since 1995 that examined health outcomes associated with reduced dietary sodium showed a benefit to the general population in terms of health outcomes such as reduced incidence of heart attacks and strokes; in fact, some studies actually found a connection between low sodium diets and adverse health outcomes, i.e., a greater incidence of heart attacks. Another comment pointed out that too little sodium can actually be harmful, especially for people with low blood pressure and those living in hot climates. A few of the comments suggested that the NIH/NHLBI study ''Dietary Approaches to Stop Hypertension—Sodium,'' known as the DASH-Sodium study, should be examined more closely before the agency comes to any conclusion about the need to reduce sodium in foods.[2] As discussed in detail under comment 2 of this document, one comment questioned the accuracy and objectivity of this study, whose reported conclusions were that both hypertensive and nonhypertensive individuals can lower blood pressure by reducing dietary sodium.

Other comments expressed concern about the lack of scientific data to support changes in the sodium level for ''healthy,'' stating that the commenters were not aware of any studies showing improved health outcomes with reductions of 120 mg of sodium for individual foods. Another comment stated that the commenter was not aware of any scientific research since 1997 that increased concerns about the sodium content of foods or that showed a need for a 25 percent reduction in sodium to ensure consumer health. Still other comments suggested that before making its decision, the agency should await the outcome of the Institute of Medicine (IOM), National Academy of Science's (NAS) report on Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate (The Electrolyte Report) (Ref. 2), possible revisions of the Dietary Guidelines for Americans, 2000 and Food Guide Pyramid, as well as the DASH-Sodium study, in the hope that examination of the issue through these deliberative processes would shed more light on the matter.

(Response) The effects of sodium on blood pressure are well documented. The IOM has recently completed its in-depth evaluation of a variety of electrolytes and established dietary reference intakes (DRI's) for these nutrients. The other scientific studies and evaluations mentioned in comments (the DASH-Sodium study and revisions of the Dietary Guidelines for Americans, 2000 and Food Guide Pyramid) have also been completed. The IOM's most recent evaluation of the role of sodium is summed up in its 2004 report (The Electrolyte Report) (Ref. 2). The Summary section of the Sodium and Chloride chapter of the Electrolyte Report states in part:

> The major adverse effect of increased sodium chloride intake is elevated blood pressure, which has been shown to be an etiologically related risk factor for cardiovascular and renal diseases. On average, blood pressure rises progressively with increased sodium chloride intake. The dose-dependent rise in blood pressure appears to occur throughout the spectrum of sodium intake. However, the relationship is non-linear in that blood pressure response to changes in sodium intake is greater at sodium intakes below 2.3 g (100 mmol) per day than above this level. The strongest dose-response evidence comes from those clinical trials that specifically examined the effects of at least 3 levels of sodium intake on blood pressure. The range of sodium intake in these studies

[2] The primary objective of the DASH-Sodium trial was to test the effects of two dietary patterns (a control diet and the DASH diet) and three sodium intake levels on blood pressure in adult men and women with blood pressure higher than optimal or at stage 1 hypertension (systolic 120–159 (millimeters of mercury (mm Hg) and diastolic 80–95 mm Hg). The DASH diet is rich in fruits, vegetables, and low fat dairy products and reduced in saturated and total fat. Consequently, it is rich in potassium, magnesium, and calcium.

varied from 0.23 g (10 mmol) per day to 34.5 g (1,500 mmol) per day. Several trials included sodium intake levels close to 1.5 g (65 mmol) per day and 2.3 g/day (100 mmol/day).

While blood pressure, on average, rises with increased sodium intake, there is well recognized heterogeneity in the blood pressure response to changes in sodium chloride intake. Individuals with hypertension, diabetes, and chronic kidney diseases, as well as older-age persons and African Americans, tend to be more sensitive to the blood pressure raising effects of sodium chloride intake than their counterparts. Genetic factors also influence the blood pressure response to sodium chloride. There is considerable evidence that salt sensitivity is modifiable. The rise in blood pressure from increased sodium chloride intake is blunted in the setting of a diet high in potassium or that is low in fat, and rich in minerals; nonetheless, a dose-response relationship between sodium intake and blood pressure still persists. In non-hypertensive individuals, a reduced salt intake can decrease the risk of developing hypertension (typically defined as a systolic blood pressure ≥ 140 mm Hg or a diastolic blood pressure ≥ 90 mm Hg).

The adverse effects of higher levels of sodium intake on blood pressure provide the scientific rationale for setting the Tolerable Upper Intake Level (UL). Because the relationship between sodium intake and blood pressure is progressive and continuous without an apparent threshold, it is difficult to precisely set a UL, especially because other environmental factors (weight, exercise, potassium intake, dietary pattern and alcohol intake) and genetic factors also affect blood pressure. For adults, a UL of 2.3 g (100 mmol) per day is set. In dose-response trials, this level was commonly the next level above the AI [Adequate Intake] that was tested. It should be noted that the UL is not a recommended intake and, as with other ULs, there is no benefit to consuming levels above the AI. Among certain groups of individuals who are most sensitive to the blood pressure effects of increased sodium intake (e.g., older persons, African Americans, and individuals with hypertension, diabetes, or chronic kidney disease), their UL may well be lower. These groups also experience an especially high incidence of blood pressure-related cardiovascular disease. * * *

It is well-recognized that the current intake of sodium for most individuals in the United States and Canada greatly exceeds both the AI and UL.

(The Electrolyte Report, pp. 270–272 (footnote omitted).)

The IOM also looked at cardiovascular disease and high blood pressure. Page 323 of the Electrolyte Report states that ''[d]ata from numerous observational studies provide persuasive evidence of the direct relationship between blood pressure and cardiovascular disease,'' citing a recent meta-analysis (Lewington et al., 2002) of 60 prospective observational studies with almost 1 million enrolled adults. Individuals with preexisting vascular disease were excluded. With 12.7 million person years of followup and the total number of deaths at 122,716, about half of the deaths in these studies occurred as a result of cardiovascular disease (11,960 deaths from stroke, 34,283 from ischemic heart disease, and 10,092 deaths from other vascular causes). The IOM further commented (pp. 324–325):

[S]troke mortality progressively increased with systolic blood pressure * * * and diastolic blood pressure * * * in each decade of life. Similar patterns were evident for mortality from ischemic heart disease and from other vascular diseases. In analyses that involved time-dependent correction for regression-dilution bias, there were strong, direct relationships between blood pressure and each type of vascular mortality. Importantly, there was no evidence of a blood pressure threshold—that is, vascular mortality increased throughout the range of blood pressures, in both non-hypertensive and hypertensive individuals.

The IOM also looked at the effects of reduced sodium intake on blood pressure using evidence from intervention studies in both nonhypertensive and hypertensive individuals (page 329). Although the studies differed in size (<10 to > 500 persons), duration (range 3 days to 3 years), extent of sodium reductions, background diet (e.g., intake of potassium), study quality and documentation, the studies provided relatively consistent evidence that a reduced intake of sodium lowers blood pressure in both hypertensive and nonhypertensive adults. In these intervention trials, the extent of blood pressure reduction from a lower intake of sodium in hypertensive participants was more pronounced than that observed in nonhypertensive participants. (See The Electrolyte Report, Tables 6–12 and 6–13.)

The NIH/NHLBI DASH-Sodium study tested the effects of two dietary patterns (a control diet and the DASH diet described previously) and three sodium intake levels on blood pressure in adult men and women with blood pressure higher than optimal or at stage 1 hypertension. The overall blood pressure range for the study was systolic 120–159 mm Hg and diastolic 80–95 mm Hg. The reported conclusions of the DASH-Sodium study were that both hypertensive and nonhypertensive individuals can lower blood pressure by reducing dietary sodium. These conclusions were generally consistent with those of the other intervention studies, showing a connection between reduced sodium intake and lowered blood pressure in both hypertensive and nonhypertensive subjects, with a greater effect observed in the hypertensive subjects.

The IOM considered the DASH-Sodium trial in the Electrolyte Report, which describes the results of the subgroup analysis as follows:

On the control diet, significant blood pressure reduction was evident in each subgroup. Reduced sodium intake led to greater systolic blood pressure reduction in individuals with hypertension compared with those classified as non-hypertensive, African Americans compared with non-African Americans, and older individuals (> 45 years old compared with those ≤ 45 years old). On the DASH diet, a qualitatively similar pattern was evident; however, some sub-group analyses did not achieve statistical significance, perhaps as a result of small sample size. Comparing the combined effect of the DASH diet with lower sodium with the control diet with higher sodium, the DASH diet with lower sodium reduced systolic blood pressure by 7.1 mm HG in non-hypertensive persons and by 11.5 mm Hg in individuals with hypertension.

(The Electrolyte Report, p. 347.)

The DASH-Sodium study and the other studies summarized in The Electrolyte Report, as evaluated by the IOM, demonstrate that the intake of excess sodium in the diet is indeed a public health issue. FDA further agrees with the IOM's recommendations for addressing this issue:

It is well-recognized that the current intake of sodium for most individuals in the United States and Canada greatly exceeds both the AI and the Tolerable Upper Intake Level (UL). Progress in achieving a reduced sodium intake will be challenging and will likely be incremental. Changes in individual behavior towards salt consumption will be required as will replacement of higher salt foods with lower salt versions. This will require increased collaboration of the food industry with public health officials, and a broad spectrum of additional research. The latter includes research designed to develop reduced sodium food products that maintain flavor, texture, consumer acceptability, and low cost. Such efforts will require the collaboration of food scientists, food manufacturers, behavioral scientists, and public health officials.

(The Electrolyte Report, pp. 395–396.)

Consequently, the agency continues to believe that individuals should be encouraged to reduce the amount of sodium in their diets and that manufacturers should be encouraged to produce sodium controlled products which are palatable and otherwise acceptable to consumers.

Further, the recently published ''Dietary Guidelines for Americans 2005'' (Ref. 3), recommends that individuals consume less than 2,300 mg (approximately 1 teaspoon (tsp) of salt) of sodium per day. This is a decrease of 100 mg from FDA's sodium Daily Value of 2,400 mg (§ 109.9(c)(9) (21 CFR

101.9(c)(9)))) which was cited in the 2000 Dietary Guidelines.

The new USDA pyramid (*http://www.mypyramid.gov*) (Ref. 4) encourages consumers to use the Nutrition Facts label to determine the amount of sodium in processed foods, particularly meats and canned vegetables, and to keep sodium consumption below 2,300 mg per day by looking for lower sodium foods. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

(Comment 2) One comment argued that FDA should delay consideration of the 2003 proposed rule until the NHLBI of NIH responds to a joint request for correction filed by the Salt Institute and the U.S. Chamber of Commerce under the Information Quality Act (IQA) (Public Law 106–554, H.R. 5658, § 515, 114 Stat. 2763, 2763A–153 to -154 (2000)), and NIH Information Quality Guidelines, *http://aspe.hhs.gov/infoquality/Guidelines/NIHinfo2.shtml*. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) This comment questioned the accuracy and objectivity of NHLBI's conclusion, based on the DASH-Sodium study, that all segments of the population can lower their blood pressure by reducing sodium intake. The comment argued that because not all of the data from the DASH-Sodium study were made available for review by interested parties and therefore could not be evaluated and validated by others, FDA should defer consideration of the study until the data are released and any necessary reexamination of NHLBI's conclusions about sodium intake and blood pressure has been accomplished. A second comment similarly argued that FDA should not consider the DASH-Sodium study or any other studies ''until such time that they are in accord with the [IQA].''

(Response) Under the IQA, affected persons must be afforded an administrative mechanism through which they may seek and obtain correction of information disseminated by Federal agencies (Public Law 106–554, H.R. 5658, § 515(b)(1)(B)). The joint Salt Institute—Chamber of Commerce request for correction asked NIH to make publicly available the DASH-Sodium data for all study subgroups, but did not ask NIH to withdraw or correct any of its public statements recommending that consumers reduce sodium intake to lower blood pressure, which relied on the DASH-Sodium data. At the time the comments were filed, NIH had not yet responded to the joint IQA request for correction. NIH denied the request by letter on August 19, 2003 (Ref. 5). See *http://aspe.hhs.gov/infoquality/request&response/reply_8b.shtml*. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) The NIH response informed the requesters that the appropriate mechanism to request access to data produced in grant-funded research such as the DASH-Sodium study is a request for government records under the Freedom of Information Act rather than a request for correction under the IQA; however, the response also stated that NHLBI's public statements about sodium intake and blood pressure satisfied NIH's information quality standards, pointing out that both the DASH-Sodium study itself and NHLBI's public statements based on it had been subjected to thorough multiple rounds of review, including peer review, and that the DASH-Sodium study was only one piece of evidence in a substantial, cumulative body of evidence that shows a clear causal relationship between sodium intake and blood pressure.

The Salt Institute and Chamber of Commerce requested reconsideration of the request for correction. NIH's response (Ref. 6) (see *http://aspe.hhs.gov/infoquality/request&response/8d.shtml*) affirmed the denial of the original request and gave additional reasons why NHLBI's public statements about sodium intake and blood pressure complied with the NIH Information Quality Guidelines. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) The Salt Institute and Chamber of Commerce then sued NIH in the U.S. District Court for the Eastern District of Virginia, alleging that NIH had violated the IQA by failing to disclose the data and methods underlying the DASH-Sodium study. The court dismissed the case, ruling that an agency response to a request for correction under the IQA is not subject to judicial review. (*Salt Institute* v. *Thompson*, 345 F. Supp.2d 589 (E.D. Va. 2004), appeal docketed, No. 05–1097 (4th Cir. Jan. 25, 2005).) Although an appeal of that ruling is pending, FDA does not believe that further delay in issuing a final rule is justified by the pendency of this appeal.

FDA is relying on a large and well-established body of evidence about sodium and hypertension summarized in The Electrolyte Report, not solely on the DASH-Sodium study or NHLBI's conclusions about that study expressed in its public statements. Further, as discussed in response to comment 1 of this document, the IOM's conclusions about the DASH-Sodium study data are consistent with those of NHLBI. For the reasons discussed in NHLBI's responses to the IQA request for correction and request for reconsideration (Refs. 5 and 6), FDA is satisfied that the data that were the subject of the IQA request for correction submitted to NHLBI, as well as the other data on sodium and blood pressure considered in this rulemaking, are objective and reliable.

B. Public Health Goals

(Comment 3) Comments said that the ''healthy'' claim should be used to promote development of foods that are indeed more healthful and to encourage consumers to eat such foods. A number of comments cited the Secretary of Health and Human Services' statement that food companies should be encouraged and rewarded for creating healthy products. They also said that FDA should develop criteria that would allow for a sufficient number and variety of ''healthy'' products yet would be stringent enough for these products to fit within dietary guidelines.

Many comments expressed concern that making the requirements for use of the term ''healthy'' too stringent will run counter to public health goals. These comments contended that the lower (second-tier) sodium levels will decrease the incentive to develop healthy foods because fewer foods will be able to meet these levels and still be palatable. They argued that products that can currently meet the ''healthy'' first-tier criteria for sodium are better nutritionally than products that do not bear the ''healthy'' claim and are therefore not required to meet any of the various nutrient requirements for ''healthy''. Consequently, the comments said, it is better overall to allow the currently marketed ''healthy'' products with slightly higher sodium content to continue to bear the term ''healthy'' than to implement the more restrictive sodium requirement and risk losing these nutrient controlled products altogether. Comments argued that if consumers are disinclined to eat ''healthy'' foods at the current first-tier sodium levels, they will be even less likely to eat similar foods at the lower sodium levels, thus eliminating many ''good-for-you'' products. However, another comment argued in favor of implementing the second-tier levels, stating that food manufacturers did not reformulate their products to reduce

levels of other nutrients whose consumption should be controlled until nutrient content claim regulations forced industry to lower the levels to use such claims.

Several comments argued that, instead of focusing narrowly on reducing the sodium content of foods with ''healthy'' claims, the agency should direct its efforts toward higher-impact public health measures such as reducing the overall level of sodium in the food supply and fighting obesity. Several comments pointed out that the Surgeon General has targeted obesity and educating people about eating a balanced diet as current U.S. health goals. They said that focusing limited resources on lowering sodium levels in foods labeled as ''healthy'' appears to be out of touch with these goals. These comments suggested that the best way to combat high blood pressure is by offering a reasonable level and balance of all nutrients in foods that tempt the palate. Implementing the second-tier sodium levels, they said, will do the opposite.

(Response) The agency agrees with the comments that it is important that consumers be encouraged to consume foods that will help them achieve a healthy diet. The agency views the ''healthy'' claim as a valuable signal that a food that bears the claim is consistent with dietary guidelines in that it meets a very strict set of nutrient requirements. Such a food must be low in fat and saturated fat (or extra lean), have limited amounts of cholesterol and sodium, but contain a sufficient amount (10 percent of the Daily Value) of at least one of several desirable nutrients. The agency believes that it is important to keep the term ''healthy'' as a viable tool to signal these desirable nutrient characteristics.

The intent of the two-tiered sodium levels established by the 1994 final rule was to encourage industry to be innovative and further lower sodium levels in foods bearing the term ''healthy''. However, based on comments and other data that have become available since 1994, FDA is concerned that this goal will not be realized and that implementing the second-tier sodium level requirements for the ''healthy'' claim could in fact result in a smaller selection of nutritionally desirable foods on the market. The agency agrees with the majority of comments that lowering the amount of sodium in ''healthy'' foods to the second-tier levels would run counter to public health goals if it discouraged manufacturers from producing ''healthy'' foods and consumers from eating them.

With regard to the comments that expressed concern about whether the problem of obesity in the United States is being effectively addressed, FDA and its parent agency, HHS, are actively working to confront this public health problem. FDA's plan of action for tackling obesity, which encompasses consumer education, rulemaking to make food labels more useful for people who are trying to lose weight, enforcement against products with misleading serving sizes or unsubstantiated weight loss claims, and research and education partnerships with other government agencies and organizations, is described in ''Calories Count: Report of the Working Group on Obesity'' March 12, 2004 (Ref. 7) (*http://www.cfsan.fda.gov/~dms/owg-toc.html*).

C. Consumer Understanding

(Comment 4) Several comments expressed confusion about the current regulations for the term ''healthy''. A couple of comments stated that consumers and food manufacturers do not understand the requirements for using the ''healthy'' claim in food labeling. Comments suggested that food labeling can mislead consumers and FDA about the nutritional value of food and asked FDA to address this problem. One comment from a consumer remarked that the term ''healthy'' is abused, misused, and misunderstood on all sides and that there should be a well publicized chart showing which foods qualify for the term. This comment added that manufacturers believe that only fat and cholesterol content are pertinent criteria; this comment questioned whether many ''healthy'' products actually meet all the ''healthy'' criteria.

(Response) FDA's nutritional criteria for foods that bear a nutrient content claim ensure that such foods are consistent with the dietary guidelines regarding the nutrient that is the subject of the claim. Because ''healthy'' is an implied nutrient content claim (versus an explicit nutrient content claim such as ''low fat''), the desirable nutrient characteristics of a food bearing this claim are less apparent to consumers. Nevertheless, the agency believes that the nutrient content claim ''healthy'' does send a clear message to the consumer that the food is consistent with dietary guidelines and can be used as part of a healthy diet. The definition for ''healthy'' as well as other nutrient content claims can be easily found on the FDA Web site by searching on the word ''definition'' preceded by the word ''nutrient'' or the term(s) used in the claim. In response to the comment asking FDA to publicize the requirements for ''healthy'' claims, the agency has added a direct link to the ''healthy'' definition, which may be accessed by clicking on ''healthy'' in the drop down ''Select a Topic-Labeling'' menu on the Food Labeling and Nutrition page of the FDA Center for Food Safety and Applied Nutrition (CFSAN) Web site (*http://www.cfsan.fda.gov/label.html*). Finally, the agency has done considerable nutrition outreach, including outreach about requirements for the ''healthy'' claim and various other nutrient content claims.

The agency does not agree that manufacturers are unaware of the definition of the ''healthy'' claim, as the definitions of this and other nutrient content claims are readily available to industry, and manufacturers are required to know the laws and regulations that apply to products they market. As with any nutrient content claim, any food labeled as ''healthy'' that deviates from the requirements in the regulation defining that term (§ 101.65(d)) is subject to enforcement proceedings under the act.

D. Role of Salt in Manufacturing

(Comment 5) Many comments, particularly from industry, emphasized salt's importance as a food ingredient. They stated that salt is essential for developing taste, and sometimes also for texture and microbiological stability. The comments said that no single substitute for the technical functions of salt was likely to be available soon. One comment explained that the tongue only recognizes sodium chloride (NaCl) as salty and that this makes creating palatable lower sodium versions of products difficult. An industry comment identified a number of manufacturing and technical issues with lowering the amount of salt in a product to the second-tier level. This comment said that hot dogs fall apart, processed meats have reduced microbial protection and lose their characteristic texture, and consumers will not eat certain products with sodium less than 360 mg because the products do not taste good or do not taste as expected. Several comments argued that because consumers will not buy products that meet the second-tier sodium levels, companies will have to discontinue their ''healthy'' products if the second-tier sodium levels go into effect. As discussed in the response to comment 11 of this document, some comments submitted data to support this argument. One comment stated that FDA recognized that the second-tier levels may be overly restrictive in

soliciting comments in the 1997 ANPRM about the technological feasibility of reducing sodium and on consumer acceptance of products with reduced sodium.

(Response) The agency acknowledges manufacturers' concerns about the technical importance of salt. The agency had anticipated that phasing in the lower second-tier sodium level requirement for the term ''healthy'' would allow the food industry time to develop technically and commercially viable alternatives to salt. Although it is unfortunate that no viable alternative has been found, FDA understands the manufacturing difficulties that are presented by the absence of a suitable substitute for salt and has taken them into consideration in deciding how to regulate the sodium content of foods bearing the ''healthy'' claim.

E. Number of ''Healthy'' Products on the Market

(Comment 6) A comment contended that the agency had miscounted the number of products with a ''healthy'' claim in the 2003 proposed rule. The comment asserted that in estimating that there were over 800 products bearing a ''healthy'' claim, the agency had erroneously counted certain products in the Food Labeling and Package Survey (FLAPS) data. Examples cited in the comment included products like chewing gum and sugar substitutes that used the term ''health'' in ingredient warnings, such as warnings that saccharin and phenylalanine are bad for your health; products that did not use the term ''healthy'' as a nutrient content claim; and products that used the ''healthy'' claim illegally. The comment also criticized FDA for using 1999 Information Resources, Inc. (IRI) data[3] as a basis for the proposed rule's estimate of the number of ''healthy'' products on the market, and provided the agency with updated 2003 IRI data.

(Response) The comment is incorrect in suggesting that FDA's estimate that over 800 products bore a healthy claim was derived primarily from examination of the FLAPS data. In deriving this number, the agency looked first to the IRI data, which indicated that at the time the data were collected there were over 800 products bearing a ''healthy'' brand name (Ref. 8). Because the IRI data represented only a sampling of the marketplace and captured only ''healthy'' claims that were part of the product's brand name, the agency then used the FLAPS data to evaluate whether there were additional ''healthy'' claims in the marketplace.

FLAPS is an FDA survey which essentially provides a ''snapshot'' of marketed products. The survey involves purchasing representative products and examining them for a variety of label statements that are recorded in a database. In developing the 2003 proposed rule, FDA examined this database to determine the regulatory classification of label statements from this sample. One example of an additional ''healthy'' claim identified using the FLAPS survey is ''Apple sauce is a delicious and healthy fruit product which contains no fat, very low sodium, and no cholesterol.'' This ''healthy'' claim would not have been captured by the IRI data because it is not part of a brand name. On the basis of this and other claims identified in FDA's analysis of the data collected in the FLAPS survey, the agency concluded that ''it is likely that the number of 'healthy' individual foods included in the 1999 market place analysis [using only IRI data] underestimates the number of individual food products bearing 'healthy' claims'' (68 FR 8163 at 8166). Thus, rather than using the FLAPS data to augment its numerical estimate of products bearing a ''healthy'' claim as the comment assumed, FDA used these data only to support its assertion that the numerical estimate generated from the IRI data by counting the products with ''healthy'' claims in their brand names had likely underestimated the number of products bearing a ''healthy'' nutrient content claim somewhere in their labeling.

The comment's criticism of FDA's estimate also reflects a misunderstanding of which products identified in the FLAPS survey were counted as bearing a ''healthy'' claim. The examples of illegitimate ''healthy'' claims cited in the comment appear to have come from attachment B of reference 4 of the 2003 proposed rule. Reference 4 of the 2003 proposed rule (Ref. 9) is a 2001 cover memorandum entitled ''1997 Food Labeling and Package Survey (FLAPS) Product Label Evaluation for 'Healthy' Claims''. Attachment B is a list of all label statements identified in the 1997 FLAPS survey that included the word ''healthy'' or a variant (e.g., ''health'' or ''healthful''). Contrary to the comment's assumption, however, this list is not the list of FLAPS products that FDA counted as bearing a ''healthy'' claim. Compiling this list was only a preliminary step in FDA's marketplace data analysis. When the proposal was being developed, each statement in this list was carefully examined to determine whether or not it was in fact a ''healthy'' claim.

The agency agrees with the comment that label statements about the health effects of phenylketonurics and saccharin are not ''healthy'' claims and that products with such statements should not be counted as products with a ''healthy'' claim. It also agrees that statements in labeling such as ''eat healthy, eat well'' should not be counted as ''healthy'' claims because they do not imply that the food has levels of nutrients that meet the ''healthy'' definition. Rather, such statements provide dietary guidance to consumers or make general statements about health and diet. A careful reading of the 2001 cover memorandum (Ref. 9) demonstrates that FDA recognized during the development of the 2003 proposed rule that the statements listed in Attachment B were not all ''healthy'' claims:

> Some of the statements are dietary guidance statements (e.g., ''Eat 5 servings of fruits and vegetables every day for better health'') or hazard warnings (e.g., ''Phenylketonurics: Contains phenylalanine. Use of this product may be hazardous to your health.''), neither of which are implied nutrient content claims for ''healthy.''

The comment is correct that the 2003 proposed rule did not use the most recent IRI data on the number of ''healthy'' individual foods in the marketplace; however, the 2003 IRI data submitted with the comment only reinforce FDA's ultimate conclusions about the downward trend in the number of such products. Due to budget constraints, the 1999 IRI data were the most recent available to FDA at the time the 2003 proposed rule was being developed. The 2003 proposed rule specifically asked for additional marketplace data, and the agency received the more recent data provided by the comment that further support the difficulty of making and marketing products which may be labeled as ''healthy.'' As discussed in section III.F.3 of this document, the agency has taken these data into consideration in deciding how to regulate the sodium

[3] The IRI InfoScan database contains dollar sales information for food and dietary supplement products. InfoScan includes information collected weekly from a selected group of grocery, drug, and mass merchandiser stores across the continental United States with annual sales of $2 million and above (sample store data)—more than 32,000 retail establishments. The retail stores are statistically selected and meet IRI's quality standards. The database contains sales data for all products in these retail stores that are scanned (i.e., sold) at checkout. IRI applies projection factors to the sample store data to estimate total sales in the continental United States from stores that have annual sales of $2 million and above. The database does not include data from stores with annual sales of less than $2 million. The database provides information by brand name only and cannot be used to determine the number of products with claims outside the brand name.

content of foods bearing the ''healthy'' claim.

Further, FDA's analysis of the IRI and FLAPS marketplace data was intended to provide only an estimate of the number of ''healthy'' products, not an exact count. It would be extremely difficult, if not impossible, to get an accurate count of the exact number of products that bear and qualify for the ''healthy'' claim. Obtaining an accurate count would involve examining all panels of the labels of all FDA-regulated food products, including those that use ''healthy'' as part of their brand name, to determine whether the label bore the term ''healthy'' as a nutrient content claim. Once products bearing the ''healthy'' claim were identified, the person responsible for the count would have to check the nutrition facts panel to determine if the product met the requirements for this claim. Even then, without a laboratory analysis of the product, it would be impossible to determine conclusively whether the product actually complied with the definition of ''healthy.'' Thus, getting an exact count of products legitimately labeled with the ''healthy'' claim would be an extremely burdensome and resource-intensive task. In light of the need to move forward with the 2003 proposed rule and other regulatory priorities, the agency was justified in using its available resources to make an estimate, rather than an exact count, of the number of products bearing the claim ''healthy.''

F. Sodium Level Requirement for ''Healthy'' Claims

1. Need for Sodium Level

(Comment 7) One comment argued that sodium content should not be a criterion for whether a food can be labeled as ''healthy'' because, according to the comment, current nutritional science does not show beneficial health outcomes from reducing sodium in the diet. The comment recommended that FDA revise the ''healthy'' regulation to remove the sodium level requirements entirely.

(Response) FDA disagrees with the comment that advocated dropping all sodium criteria for the ''healthy'' claim. As discussed previously in response to comment 1 of this document, there is ample evidence that sodium has an adverse impact on cardiovascular disease, particularly hypertension, and that as a consequence, the amount of sodium in an individual food or meal type product should be controlled in order for such a product to be labeled as ''healthy''.

2. Sodium Level for Meal and Main Dish Products

(Comment 8) Most comments supported or did not object to maintaining the current first-tier sodium level of 600 mg for meals (as defined in § 101.13(l)) and main dishes (as defined in § 101.13(m)). Comments emphasized the importance of making sure that ''healthy'' meals and main dishes, which present a more healthful alternative to standard processed foods, can continue to be marketed without sacrificing taste and commercial viability. These comments took the view that it is better to avoid driving nutritious, controlled-sodium alternatives to standard processed foods out of the marketplace than to bring about the small incremental reduction in sodium that would result from allowing the second-tier level for meals and main dishes from going into effect. One comment suggested that the current regulations have already had a chilling effect on the term ''healthy'' on meal and main dish products. According to this comment, the number of brands of frozen entrees or dinners bearing the ''healthy'' claim decreased from seven to one between 1994 and 2003. The comment suggested that maintaining the first-tier sodium levels for meals and main dishes would help achieve the goals FDA articulated in the ANPRM and 2003 proposed rule: To develop sodium criteria for the definition of ''healthy'' that allow a significant number and variety of products to be labeled as ''healthy,'' yet that are not so broadly defined as to cause the term to lose its value in identifying products that are useful for constructing a healthy diet consistent with dietary guidelines. See 62 FR 8163 at 8165; 62 FR 67771 at 67772.

Of the few comments that opposed FDA's proposal to retain the first-tier sodium level requirement for meals and main dishes, one consumer comment suggested that the rules for sodium content of meals and main dishes should be stricter than the first-tier level currently in effect but did not specify whether FDA should implement the second-tier level or an even lower level. Another comment took issue with the agency's rationale for proposing to retain the current first-tier sodium level of 600 mg for meals and main dishes. This comment argued that the agency's concern about driving ''healthy'' meals and main dishes from the market by implementing the lower second-tier sodium level requirement of 480 mg is not a legitimate reason for retaining the more lenient 600 mg sodium requirement and thus allowing unhealthy products to be labeled as ''healthy''. The comment argued that because the intent of the regulation was to promote health, FDA should not retain the current 600 mg sodium level because it would not guide individuals to build a diet that meets Federal nutrition recommendations. This comment reasoned that the 2000 Dietary Guidelines (Ref. 1) recommend that sodium intake not exceed 2,400 mg per day[4] and that the Food Guide Pyramid recommends a minimum of 15 servings of food per day to meet nutrient needs. The comment stated that, on average, sodium intake should not exceed 160 mg per serving of food. Given that a meal contains 2–3 servings of food, the comment reasoned that a meal should contain no more than 480 mg sodium. As discussed in comment 7 of this document, one comment suggested that the sodium requirement for meals should be dropped altogether.

(Response) The agency acknowledges the comments' concerns about the amount of sodium in meal and main dish products and agrees that FDA should encourage manufacturers to limit the amount of sodium in these products. However, the comments presented no data to substantiate the technical and commercial feasibility of implementing the second-tier sodium criterion for meals and main dishes at the 480 mg per labeled serving level. Consequently, the agency has no basis to change its position on this issue. In the 2003 proposed rule, the agency described the reasons why FDA had tentatively concluded that the first-tier sodium level for ''healthy'' meals and main dishes should be retained:

> Based on the marketplace data analysis, the agency found that there were a limited number of ''healthy'' meal and main dish products that met the current first-tier sodium level. The agency further found a general decline in the number of meal and main dish products available in 1999 compared to 1993. * * *
>
> This appears to indicate that providing consumers with a palatable ''healthy'' product at the current, first-tier sodium level is difficult.
>
> The limited number of ''healthy'' meal and main dish products affects FDA's goal to provide a definition for ''healthy'' that permits consumers access to a reasonable number of products that bear the ''healthy'' claim. If FDA were to allow the second-tier sodium level for ''healthy'' meal and main dish products to take effect, there would likely be an even greater reduction in the number of available ''healthy'' meal and main dish products in the marketplace.

[4] The current recommendation for sodium for adults in the ''Dietary Guidelines for Americans 2005'' is 2,300 g per day (Ref. 3). This is also the UL for sodium found in The Electrolyte Report (Ref. 2).

Furthermore, some manufacturers of ''healthy'' meal and main dish products might choose to limit only fat or calorie levels and change to ''lean,'' ''low calorie,'' or ''low fat'' claims. Although those claims do provide some assistance to consumers who are trying to construct a diet consistent with dietary guidelines, there are additional nutritional benefits in products bearing a ''healthy'' claim. * * *

Moreover, FDA finds the petitioner's comment that a number of meal and main dish products would ''disappear'' to be persuasive because the petitioner is one of only a few manufacturers currently producing ''healthy'' meal and main dish products. The marketplace data analysis * * * showed that there were a limited number of ''healthy'' meal and main dish manufacturers, with one manufacturer producing most of the ''healthy'' meal and main dish products. * * * Five brands that were available for sale in 1993 had completely disappeared from the market by 1999. * * * Considering the petitioner's expertise in the ''healthy'' frozen meal and main dish market, and the trends seen in the marketplace, FDA believes that the petitioner raised valid concerns about the second-tier sodium level for meal and main dish products * * * .

Furthermore, the first-tier sodium level proposed for ''healthy'' meal and main dish products is proportionate to and adequately reflects their contribution to the total daily diet while remaining consistent with current dietary guidelines. If each meal or main dish product has a maximum of 600 mg sodium and if one meal or main dish product is consumed at each of three meals during a typical day, then this accounts for a total of 1,800 mg sodium from meal and main dish products. This is consistent with previous agency assumptions that daily food consumption patterns include three meals and a snack with about 25 percent of the daily intake contributed by each (final rule on nutrient content claims (58 FR 2302 at 2380, January 6, 1993)). The 1,800 mg sodium level is well below the suggested 2,400 mg recommendation[5] and allows for flexibility in the rest of the daily diet (i.e., the snack). * * *

FDA tentatively concludes that the first-tier sodium level for meal and main dish products allows a ''healthy'' definition that is neither too strictly nor too broadly defined. The first-tier sodium level will allow consumers to meet current dietary guidelines for sodium intake while still maintaining flexibility in the diet. Additionally, the agency believes that by retaining the first-tier sodium level, a reasonable number of ''healthy'' meal and main dish products will remain available to consumers. Therefore, the agency has tentatively concluded that the current first-tier level of 600 mg sodium per serving size should be retained as the sodium criterion for ''healthy'' meal and main dish products. * * *

(68 FR 8163 at 8169–8170 (reference omitted).)

[5] The recommendation in the current edition of the Dietary Guidelines is 2,300 mg/day. See footnote 4 in this document.

Having received no data that would justify changing the tentative conclusions outlined in the 2003 proposed rule, FDA has decided to eliminate the second-tier (480 mg) requirement for ''healthy'' meals and main dish products that was adopted in the 1994 final rule and that would have gone into effect when the partial stay of that rule expired.

In addition, although there may be difficulties in formulating products that control sodium in addition to other nutrients, the marketing of a variety of these nutrient controlled products shows that it is possible to limit the sodium level in meal-type products to the first-tier level, 600 mg. Consequently, the agency does not see the merit or necessity of eliminating the sodium criterion altogether.

Therefore, as proposed, FDA is amending the requirements for use of the term ''healthy'' on meal and main dish products to do the following: (1) To make permanent the current first-tier sodium level requirement of 600 mg per labeled serving, and (2) to delete the more restrictive second-tier sodium level requirement of 480 mg per labeled serving that was adopted in the 1994 final rule and would have become effective when the partial stay of that rule expired.

3. Sodium Level for Individual Foods

(Comment 9) A few comments supported implementing the more restrictive second-tier sodium level of 360 mg per RACC and per labeled serving for individual foods. One comment asserted that promoting good health should be a higher priority than manufacturers' difficulties with formulating and marketing lower sodium products. This comment argued that the fact that truly ''healthy'' products may not be available does not justify stamping ''healthy'' on unhealthy products. Another comment hypothesized that the number of products qualifying as ''healthy'' is not extensive because food processors have resisted efforts to reduce the sodium content. This comment expressed disagreement with the petitioner's contention that the second-tier sodium level cannot be met, and asserted that the available data do not justify such a conclusion.

(Response) The agency agrees with the comments that foods labeled as ''healthy'' should in fact promote good health. When FDA issued the 1994 final rule providing for a phased-in second-tier sodium level of 360 mg per RACC and per labeled serving, the agency had anticipated that with the passage of time, there would be sufficient technological progress to make it feasible to implement this lower sodium level requirement for foods labeled as ''healthy.'' However, in both the 1997 ANPRM and the 2003 proposed rule, the agency recognized that technological and safety concerns might justify reconsidering the second-tier sodium level. For example, in the ANPRM FDA said (62 FR 67771 at 67773):

If the petitioner is correct that the technology does not yet exist that will permit manufacturers, by January 1, 1998, to produce certain types of low fat foods at the lower levels of sodium required in § 101.65(d) that are still acceptable to, and safe for, consumers, then the possibility exists that ''healthy'' will disappear from the market for such foods. This result would force consumers who are interested in foods with restricted fat and sodium levels to choose among foods in which an effort has been made to lower the level of one or the other of these nutrients but not necessarily both. * * * Therefore, the agency has decided that, before allowing the new sodium levels for ''healthy'' to go into effect, it needs to explore whether it has created an unattainable standard * * * .

The 2003 proposal summarized the technological and safety considerations presented in the 1997 ANPRM, including consumer acceptance of foods at the second-tier sodium levels, availability of sodium substitutes, difficulties in manufacturing foods with reduced sodium levels, and the impact of lower sodium levels on the shelf-life, stability, and safety of the food (68 FR 8163 at 8164). In addition, the proposed rule reiterated FDA's goal of ensuring continued availability of ''healthy'' foods for consumers to purchase (68 FR 8163 at 8165):

The fundamental purpose of a ''healthy'' claim is to highlight those foods that, based on their nutrient levels, are particularly useful in constructing a diet that conforms to current dietary guidelines * * * . To assist consumers in constructing such a diet, a reasonable number of ''healthy'' foods should be available in the marketplace.

[FDA's] goal was to establish sodium levels for the definition of ''healthy'' that are not so restrictive as to preclude the use of the term ''healthy'' * * * .

In keeping with this goal, FDA solicited comments on the potential impact of the second-tier sodium level on specific categories of individual foods (68 FR 8163 at 8167). As discussed in comment 11 of this document, the majority of comments opposed the agency's proposal to allow the second-tier sodium level to go into effect. Some of these comments included data supporting their position. In contrast, the proponents of the second-tier sodium requirement did not provide supporting data as to why this lower level is appropriate and how it could be technologically accomplished.

(Comment 10) One comment that did not agree with implementing the second-tier sodium levels suggested an alternative. This comment suggested that FDA set sodium level requirements for ''healthy'' individual foods on a case by case basis instead of applying the second-tier sodium level to all types of individual foods. For example, the comment suggested that the sodium requirement for soups be lowered from the first-tier requirement by 30–50 mg per serving rather than 120 mg as required by the second-tier sodium level, to retain the palatability of ''healthy'' soups. To create broad incentives for companies to lower the sodium content of processed foods, this comment recommended that FDA take a similar approach for other categories of foods and set appropriate sodium levels (higher than the second-tier level, but lower than the first-tier level) on a category-by-category basis. According to the comment, modest reductions in sodium across a wide range of individual processed foods in the total diet could have a significant effect.

(Response) Although the alternative suggested in this comment has some appeal as a compromise between the first- and second-tier levels, the comment did not include supporting data, unlike comments advocating that FDA retain the first-tier level for individual foods. With regard to the comment's specific recommendation to lower the sodium level requirement for ''healthy'' soups by 30–50 mg per reference amount and per labeled serving below the first-tier level (rather than the 120 mg reduction required by the second-tier level), the comment provided no data on the benefits of reducing the sodium requirement by 6–10 percent as opposed to the 25 percent reduction that would result from the second-tier sodium requirement, on whether a 6–10 percent reduction would be feasible, or on the effect that such a reduction would have on the overall amount of sodium in soups that currently use ''healthy'' claims or that have used ''healthy'' claims in the past. In contrast to the absence of data supporting this alternative regulatory approach, FDA has enough data about the feasibility of formulating and selling ''healthy'' foods at the current first-tier sodium level to be confident that retaining this level will promote the continued availability of nutritious processed foods that will assist consumers in following dietary guidelines.

Moreover, this comment advocates a regulatory approach based on product categories (i.e., different sodium level requirements for different product categories like soups and cheeses); such an approach would not be consistent with the principles of consistency and uniformity that have always guided FDA's regulation of nutrient content claims. Although FDA does vary the criteria for nutrient content claims somewhat for broad classes of products (such as meals and main dishes, seafood and game meat, and foods with small servings) to accommodate inherent differences in the nutrient characteristics of different classes of foods, the agency has never created food-specific exemptions or nutrient criteria to accommodate the making of a nutrient content claim for an individual food category, such as soups, that otherwise could not qualify for the claim.

When the nutrient content claims requirements were being developed, the agency rejected the notion of having variable nutrient requirements for various commodities. In the proposed rule on general requirements for nutrient content claims in food labeling, FDA explained its view as follows:

> The use of different criteria for different food categories has several disadvantages that affect both consumers and the food industry. When different criteria are used for different categories of foods, consumers cannot use the descriptors to compare products across categories and will likely find it difficult to use the descriptors for substituting one food for another in their diets.
>
> * * * [T]he agency believes that such a system would have a high potential for misleading the consumers about the nutrient content of foods * * * . [W]ith different criteria for different food categories, it would be possible that some foods that did not qualify to use the descriptor would have a lower content of the nutrient than foods in other categories that did qualify. * * *
>
> FDA has received many comments asking for increased consistency among nutrient content claims to aid consumers in recalling and using the defined terms. In addition, the IOM report recommended that ''low sodium,'' for example, should have the same meaning whether it is applied to soup, frozen peas, or meat. Accordingly, the agency concludes that establishing different cutoff levels for each nutrient content claim for different food categories would greatly increase the complexity of using such claims to plan diets that meet dietary recommendations. * * *

(56 FR 60421 at 60439, November 27, 1991 (reference omitted).)

Further, as stated in the comments on consumer understanding summarized in section II.C of this document, there may already be some confusion as to what the term ''healthy'' means. This confusion could worsen if the definition for ''healthy'' meant different sodium levels for different foods. Consequently, the agency is not establishing a different sodium criterion for ''healthy'' for soups or other individual product categories.

(Comment 11) A majority of the comments supported retaining the less restrictive, first-tier sodium level for individual foods. Comments argued that if the lower second-tier sodium level for ''healthy'' individual foods takes effect, many foods that meet the current criteria for ''healthy'' would disappear from the marketplace because the second-tier standard is difficult or impossible to meet while maintaining palatability. They expressed the view that although the first-tier level for sodium is not perfect, it is preferable to seeing products labeled as ''healthy'' disappear from the marketplace.

Several comments stated that consumers will not accept or purchase foods that meet the second-tier level for sodium, explaining that consumers want good taste and that these lower sodium products do not taste as good as products with more sodium. Some of these comments pointed out that lowering the sodium content of a food can affect its texture, which in turn may also affect whether consumers are willing to purchase the food. One comment from a food manufacturer stated that even under the current, less restrictive first-tier sodium criterion, production and consumer acceptance are difficult. This comment cited data showing that consumers buy relatively few ''healthy'' products; for example, ''Healthy Choice'' makes up less than 1/10th of 1 percent of all food products (Ref. 10). This comment also asserted that eating trends had changed between 1994 and 2003. The comment stated that according to National Eating Trends 2003 data, consumption of foods free of or low in salt or sodium was currently 1.5 percent, down from 3.3 percent in 1994.[6]

According to the comment, a 1994 *Prevention Magazine* article entitled ''Eating in America: Perception and Reality'' reported data from the Food Marketing Institute showing that of 597 shoppers surveyed, 89 percent said that taste was the most important factor in food selection.[7] The comment also asserted that taste tests conducted in 2003 by the manufacturer who

[6] The comment did not include a copy of this reference, and FDA was unable to locate it.

[7] FDA determined that this information, though accurate, did not come from the *Prevention* article cited in the comment but rather from a report summarizing data collected for the Food Marketing Institute by Abt Associates. The report ''Trends in the United States—Consumer Attitudes and the Supermarket, 1996'' states that in each year from 1991 to 1996, taste ranked highest in importance (89–91 percent) of various factors (e.g., nutrition, product safety, and price) in food selection (Ref. 11).

submitted the comment found that modern ''salt enhancers'' and bitter blockers (substances that block bitter tastes in foods) were not sufficient to make soup containing only 360 mg sodium appealing to consumers, while the manufacturer's current soup version at 480 mg sodium was found to be acceptable to consumers (Ref. 12).

The comment also cited IRI data on soup sales (Ref. 13). These data showed that the soup category currently has $ 2.7 billion in sales, of which only $ 19 million is for soup with 360 mg or less sodium. The comment calculated that soups with 360 mg or less sodium account for only 1.7 percent of ''Ready to Serve'' soup sales. ''Low sodium'' soups (less than 140 mg) make up less than 0.4 percent of the ready to serve market, and sales of these soups are falling. Further, there are no low sodium condensed soups on the market.

In addition, this comment included a graph of the market sales of a leading manufacturer of soups labeled as ''healthy.'' This graph shows a drop in sales of roughly 75 percent from 1999 to 2003, when the sodium level in the soups was reportedly reduced from 480 mg to 360 mg. The comment cited a case of another major manufacturer marketing ''healthy'' soups that reportedly increased the sodium in its products by 1/3 to 1/2; this increase in sodium content was followed by an increase in product sales.

The comment further stated that there are very few manufacturers left that produce foods that qualify to bear the term ''healthy.'' The comment asserted that in eight of the nine food categories in which the manufacturer that submitted the comment competes, its product is the only product with the term ''healthy'' in its brand name.

Other comments also focused on the limited selection and dwindling numbers of ''healthy'' products. One comment stated that in the past 5 years there has not been a significant number of new ''healthy'' product offerings (only 80 such new products, or about 16 per year). The comment added that of these new products, 76 percent of them were under the same brand name, ''Healthy Choice.'' In contrast, there are approximately 20,000 ''non-healthy'' new product offerings each year. The comment said that certain product categories such as ''healthy'' cheese had already disappeared and expressed concern that if the lower second-tier sodium level for a ''healthy'' claim was implemented, even more products would disappear from the market. Another comment took a different view, suggesting that the absence from the market of ''healthy'' cheese could have a positive impact by encouraging consumers to switch to more healthful whole foods such as fruits, vegetables, grains, and legumes.

One comment added that consumer acceptance of food products with sodium content low enough to meet the second-tier sodium requirement has not been encouraging and that lowering the sodium level will decrease flavor and reinforce the concept that healthy foods taste bad. Another comment contended that implementing the lower sodium level requirement for ''healthy'' would be counterproductive to the goal of encouraging the creation of more foods that qualify for the ''healthy'' claim. This comment argued that if consumers will not eat current ''healthy'' foods, they are less likely to eat new ones with even lower sodium. According to the comment, by disqualifying many ''good-for-you'' products from being labeled as ''healthy,'' FDA risks less development and commercialization of similarly healthful products.

A number of comments stated that lowering the sodium level by 120 mg for already reduced sodium products will not have a positive effect. Several comments asserted that reducing the number of ''healthy'' products further will force products off the shelves, leaving only higher sodium alternatives.

A comment from a consumer group concurred, suggesting that the ''Healthy Choice'' brand has an incentive effect on the market. If the ''Healthy Choice'' products disappear from the market because of the second-tier sodium requirement, there will be no more incentive. Consumers will be left with higher sodium alternatives, will not be likely to search for the next best alternative, and will return to full sodium soups at 800–1000 mg of sodium per serving. An industry comment stated that the first-tier level requirement had brought down the average sodium level for all soups by 32 mg per serving from 882 to 850. This comment predicted that if the level required to bear the term ''healthy'' is dropped further, the average sodium level will go back up.

As evidence that the second-tier sodium level is too restrictive, another comment pointed out that some products that qualify for a coronary heart disease health claim or American Heart Association's (AHA's) heart check program, such as ready to eat cereals with fiber, would not be able to qualify for the term ''healthy'' under the more restrictive second-tier sodium requirement.

In summary, many comments stated that the potential benefit of having ''healthy'' products with a slightly lower sodium level was not worth the risk of losing currently marketed ''healthy'' products. These comments emphasized that while the current option is not perfect, ''healthy'' products are better than their standard alternatives even at the higher first-tier sodium level. They believe that lowering the sodium limit could reverse progress made since the term ''healthy'' was defined in 1994.

(Response) The agency has taken into account these comments and the supporting data provided. FDA believes it is essential that low fat, nutritious products that are also reduced in sodium be available for consumers who wish to control both fat and sodium. The agency finds persuasive the information on technological barriers to reducing sodium in processed foods and the data demonstrating the difficulty in achieving palatable products that meet the second-tier sodium requirement. Without consumer acceptance of ''healthy'' foods, public health goals of reducing dietary sodium and fat (as well as saturated fat and cholesterol) will not be met, and the ''healthy'' claim will not foster better dietary practices in the long run. FDA has also taken into account the data on decreased market shares of existing ''healthy'' products and the dearth of new ''healthy'' products as companies have begun preparing to comply with the second-tier sodium requirements. These data make a persuasive case that, rather than encouraging the development of new products, allowing the second-tier sodium requirement for individual foods to go into effect would have the opposite effect on the market.

Therefore, the agency has decided to eliminate the second-tier sodium level requirement for ''healthy'' individual foods that was adopted in the 1994 final rule and would have gone into effect when the partial stay of that rule expired. For consistency across all categories of individual foods (see response to comment 10 of this document), the agency has also decided to eliminate the second-tier sodium level requirement for ''healthy'' raw, single ingredient seafood and game meat.

Therefore, FDA is amending the requirements for use of the term ''healthy'' on individual foods and raw, single ingredient seafood and game meat (1) to make permanent the current first-tier sodium level requirement of 480 mg per reference amount customarily consumed and per labeled serving or, if the serving size is small (30 g or less or 2 tablespoons or less), per 50 g; and (2) to delete the more restrictive second-tier sodium level requirement of 360 mg that was adopted in the 1994 final rule and

that would have become effective when the partial stay of that rule expired.

G. Legal Issues

(Comment 12) A few comments raised legal objections to FDA's proposal to implement the second-tier sodium level requirement for individual foods labeled as ''healthy.'' Specifically, comments alleged that allowing the second-tier sodium level to go into effect would facilitate the use of a false and misleading statement in food labeling in violation of the act, would be arbitrary and capricious in violation of the Administrative Procedure Act, would violate manufacturers' commercial speech rights under the First Amendment to the United States Constitution, and would effect an unconstitutional regulatory taking under the Fifth Amendment.

(Response) Because FDA is not adopting the proposal to allow the second-tier sodium level requirement for ''healthy'' individual foods to go into effect, but instead is removing that requirement from the ''healthy'' regulation, these comments are moot and need not be addressed.

H. Clarification in Regulatory Text

In the 2003 proposed rule (68 FR 8163 at 8171), FDA proposed to amend the ''healthy'' definition in § 101.65(d)(1) to specify that a claim that suggests that a food, because of its nutrient content, may be useful in maintaining healthy dietary practices, is an implied nutrient content claim if it is made in connection with either an explicit or implied claim or statement about a nutrient. The purpose of this proposed change was to clarify the scope of ''healthy'' claims covered under § 101.65(d) and to make the regulatory text consistent with preamble discussions in the 1993 proposed rule (58 FR 2944 at 2945, January 6, 1993) and 1994 final rule (59 FR 24232 at 24235), where FDA made clear that claims made in connection with an implied claim or statement about a nutrient would be covered by the ''healthy'' regulation.

FDA received no comments on this provision of the proposed rule and is adopting it as proposed.

I. Plain Language

In the 2003 proposed rule, FDA proposed changes to the format and regulatory text of the ''healthy'' regulation to be consistent with the Presidential Memorandum on Plain Language (Ref. 14) and to make the regulation easier to understand and follow. The proposed changes consisted of converting the nutrient requirements in § 101.65(d) for foods labeled as ''healthy'' from a text-based format to a table-based format. The agency also proposed several minor changes in the wording of § 101.65(d) to make the regulation more concise and easier to understand.

(Comment 13) There was only one comment concerning plain language. This comment took issue with the length and complexity of the preamble, but not the content of the codified.

(Response) As there were no suggestions as to how the codified might be revised to more closely comply with the Presidential Memorandum instructing Federal agencies to use plain language, the agency is making no changes in response to this comment.

FDA is adopting the proposed table-based format for the ''healthy'' nutrient criteria. In addition, proposed § 101.65(d)(2)(iv) and (d)(2)(v) have been incorporated into the first table in this final rule.

For the most part, the agency is also adopting the proposed changes to the regulatory text itself. However, on further consideration, the agency has decided to return to the original language of § 101.65(d) in a few instances to avoid creating inconsistencies with the language of existing nutrient content claims regulations. For example, the agency has decided not to change the term ''labeled serving'' to ''serving size'' (SS) to clarify that there is no difference in meaning from other nutrient content claim regulations that specify nutrient criteria for the claim using ''labeled serving'' (e.g., § 101.62(b), defining nutrient criteria for ''fat free''). LS refers to the serving size that is determined according to the rules in § 101.9(b) and specified in the Nutrition Facts or Supplement Facts panel on the product label.

As FDA explained in the 2003 proposed rule (68 FR 8163 at 8171), the new format and other plain language changes are not intended to affect the meaning of the ''healthy'' regulation.

J. Effective Date

Under the Administrative Procedure Act (5 U.S.C. 553(d)), and FDA's regulations (§ 10.40(c)(4) (21 CFR 10.40(c)(4)), publication of a rule must normally take place 30 days before the rule's effective date. However, exceptions to this requirement are permissible in the case of ''a substantive rule which grants or recognizes an exemption or relieves a restriction'' (5 U.S.C. 553(d)(1); see also § 10.40(c)(4)(i).

This rule is a substantive rule that relieves a restriction. If FDA did not issue this rule, the second-tier sodium level requirements for the ''healthy'' claim would go into effect on January 1, 2006, when the stay of these requirements expires (see 67 FR 30795). The second-tier sodium level requirements are more restrictive than the first-tier sodium level requirements and would allow fewer products to bear the ''healthy'' claim. By revoking the more stringent second-tier sodium level requirements for the ''healthy'' claim and making permanent the less stringent first-tier sodium level requirements for this claim, this rule relieves a restriction.

IV. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

A. Regulatory Impact Analysis

FDA has examined the impacts of this final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. The Office of Management and Budget has determined that this rule is a significant regulatory action under Executive Order 12866, although it is not economically significant.

1. The Need for Regulation

To bear the term ''healthy,'' products must not exceed established levels for fat, saturated fat, cholesterol, and sodium. The existing regulation states that meals and main dishes, as defined in § 101.13(l) and (m) respectively, must have sodium levels no higher than 600 mg per labeled serving (either a large

portion of a meal or the entire meal) in the first-tier compliance period, and sodium levels no higher than 480 mg per labeled serving in the second-tier compliance period, which was originally scheduled to begin on January 1, 1998. The regulation also states that ''healthy'' foods other than meals and main dishes must have sodium levels no higher than 480 mg per reference amount and per labeled serving or, if the serving size is small (30 g or less or 2 tablespoons or less), per 50 g, in the first-tier compliance period, and sodium levels no higher than the second-tier 360 mg per reference amount and per labeled serving thereafter. The agency initially stayed the second-tier sodium levels until January 1, 2000 (62 FR 15390, April 1, 1997). FDA has since extended the stay twice: First until January 1, 2003 (64 FR 12886, March 16, 1999), and more recently until January 1, 2006 (67 FR 30795, May 8, 2002).

This rule modifies the definition of the term ''healthy'' by making permanent the first-tier sodium levels of 600 mg per labeled serving for meals and main dishes and 480 mg per reference amount and per labeled serving (or per 50 g if the serving size is small) for individual foods. Making the first-tier levels permanent will help preserve the ''healthy'' claim as a signal that products bearing that claim in their labeling are nutritious and will help contribute to a healthy diet. Without this modification, the second-tier sodium levels would take effect; as a result, many producers would likely cease using the ''healthy'' claim (or perhaps cease marketing the product), leading to a reduction in the eating options and health-related information available to consumers.

2. Regulatory Options

FDA identified several options in the 2003 proposed rule (68 FR 8163 at 8171 to 8172): (1) Make no change to the current rule, which would allow the second-tier sodium levels to go into effect; (2) amend the definition of ''healthy'' to eliminate the second-tier sodium levels for some or all products; (3) continue the stay to give producers time to develop technological alternatives to sodium; or (4) consider different second-tier sodium limits. Analyzing probable technological change (option 3) is beyond the scope of this analysis; innovation is difficult to predict. Also, analyzing alternative second-tier sodium limits in terms of net benefits (option 4) is not feasible in this analysis because FDA has no way of differentiating health effects or manufacturing costs due to marginal differences in the allowable sodium content of ''healthy'' food products.

The optimum sodium level for individual foods, meals, and main dishes balances the health benefits of limiting sodium intake with the cost to the food industry of making product preparation more complicated and the cost to consumers of limiting product choice. In the analysis that follows, we conclude that the first-tier sodium level strikes that balance better than the second-tier level for all categories of FDA-regulated foods.

The options we consider in this analysis are option 1 (allow second-tier levels to take effect) and 3 versions of option 2 (adopt as permanent the first-tier sodium levels for some or all products):

1. Implement the current rule (i.e., § 101.65(d)) without modification, which would make the second-tier sodium levels effective on January 1, 2006.

2a. Amend the current rule, adopting as permanent the first-tier sodium level for all or specific ''healthy'' individual foods.

2b. Amend the current rule, adopting as permanent the first-tier sodium level for ''healthy'' meals and main dishes.

2c. Amend the current rule, adopting as permanent the first-tier sodium levels for ''healthy'' meals and main dishes and for all or specific ''healthy'' individual foods.

The final rule adopts option 2c.

The baseline in this case is the current rule, or option 1, so the benefits of the other options are the reformulation, rebranding, and relabeling costs avoided by retaining the first-tier sodium content requirements for individual foods or meals and main dishes. The costs of the other options are the negative health effects associated with the potential net increases in sodium intake under options 2a, 2b, and 2c.

Since the baseline is the current rule, or option 1, the market data used to analyze the marginal and total costs and benefits of options 2a, 2b, and 2c are a snapshot of the market before the 2003 proposed rule was published. Predicting an amendment to the current rule, based on the publication of the 2003 proposed rule, some manufacturers of meals and main dishes may have already reacted by reformulating or changing their product lines (e.g., manufacturers who had begun preparing for the effective date of the second-tier sodium level by producing ''healthy'' meals and main dishes with sodium content below the first-tier level may have reformulated these products back to the first-tier level for taste and texture after FDA proposed to make the first-tier level permanent for meals and main dishes). To estimate the net effects of this final rule compared with the scheduled second-tier levels adopted in the 1994 final rule, it is necessary to use data from before the 2003 proposed rule so as not to incorporate changes made in anticipation of this final rule. Therefore, the data used to calculate the baseline are from before the publication of the 2003 proposed rule.

Option 2a: Retain the First-Tier Sodium Level for All or Specific ''Healthy'' Individual Foods.

Costs of Option 2a. The principal costs of this option are associated with the deterioration of ''healthy'' as a signal of foods with strictly controlled levels of sodium and the consequent potential increase in overall sodium intake. These costs would in large part be mitigated by the countervailing risks avoided by retaining a larger selection of ''healthy'' products. ''Healthy'' products are not only controlled in sodium, but also low in fat and saturated fat, controlled in cholesterol, and have at least 10 percent of the DV of one of the following: Vitamin A, vitamin C, calcium, iron, protein, or fiber. If products were forced off the market by a more restrictive sodium requirement, consumers would have fewer choices not only among products that are controlled in sodium, but also among products that are low in fat and saturated fat, and controlled in cholesterol.

According to information provided in the comments, it appears that most ''healthy'' individual foods other than soups and cheeses could meet the second-tier sodium limit without substantial adverse changes in taste or texture. Retaining the first-tier sodium level for all individual foods would diminish the effectiveness of the ''healthy'' controlled sodium signal compared with option 2b (retaining the first-tier sodium level for meals and main dishes) because there are more individual foods on the market than meals and main dishes. Alternatively, if FDA retained the first-tier ''healthy'' sodium level only for soups and cheeses, this inconsistency would diminish the usefulness of the term ''healthy'' as a signal to identify individual foods with uniformly controlled levels of sodium.

In addition, retaining the first-tier level for individual foods under option 2a would be less consistent with the ''healthy'' definition for meals and main dishes than allowing the second-tier sodium level to go into effect under option 1. The first-tier sodium level for combinations of ''healthy'' individual foods allows more sodium than when those same foods are combined into meals and main dishes. ''Healthy'' meal and main dish products must contain at least three and two non-condiment food groups respectively, and still can only

contain 600 mg sodium per meal or main dish under the first-tier sodium level. By contrast, two ''healthy'' individual foods combined in exactly the same way could contain 720 mg sodium under the stayed second-tier level, and up to 960 mg sodium under option 2a (first-tier level), or 40 percent of the Daily Reference Value (DRV). This difference in sodium levels between a meal and two individual foods could have a health effect if consumers are using ''healthy'' specifically as a signal to identify foods with strictly controlled levels of sodium. However, because consumers, under option 2a, could consume three ''healthy'' meal or main dish products plus a ''healthy'' snack (individual food), or five servings of ''healthy'' individual foods, and still remain within the DRV for sodium, the agency concludes that the ''healthy'' signal, though somewhat less effective due to the discrepancy described previously in this document, would still be useful under option 2a.

Sodium intake from soups could either increase or decrease under this option. If consumers of ''healthy'' soups at the current first-tier sodium level will not eat ''healthy'' soups at the more restrictive second-tier sodium levels, they will either switch to another type of soup or to another food category altogether. If most former consumers of ''healthy'' soup, under a more restrictive sodium requirement, simply switch to other brands of soup, which have an average of 850 mg of sodium per serving, sodium consumption could actually increase under this option despite the more restrictive sodium level requirement for products labeled as ''healthy.'' If most former consumers of ''healthy'' soups choose to substitute a different type of controlled or low sodium food for soup, however, sodium consumption could decrease under this option. Since the agency has no data concerning what products consumers will choose if ''healthy'' soups disappear from the market, the change in sodium intake from soup (or products substituted for it) under this option is indeterminate.

Under option 2a, sodium intake from other individual foods is likely to increase slightly. Since most products other than cheeses and soups would be able to meet the second-tier sodium requirement, sodium levels of some of these products may increase relative to what would happen under option 1, which would require individual foods to stay within the lower second-tier sodium level. For most types of individual foods (ice cream and bread, for instance), neither the first-tier nor the second-tier sodium level requirement for the ''healthy'' claim would be a limiting factor because these product categories do not require much sodium to taste good. Therefore, most ''healthy'' individual food products would be expected to contain similar levels of sodium under either the first-tier or second-tier sodium level requirement. Manufacturers of products for which the second-tier sodium levels would be difficult to meet, such as pasta sauce and microwave popcorn, may use more sodium in their products under option 2a than under option 1. However, as with soups, the net effect on sodium consumption is indeterminate. If the more restrictive second-tier sodium requirement caused fewer ''healthy'' options in these product categories to be available and consumers reacted by substituting towards higher sodium alternatives, sodium consumption could actually be lower under option 2a (first-tier sodium level) than under option 1 (second-tier sodium level). On the other hand, if consumers reacted by substituting toward other low sodium or sodium-controlled products, sodium consumption under option 2a would likely be similar to or higher than under option 1. As with soups, without data allowing a prediction of consumer response, the change in sodium consumption under option 2a relative to baseline, though likely to be small, is indeterminate.

It is also important to recall the other requirements for the ''healthy'' claim. ''Healthy'' products are not only controlled in sodium, but also limit fat, saturated fat, and cholesterol, and are significant sources of at least one important nutrient. If ''healthy'' soups and other ''healthy'' individual foods are forced off the market by a more restrictive sodium requirement, there will be fewer relatively healthy food choices for consumers.

The costs of an increased health risk due to a potential increase in average daily intake of sodium are uncertain, although they are likely to be small. The costs of an increased health risk due to a potential increase in average daily intake of sodium are uncertain, although they are likely to be small for three reasons: (1) The increase in sodium intake, as explained previously in this document, is likely to be small; (2) the increased health risk associated with a small increase in sodium consumption is small; and (3) any increased health risk due to increased sodium intake will be offset somewhat by the continued consumption of products that limit fat, saturated fat, and cholesterol, and that are significant sources of at least one important nutrient.

Benefits of Option 2a. The benefits of this option are the reformulation, rebranding, and relabeling costs avoided by manufacturers if they do not have to modify their products to meet the second-tier sodium level for individual foods. The benefits of avoiding these costs under this option are substantial. In the market analysis, FDA identified 870 individual food products among 69 brands that make a ''healthy'' claim (Ref. 8).[8] The FLAPS survey also identified several additional individual foods that make a ''healthy'' claim but are not from a ''healthy'' brand (Ref. 9). According to the comments and subsequent analysis by FDA, only 3 of the over 80 food product categories would have material trouble meeting the second-tier ''healthy'' sodium level: Soups, cheeses, and meats (primarily frankfurters and ham). Of these three food product categories affected by this option, ''healthy'' meats are regulated by USDA and therefore are not part of this analysis, and discussions on cheese and soup categories follow in this section of the document.

Other individual foods in other categories may have costs associated with meeting the second-tier sodium level, but FDA has no specific information concerning costs for those other individual foods.

Cheese. Reformulating cheeses to meet the second-tier sodium level would be difficult. However, as of May 2001, every ''healthy'' cheese product had apparently been taken off the market. FDA identified 32 ''healthy'' cheeses, under one brand, on the market in 1999 according to the marketplace data analysis (Ref. 8). In an informal telephone inquiry, FDA confirmed that by May 2001, there were no longer ''healthy'' cheeses produced under this brand (Ref. 15).

With no products to analyze, FDA cannot assess the potential impact of the second-tier sodium level on cheese. ''Healthy'' cheeses could have been taken off the market for any one of three different reasons, each with different implications for the effects of option 2a. First, characteristics of the products in addition to or unrelated to sodium content (e.g. lower fat requirements) could have led to low product demand and eventual product withdrawal. If so, option 2a would not lead to any societal benefits through influencing the market for cheese. Second, firms may not be

[8] One comment on the 2003 proposed rule criticized this estimate. See comment 10 in section II.E of this document for a detailed summary of the comment and FDA's response.

able to create an acceptable ''healthy'' cheese product even under the first-tier sodium level for individual foods, so there would be no cost or benefit difference between the first and second tiers of sodium content. Third, if ''healthy'' cheeses were taken off the market in anticipation of being unable to comply with the second-tier sodium level, adopting option 2a would probably encourage producers to reintroduce ''healthy'' cheese products.

Sodium content was probably not the primary factor in the decision to take ''healthy'' cheeses off the market. Many light mozzarella cheeses, for example, currently have sodium content lower than the second-tier sodium level—between 167 and 357 mg sodium per 50 g cheese in our examples from Washington, DC, area grocery stores (Ref. 15). The ''healthy'' version of this cheese was among the most popular sellers among all ''healthy'' cheeses but was still pulled from the market (Ref. 8).

Soups. Costs associated with the current rule, and therefore benefits of avoiding these costs under option 2a, would be substantial for soups. According to a comment on the 2003 proposed rule, ''healthy'' soups had about a 7 percent share of market sales in 2003, and a major producer of ''healthy'' soups stated that its products would likely be discontinued under the second-tier levels. The producer provided evidence in the form of taste tests and survey results for soups containing 360 mg of sodium per serving. The taste tests and survey results indicated that the products would be unsuccessful. Further, ''healthy'' soups with sodium levels near or at 480 mg/serving held around 8 times the market share of ''healthy'' soups with sodium levels near 360 mg per serving. This evidence shows that major producers of ''healthy'' soups would probably either cease producing some or all of their ''healthy'' soups or remove the ''healthy'' claim from product labels rather than reformulate down to 360 mg sodium per serving.

Producers would have to spend resources to reformulate their products to meet the second-tier sodium level. Lost market share due to product reformulation would not be a net loss, but rather a transfer from one company to another. Reformulation costs themselves are the lower limit of the cost to society of allowing the second-tier levels to take effect. If producers could reformulate perfectly, without altering any characteristic of the product other than sodium content, then reformulation would be the total cost of the second-tier levels. But if they could not replicate the desirable characteristics of their product, consumers would also suffer the utility loss of a market with fewer product choices for those who want to buy processed foods that contribute to better nutrition and health in several ways, not solely with respect to sodium content.

FDA lacks data needed to predict how ''healthy'' soup producers would respond to the implementation of the second-tier level of sodium for individual foods. However, a comment to the proposal provided data showing that in 2003, two brands making up more than 90 percent of the ''healthy'' soup market had significantly more than the second-tier levels of sodium in their products. Each of these soups had sodium content at or near the first-tier level of 480 mg/serving. One of these producers stated that it could achieve taste parity for soups reformulated to meet the second-tier sodium level; the other said that it would be forced to discontinue its line of ''healthy'' soups if the second-tier sodium level went into effect. Both of these producers had a similar market share in their respective markets (one in ready-to-eat soup and the other in condensed soup). Therefore, FDA assumes that 50 percent of the 30 products produced by these brands would be reformulated to meet the second-tier level. The other 50 percent of the ''healthy'' soups in these brands would be marketed without the ''healthy'' claim (and possibly also reformulated to increase the sodium content of the soups) or would be discontinued completely. Because the assumption of 50 percent reformulation is uncertain, we also show the costs for 25 percent reformulation and 75 percent reformulation in table 1 of this document.

TABLE 1.—BENEFITS OF AVOIDED COSTS DUE TO OPTION 2A (IN MILLIONS)

Level of Reformulation	50%	25%	75%
Initial Annual Costs Avoided (First 2 Years)	$20.77	$27.97	$13.80
Long Run Annual Costs Avoided	$17.47	$26.21	$8.74

We do not have detailed reformulation cost estimates for each food category. The following reformulation cost estimations are based on a detailed example of tortilla chip reformulation (see 64 FR 62745 at 62781 to 62782, November 17, 1999), but the steps are typical of food reformulation in general.

Reformulation typically starts in a laboratory, where researchers develop a new, lower sodium formula for their product. Then the company investigates availability and price of new ingredients (herbs, for example) and new equipment. If the reformulated food passes these obstacles, it moves to the test kitchen, where researchers produce the product in small batches. If approved at this level, the product graduates to a pilot plant. Cooking the product in large runs at the pilot plant may prove unsuccessful and require a manufacturer to restart the reformulation process, incurring additional expense. However, if pilot plant tests go well, full scale plant trials commence.

For reformulation of an individual food, FDA assumes 5,000 hours of professional time at $30 per hour, $190,000 for development and pilot plant operating expenses, and $100,000 for market testing per product, based on this industry example. Since this reformulation would be undertaken to keep the ''healthy'' claim on an existing product, we assume negligible relabeling or marketing costs. The total reformulation costs are therefore $440,000 per product, or $6.60 million for the 15 products assumed to be reformulated if ''healthy'' soup producers reformulate 50 percent of their products (reformulation costs are $3.52 million for 8 products under 25 percent reformulation and $10.12 million for 23 products under 75 percent reformulation). This cost would be incurred in the first year or two after the effective date of the rule. Assuming 50 percent of the cost is incurred per year for 2 years, and ignoring the time discount, the cost is $3.3 million per year.

Regardless of the relative costs of reformulation, FDA assumes that a substantial number of market participants will choose to rebrand or relabel their products out of the ''healthy'' category if it becomes too restrictive. This shift has already happened in some product categories

under the current first-tier level: The number of ''healthy'' meals and main dish products dropped from 210 to 148 from 1993 through 1999, and the number of ''healthy'' brands dropped from 13 to 10. This time period spans the adoption of the current definition of ''healthy'' in 1994.

If producers remove ''healthy'' from product labels as a result of the second-tier sodium levels, the direct costs of relabeling the product and conducting a marketing campaign are social costs, since they represent extra investment that does not increase or improve the choice of products for consumers. Although FDA has no information about the costs of this type of rebranding activity to the manufacturer, they are most likely substantial.

The market puts a premium on ''healthy'' brands and products. This premium reflects what consumers are willing to pay for the ''healthy'' signal. Since consumers would presumably be paying less for a less valuable product, the total effect of rebranding on consumer utility is negative but limited. However, firms have made an investment in the ''healthy'' brand based on an expected return closely related to the ''healthy'' premium consumers are willing to pay, and this investment would now be worthless if the product cannot use the ''healthy'' claim.[9] In the impacts analysis of the original regulation defining ''healthy'' (59 FR 24232 at 24247, May 10, 1994), FDA estimated that the average premium (measured as the selling price difference) that the market placed on ''healthy'' brand goods was $0.57 per 16 ounce (oz) equivalent. FDA used a Washington, DC store sample of 106 frozen meals and main dishes referred to earlier to reestimate this premium using data collected in 2000, with similar results (Ref. 15).

According to the analysis in FDA's technical memorandum (Ref. 15), the ''healthy'' brand competitor had a significant $0.32 premium over the other major health positioned producer in this market, and at least as high a premium over the other major claims producer. Adjusting for serving size (10 oz in the products sampled), the $0.32 premium translates to a $0.51 premium per 16 oz, which is very close to the $0.57 premium estimated in 1994.

We estimate the total value of each brand by multiplying the premiums and average sales volumes. According to a comment on the 2003 proposed rule, sales of ''healthy soups'' still on the market were approximately 3.64 million units per product in 2003. Under the assumption of 50 percent loss of ''healthy'' soups if the second-tier sodium level requirement were to go into effect, 15 products would be taken off the market, either by rebranding or relabeling them out of the ''healthy'' category or by discontinuing them altogether, with a total lost premium of $17.47 million per year (15 products x $0.32 premium lost x average sales of 3.64 million units per product per year).

Adding this lost utility to the cost of reformulating the other 15 ''healthy'' soup products yields a total cost estimate of $20.77 million for years one and two, and a residual of the lost premium of $17.47 million for what would have been the rest of the normal life cycle of the lost ''healthy'' claim. These costs and the costs under 25 percent and 75 percent reformulation assumptions are shown in table 1 of this document. Avoiding these costs represents a large benefit of option 2a.

Option 2b: Retain the First-Tier Sodium Level for Meals and Main Dishes.

Costs of Option 2b. The cost of this option, as in option 2a for individual foods, is the increased health risk due to higher sodium intake. However, FDA finds that option 2b will not significantly affect the average amount of sodium consumed in an overall diet. The net increase in sodium intake under option 2b is insubstantial even under the most favorable assumptions of the effects of the current rule. Under some plausible scenarios, the average amount of sodium consumed could remain the same or actually increase if the current rule were implemented without amendment (i.e., under option 1).

To gather data for our impact analysis, in 1999 we took a sample of 106 frozen meals and main dishes from a Washington, DC area grocery store (Ref. 15). This sample was intended to be reasonably representative of the U.S. prepared dinner market, although it may not encompass all meal and main dish choices available nationwide. We also tested these results with a second Web-based sample in 2000 (Ref. 15). Based on data collected in the grocery store sample, the market for meals and main dishes can be characterized as having three segments. The first is the bargain segment, with two or three producers that offer basic meals, usually priced from $1 to $1.50 lower than the average product on the market. The second segment, or ''normal'' market, also has two or three major producers, with prices ranging from slightly lower to the same as the health-positioned goods in the third segment. Products in the second segment appear to compete mainly on taste or price rather than health attributes, although such products sometimes make health-related or dietary claims (e.g., ''low fat''). The third segment is the ''claims'' segment, which includes the ''healthy'' branded products, low fat products, and more expensive specialty products such as organic meals and main dishes. Many of these products prominently display fat and calorie information on the front of the package; these products clearly use nutritional content as a marketing tool.

According to our analysis set forth in a technical memorandum (Ref. 15), the ''healthy'' branded goods have the lowest average sodium content among the ''claims'' brands and the lowest average sodium content on the market. On average, they have 42 mg less sodium per meal than their next lowest competitor. Both the ''healthy'' branded goods and their main competitor that does not make ''healthy'' claims have average sodium levels under the first-tier limit of 600 mg for meals and main dishes.

We explored several possible consumer and producer responses to option 2b (retaining the first-tier sodium level for meals and main dishes only) as compared with option 1 (allowing the second-tier sodium level to go into effect for all foods) in the following scenarios. If FDA adopted option 1, firms would respond to the imposition of the second-tier sodium level for meals and main dishes in a strategic way. Producers of ''healthy'' brands would either reformulate their products to meet the second-tier level, or relabel their products without the ''healthy'' claim or the ''healthy'' brand name. The concern here is the consumer response to these actions. Reformulated products may be less palatable or more expensive, leading to a loss of market share. Rebranded (or relabeled) products would no longer carry the ''healthy'' claim and therefore would not be subject to a sodium limit. Indeed, several comments expressed concern that lowering the sodium requirement to the second-tier level could encourage consumers to switch to higher sodium alternatives.

The possible scenarios are summarized in table 2 of this document.

[9] If the new definition of ''healthy'' with the second-tier sodium level is no more useful a health signal than the old definition, this lost investment is a cost to society. However, as we explain under the *Costs of Option 2a*, the health signal may be better under the second-tier sodium level for individual foods. This health signal strength may have significant value, and its loss should be netted out of the ''willingness to pay'' premium. However, FDA believes the loss in value of healthy products due to decreased strength of signal, though possibly significant, is not substantial. Therefore the ''willingness to pay'' premium estimated here, though an upper bound, should closely resemble the actual benefit of keeping these products on the market by retaining the first-tier sodium levels.

The first number in each cell is the average amount of sodium in mg and the second number in parentheses is the market share for each brand. The average sodium content amounts of 551 mg, 593 mg, 722 mg, and 856 mg per meal come from an analysis explained in the technical memorandum (Ref. 15). The ''healthy'' brand has slightly over 9 percent of the total frozen dinner meal market when measured by sales volume, and the non-''healthy'' brand 1 in the ''claims'' segment of the market has 10.5 percent. Nonfrozen meals and main dishes, including chili, are also important in the overall market, but 99 percent of the sales of the ''healthy'' brand and 100 percent of the sales of ''claims'' brand 2 are in the frozen meal category. The ''other'' brands in table 2 of this document represent the normal and bargain market segments previously described in this document. We assume that the three ''claims'' brands in this analysis are a reasonable approximation to the ''claims'' market segment as previously described in this analysis. Each of their shares in the total market is divided by the sum of the shares of the three brands in the total market, which makes their market shares in the ''claims'' segment of the market (45 percent + 52 percent + 3 percent) equal to 100 percent.

TABLE 2.—SODIUM CONSUMPTION SCENARIO ANALYSES FOR 1999 SAMPLE OF MEALS AND MAIN DISHES AS ESTIMATED IN PROPOSED RULE

Scenario	Healthy Brand	Claim Brand 1	Claim Brand 2	Other	
	Sodium (Market Share)	Sodium (Market Share)	Sodium (Market Share)		Average Sodium (mg)
1. Market Before 2003 Proposed Rule	551 (.45)	593 (.52)	722 (.03)	856 (0)	579
2. Perfect Reformulation (option 1)	476 (.45)	593 (.52)	722 (.03)	856 (0)	544
3. Switch Point, Random Share Loss (option 1)	476 (.45-.142)	593 (.52+.047)	722 (.03+.047)	856 (.047)	579
4. Switch Point, Equal Share Loss to Health (option 1)	476 (.45-.193)	593 (.52+.097)	722 (.03+.097)	856 (0)	579
5. Reformulation Up (option 2b)	600 (.45)	593 (.52)	722 (.03)	856 (0)	600
6a. Combined Response to option 1	480 (.45-.113)	593 (.52+.056)	722 (.03+.056)	856 (0)	566
6b. Combined Response to option 2b	580 (.45+.04)	593 (.52-.02)	722 (.03-.02)	856 (0)	588
Total Effect (6b—6a)					22

Since option 1, or not amending the current rule, is the baseline for exploring the effect of option 2b, the first five scenarios are designed to demonstrate how different responses to option 1 (the current rule) and option 2b (the proposed rule) affect the average amount of sodium consumed in meals and main dishes. Scenarios 6a and 6b combine the responses in the previous scenarios in an attempt to capture the total effect of option 2b. The last row, in the last column, is the total change in sodium when comparing the response to option 2b (6b) to the response to option 1 (6a) (scenario 6-''total effect'').

Scenario 1: The Market Before the 2003 Proposed Rule. The first-tier sodium level applies until 2006, but firms, particularly before publication of the 2003 proposed rule, may have been trying to prepare for the second-tier sodium level, causing the average amount of sodium in the ''healthy'' products to be lower than it will be under the final rule.[10] The average ''claims'' segment meal, as reported in the last column of table 2 of this document, contained 579 mg sodium, the average ''healthy'' brand meal contained 551 mg sodium, and several ''healthy'' brand meals in this sample were under the second-tier sodium level of 480 mg sodium.

Scenario 2: Perfect Reformulation. Under the very optimistic perfect reformulation assumption, where the ''healthy'' manufacturer could replicate every aspect of its product except the sodium level, the sodium level of the average ''claims'' segment meal would decrease to 544 mg ((476 * 45 percent) + (593 * 52 percent) + (722 * 3 percent)) under option 1. The difference between this and the current market is 1.5 percent of the DRV for sodium, which is 2,400 mg per day (§ 101.9(c)(9)).

Scenario 3: Random Loss of Market Share. Some ''healthy'' brand consumers may switch to other products if manufacturers of ''healthy'' products cannot perfectly reformulate their products. In this scenario, the ''healthy'' brand loses market share to each of its competitors and to the rest of the market (''other'' brands) in equal amounts. If the loss of market share is small, sodium levels will still decline under option 1. However, the average sodium level per meal and per main dish would not change if the ''healthy'' brand lost 32 percent of its market (14 percent of the ''claims'' market) under these assumptions.

Scenario 4: Loss of Market Share to Claims Competitors. Consumers are likely to switch from ''healthy'' products to other products bearing claims. For example, consumers concerned with the sodium content of what they eat might switch to a product

[10] As already described in detail in this document, the baseline market conditions for the purpose of the regulatory analysis are those that existed prior to the publication of the 2003 proposed rule. Costs and benefits accrued during the rulemaking process, e.g. as a result of the publication of the 2003 proposed rule, must be accounted for in the analysis.

labeled as ''low sodium'' or ''reduced sodium.'' Since these alternatives have less sodium than the rest of the frozen foods market, the amount of ''healthy'' business lost that would still leave average sodium levels lower or unchanged would be higher than in scenario 3 under option 1. If the ''healthy'' brand lost 43 percent of its market share (which is smaller than the 45 percent of their products one major producer of ''healthy'' products stated the second-tier level would adversely affect) equally to both ''claims'' competitors, the average ''claims'' segment meal's sodium content would be unchanged at 579 mg.

Scenario 5: Reformulation Up to First-Tier Limit. Here, we assume only the possibility that the second-tier restrictions will become effective discourages the ''healthy'' product from increasing the amount of sodium up to the first-tier limit. Therefore, under option 2b, every ''healthy'' meal and main dish would contain 600 mg of sodium per meal.[11] The average meal and main dish in the ''claims'' market would increase to 600 mg as well, which is 21 mg per meal more than the current amount and 56 mg more than the total under scenario 2, the most optimistic, perfect reformulation total.

Scenario 6: Total Effect. Scenario 6, which is scenario 6a (combined total response to option 1) subtracted from scenario 6b (combined total response to option 2b), represents the agency's estimate of the total effects of option 2b, which would adopt as permanent the first-tier sodium level for ''healthy'' meals and main dishes. In scenarios 6a and 6b, we make behavioral assumptions for both option 1 and option 2b.

Scenario 6a: Combined Total Response to Option 1. Of the ''healthy'' meals and main dishes in this sample, 75 percent are above and 25 percent are below the second-tier sodium level of 480 mg.[12] If the second-tier sodium level were to take effect, we assume that the meals and main dishes already below 480 mg (25 percent of the total) would be reformulated up to 480 mg. Based on comments to the 1997 ANPRM, we assume that 37.5 percent of all ''healthy'' meals and main dishes (one-half of the 75 percent of ''healthy'' meals and main dishes currently above 480 mg) would be reformulated down to 480 mg of sodium without a loss of taste. An additional 19 percent of all ''healthy'' meals and main dishes (one-fourth of the 75 percent of ''healthy'' meals and main dishes currently above 480 mg) would be reformulated even though the reformulation would lead to some loss of taste. The remaining 19 percent of all healthy meals and main dishes (one fourth of the 75 percent of ''healthy'' meals and main dishes currently above 480 mg) would either have ''healthy'' removed from the label or cease being produced.

The total response of producers to the second-tier level of 480 mg would therefore be:

- Producers increase the sodium level to 480 mg for the 25 percent of ''healthy'' meals and main dishes that are currently below 480 mg of sodium.
- Producers reduce the sodium level to 480 mg for 56 percent of ''healthy'' meals and main dishes (37.5 percent with no loss of taste, 19 percent with some loss of taste).
- Producers either drop ''healthy'' from the label or cease producing 19 percent of all ''healthy'' meals and main dishes.

In this scenario, consumers respond to the loss of taste and disappearance of products by switching choices within the ''claims'' segment of the market, which includes ''healthy'' and similar meals and main dishes. They switch with equal probability to any one of the three brands in the ''claims'' segment, which means that one-third will switch to another ''healthy'' branded product and two-thirds will switch to products outside the ''healthy'' brand. The market share loss of the ''healthy'' brand is therefore 25 percent of its market, or two-thirds of the 37.5 percent of the market that experiences loss of taste, or disappearance of products. This is 11.3 percent of the total ''claims'' market. The average sodium intake implied by the market activity in this scenario under option 1 is 566 mg per meal.

Scenario 6b: Combined Total Response to Option 2b. We assume that producers will reformulate most, but not all, of the ''healthy'' products to the first-tier limit. We believe producers of ''healthy'' products will choose to position themselves as a slightly lower sodium alternative in this market, as they are currently positioned, but reformulate to increase sodium to improve taste. Because of improved taste, these producers increase their market share by 10 percent under this scenario, so the average sodium intake under the proposed amendment would be 588 mg per meal.

The difference between scenarios 6a and 6b gives us the difference in average sodium consumption between option 2b and option 1, the baseline. This amount, 22 mg sodium per meal, is the best estimate of the ''sodium cost'' of option 2b.

FDA's technical memorandum (Ref. 15) repeats the basic parts of this analysis for a second sample of products from the Web sites of a producer of ''healthy'' products and a ''claims'' segment producer, which we performed as a stress test[13] of the first sample conclusions. The result from this different sample of meal products is quite close to the 22 mg ''sodium cost'' calculated in scenario 6 of table 2 of this document.

According to our analysis, the sodium increase under option 2b would be insubstantial. Almost all studies linking sodium's influence on hypertension, coronary heart disease, and stroke consider the effect of a change in sodium consumption two orders of magnitude larger than these changes. A 100 millimole (mmol) (2,300 mg) difference per day is typical in both clinical and epidemiological studies; these studies do not address the relative dose-response relationship of the small sodium intake differences found in the scenarios. Even if the effect were linear (i.e., even if the health risk associated with the mg change per day in sodium under option 2b were a simple percentage of the 2,300 mg risk), the total statistical lives saved by implementing the second-tier sodium level for meals and main dishes would be less than 1 under the total effects calculation in table 2 of this document and in the results of the second sample (Ref. 15). Since FDA does not assume a linear health response to sodium intake, however, the agency concludes that the health effects from this low level of sodium increase are negligible.

Benefits of Option 2b. In the analysis of market data for the 2003 proposed rule, FDA identified 148 meals and main dishes labeled ''healthy'' among 10 brands (see 68 FR 8163 at 8169). Under option 1 (no amendment to the current rule), manufacturers would have to reformulate their products (meals and main dishes in this case) to meet the second-tier sodium level when the stay expires. Reformulation costs would be the lower limit of the cost to society of the current rule. If producers could reformulate perfectly, without altering any property other than sodium content, then reformulation would be the total cost of option 1. But if they could not

[11] Note that since the publication of the 2003 proposed rule, in which FDA proposed to make the first-tier sodium level for meals and main dishes permanent, many meal and main dish products may have already been reformulated to contain exactly or nearly 600 mg of sodium per meal.

[12] Again, these are numbers from 1999, before this rulemaking began. Some products may have been reformulated since then.

[13] A stress test is performed to see if the model results hold using a different data sample.

replicate the desirable characteristics of their product, consumers would also suffer the utility loss of a market with fewer meal choices.

In the product samples used for the scenario analyses regarding the cost of the second-tier sodium level for meals and main dishes, a significant percentage (around 75 percent in the store-based sample and 50 percent in the Web site sample) of the major ''healthy'' producer's products were above the second-tier sodium levels. If this sample represents the market as a whole, then approximately 74 to 111 products would need to reduce their sodium to meet the second-tier level. In estimating the total effects of the second-tier sodium level on meals and main dishes, we assumed that 56 percent, or 83 of the 148 products on the market (see scenario 6a in table 2 of this document), would be reformulated.

Preliminary testing costs incurred in the first stage of reformulation—according to comments on the ANPRM received from a frozen meal ''healthy'' brand producer that had begun investigating possible reformulation—were well over $1 million, but we do not have detailed reformulation cost estimates for meals and main dishes. Consistent with its estimate for individual foods (see discussion under ''Benefits of Option 2a''), FDA assumes that reformulating a meal or main dish would require 5,000 hours of professional time at $30 per hour, $190,000 for development and pilot plant operating expenses, and $100,000 for market testing per product. Since this reformulation would be undertaken to keep the ''healthy'' claim on an existing product, we assume negligible relabeling or marketing costs. The total reformulation costs are therefore $440,000 per product, or $36,520,000 for the 83 meals assumed to be reformulated if adopting the second-tier sodium levels for meals and main dishes under scenario 6a. Assuming 50 percent of the cost is incurred per year for 2 years, and ignoring the time discount, the cost is $18,260,000 per year.

The agency assumes that a substantial number of market participants would choose to rebrand or relabel their products out of the ''healthy'' category if it becomes too restrictive. As with option 2a, the direct costs of relabeling the product and conducting a marketing campaign would be social costs, since they represent extra investment that will not increase or improve the choice of products for consumers. Although FDA has no information about the costs of this type of rebranding activity, they are probably substantial. As discussed in the analysis of the benefits of option 2a in this document, there will also be a $0.32 per unit premium loss on ''healthy'' products no longer on the market. Sales of the brands still in the market were approximately 1.3 million units per product in 1999 (Ref. 8). Under the assumption of 19 percent loss of ''healthy'' meals and main dishes if the second-tier sodium level goes into effect (scenario 6a), 28 products would be taken off the market, either by rebranding or relabeling them out of the ''healthy'' category or by discontinuing them altogether, with a total lost premium of $11,648,000 per year (28 products x $0.32 premium lost x average sales of 1.3 million units per year).

Adding this cost to the reformulation costs of the 83 products yields a total cost estimate of $29.90 million for years one and two, and a residual of the lost premium of $11.65 million for what would have been the rest of the normal life cycle of the lost ''healthy'' brand. Avoiding these costs represents a large benefit of option 2b.

Option 2c: Retain the First-Tier Sodium Levels for ''Healthy'' Meals and Main Dishes and Individual ''Healthy'' Foods (the Final Rule). The benefits and costs of option 2c are close to the sum of the benefits and costs associated with options 2a and 2b. However, as explained in the discussion of option 2a, retaining the first-tier sodium levels for ''healthy'' individual foods would decrease the consistency, relative to option 2b, between sodium levels in ''healthy'' meals and main dishes and the sodium levels in meals put together by combining ''healthy'' individual foods.

Costs of Option 2c. The cost of this option, as with option 2a for individual foods and option 2b for meals and main dishes, is the increased risk due to higher sodium intake and the diminishing effectiveness of the ''healthy'' claim as a signal to identify products that contain strictly controlled levels of sodium. Since option 2c is essentially combining options 2a and 2b, the costs associated with a higher sodium intake are roughly the sum of the costs associated with options 2a and 2b.

As explained in detail in the discussion of option 2b of this document, the average increase in sodium intake occurring under option 2b relative to option 1 is insubstantial (roughly 22 mg per meal), and the health effects from this low level of sodium increase are negligible. Even under the conservative assumption of a linear dose response, the statistical lives saved by decreasing allowable sodium in ''healthy'' meals and main dishes to second-tier levels would be less than 1.

As discussed in detail under option 2a of this document, the potential change in sodium intake occurring under option 2a (relative to option 1) due to retaining the less restrictive first-tier level of sodium allowable in individual foods labeled as ''healthy,'' is uncertain. Because most individual foods are not restricted in formula under either sodium level, and because consumers may turn to higher sodium alternatives if the sodium level requirement becomes too restrictive for certain products (soups, cheeses, pasta sauces), the net increase in sodium will probably be small. Furthermore, the health costs due to a small increase in sodium intake will be largely mitigated by retaining a greater number of choices of relatively healthy foods (low in fat and saturated fat, controlled in cholesterol and sodium, and a good source of one or more beneficial nutrients).

Therefore, the costs of option 2c resulting from the reduced effectiveness of the ''healthy'' claim as a signal of foods with strictly controlled sodium and the health risks due to a potential increase in total sodium intake, though uncertain, are likely to be small.

Benefits of Option 2c. The benefits of avoiding reformulation, rebranding, and relabeling costs under this option are roughly the sum of the benefits associated with options 2a and 2b.

As discussed in the benefits section of option 2a of this document, the benefits of avoiding reformulation, rebranding, and relabeling costs by retaining first-tier sodium levels for ''healthy'' individual foods are substantial. FDA estimates the total cost avoided under option 2a to be $20.77 million for years one and two, and a residual of the lost premium of $17.47 million for what would have been the rest of the normal life cycle of the lost ''healthy'' products.

The benefits of avoiding reformulation, rebranding, and relabeling costs by retaining first-tier sodium levels for ''healthy'' meals and main dishes are also substantial. FDA estimates the total cost of reformulation and relabeling avoided under option 2b is $29.90 million for years one and two, and $11.65 million per year thereafter.

The total benefits of option 2c from the avoided reformulation and relabeling costs associated with implementing the second-tier sodium levels for both ''healthy'' meal and main dish products and ''healthy'' individual foods are equal to the sum of the benefits of options 2a and 2b: $50.67 million for years one and two, and $29.12 million per year thereafter.

Net Benefits of Option 2c. The net benefits of option 2c, retaining the first-tier level of sodium for both ''healthy'' meal and main dish products and ''healthy'' individual foods, are roughly the sum of the net benefits of options 2a and 2b.

Since the net benefits of retaining the first-tier sodium level for both ''healthy'' individual foods and ''healthy'' meal and main dish products are substantial and positive, FDA concludes that the net benefits of 2c, roughly the sum of the net benefits associated with 2a and 2b, are substantial and positive, and higher than the net benefits of the other options. Therefore, net benefits are maximized by option 2c, the final rule, which adopts the first-tier sodium levels for both individual foods and for meals and main dishes.

3. Summary of Benefits and Costs

This analysis attempts to use limited data to illustrate in some detail what would take place in the market under this final rule (option 2c) and other regulatory alternatives. The analysis for both ''healthy'' meals and main dishes and ''healthy'' individual foods shows that while the benefits of retaining the first-tier sodium level (the costs foregone) are substantial for companies that would need to reformulate to comply with the second-tier sodium level or rebrand and relabel themselves out of the ''healthy'' market, the health costs associated with retaining the first-tier sodium level are both unquantifiable and most likely insubstantial. The benefits of the foregone reformulation, rebranding, and relabeling costs, and the health benefits of keeping available a greater choice of goods that are simultaneously low in fat and saturated fat, controlled in cholesterol and sodium, and a good source of beneficial nutrients, clearly outweigh the costs due to a small loss in the strength of the ''healthy'' sodium signal and a small increase in average daily sodium intake. Therefore, the net benefits of the rule, which would adopt as permanent the first-tier sodium level for all foods, are positive.

B. Small Entity Analysis

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA finds that this final rule would not have a significant economic impact on a substantial number of small entities.

This final rule makes permanent the first-tier sodium level of 600 mg for meals and main dishes and 480 mg for individual foods. Without this final rule, the more restrictive second-tier sodium levels would raise the costs of making a ''healthy'' claim on such products. If a small business were to market a ''healthy'' meal, main dish, or individual food, it would be able to do so at lower cost under the final rule than if FDA left the current rule unmodified. FDA therefore certifies that this final rule will not have a significant impact on a substantial number of small entities.

C. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement that includes an assessment of anticipated costs and benefits before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1–year expenditure that would meet or exceed this amount.

VI. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. References

The following references have been placed on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Department of Agriculture and Department of Health and Human Services, ''Dietary Guidelines for Americans'' 5th ed., U.S. Government Printing Office, Washington, DC, 2000.

2. Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate, chapter 6, ''Sodium and Chloride'' pp 269–423. Panel on Dietary Reference Intakes for Electrolytes and Water, Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine of the National Academies, The National Academies Press 2004.

3. ''Dietary Guidelines for Americans 2005'' U.S. Department of Health and Human Services, U.S. Department of Agriculture *www.healthierus.gov/dietaryguidelines*.

4. MyPyramid.gov, U.S. Department of Agriculture first available 2005 at *http://www.mypyramid.gov*

5. Letter from Carl A. Roth, Associate Director for Scientific Program Operation, to William Kovaks, Vice President Environment, Technology, & Regulatory Affairs, Chamber of Commerce of the United States of America, and Richard Hanneman, President, The Salt Institute, August 19, 2003, *http://aspe.hhs.gov/infoquality/request&response/reply_8b.shtml*.

6. Letter from Barbara Alving, Acting Director to William Kovaks, Vice President Environment, Technology, & Regulatory Affairs, Chamber of Commerce of the United States of America, and Richard Hanneman, President, The Salt Institute, February 11, 2004, *http://aspe.hhs.gov/infoquality/request&response/reply_8d.shtml*.

7. Calories Count Report of the Working Group on Obesity March 12, 2004, *http://www.cfsan.fda.gov/~dms/owg-toc.html*.

8. Anderson, Ellen M., memorandum to file, September 3, 2002.

9. Anderson, Ellen M. and Heili Kim, memorandum to file, August 30, 2001.

10. ''Healthy Choice Total Franchise Sales vs. Total Food Sales (IRI)'' Exhibit 3A to ConAgra Comment C 127 to 91N–384H.

11. ''Trends in the United States, Consumer Attitudes and the Supermarket 1996,'' Conducted for the Food Marketing Institute By Abt Associates Inc., Published by The Research Department, Food Marketing Institute, Washington, DC.

12. ''Healthy Choice Soup 2003 Taste Test Results'' Exhibit 4 to ConAgra Comment C 127 91N–384H.

13. ''Soup Category Sales Breakdown'' Exhibit 5 to ConAgra Comment C 127 to 91N–384H.

14. National Partnership for Reinventing Government, Plain Language Action Network, Presidential Memorandum on Plain Language, *http://www.plainlanguage.gov/whatisPL/govmandates/memo.cfm*.

15. Mancini, Dominic, memorandum to file, May 23, 2002.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. Section 101.65 is amended by revising paragraph (d) to read as follows:

§ 101.65 Implied nutrient content claims and related label statements.

* * * * *

(d) *General nutritional claims.* (1) This paragraph covers labeling claims that are implied nutrient content claims because they:

(i) Suggest that a food because of its nutrient content may help consumers maintain healthy dietary practices; and

(ii) Are made in connection with an explicit or implicit claim or statement about a nutrient (e.g., ''healthy, contains 3 grams of fat'').

(2) You may use the term ''healthy'' or related terms (e.g., ''health,'' ''healthful,'' ''healthfully,'' ''healthfulness,'' ''healthier,'' ''healthiest,'' ''healthily,'' and ''healthiness'') as an implied nutrient content claim on the label or in labeling of a food that is useful in creating a diet that is consistent with dietary recommendations if:

(i) The food meets the following conditions for fat, saturated fat, cholesterol, and other nutrients:

If the food is...	The fat level must be...	The saturated fat level must be...	The cholesterol level must be...	The food must contain...
(A) A raw fruit or vegetable	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(B) A single-ingredient or a mixture of frozen or canned fruits and vegetables[1]	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(C) An enriched cereal-grain product that conforms to a standard of identity in part 136, 137 or 139 of this chapter	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(D) A raw, single-ingredient seafood or game meat	Less than 5 grams (g) total fat per RA[2] and per 100 g	Less than 2 g saturated fat per RA and per 100 g	Less than 95 mg cholesterol per RA and per 100 g	At least 10 percent of the RDI[3] or the DRV[4] per RA of one or more of vitamin A, vitamin C, calcium, iron, protein, or fiber
(E) A meal product as defined in § 101.13(l) or a main dish product as defined in § 101.13(m)	Low fat as defined in § 101.62(b)(3)	Low saturated fat as defined in § 101.62(c)(3)	90 mg or less cholesterol per LS[5]	At least 10 percent of the RDI or DRV per LS of two nutrients (for a main dish product) or of three nutrients (for a meal product) of: vitamin A, vitamin C, calcium, iron, protein, or fiber
(F) A food not specifically listed in this table	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	At least 10 percent of the RDI or the DRV per RA of one or more of vitamin A, vitamin C, calcium, iron, protein or fiber

[1] May include ingredients whose addition does not change the nutrient profile of the fruit or vegetable.
[2] RA means Reference Amount Customarily Consumed per Eating Occasion (§ 101.12(b)).
[3] RDI means Reference Daily Intake (§ 101.9(c)(8)(iv)).
[4] DRV means Daily Reference Value (§ 101.9(c)(9)).
[5] LS means Labeled Serving, i.e., the serving size that is specified in the nutrition information on the product label (§ 101.9(b)).

(ii) The food meets the following conditions for sodium:

If the food is...	The sodium level must be...
(A) A food with a RA that is greater than 30 g or 2 tablespoons (tbsp.)	480 mg or less sodium per RA and per LS
(B) A food with a RA that is equal to or less than 30 g or 2 tbsp.	480 mg or less sodium per 50 g[1]
(C) A meal product as defined in § 101.13(l) or a main dish product as defined in § 101.13(m)	600 mg or less sodium per LS

[1] For dehydrated food that is typically reconstituted with water or a liquid that contains insignificant amounts per RA of all nutrients (as defined in § 101.9(f)(1)), the 50 g refers to the ''prepared'' form of the product.

(iii) The food complies with the definition and declaration requirements in this part 101 for any specific nutrient content claim on the label or in labeling, and

(iv) If you add a nutrient to the food specified in paragraphs (d)(2)(i)(D), (d)(2)(i)(E), or (d)(2)(i)(F) of this section to meet the 10 percent requirement, that addition must be in accordance with the fortification policy for foods in § 104.20 of this chapter.

Dated: September 23, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 216 and 218

RIN 1010–AD28

Royalty Payment and Royalty and Production Reporting Requirements Relief for Federal Oil and Gas Lessees Affected by Hurricane Katrina or Hurricane Rita

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: The Minerals Management Service (MMS) is publishing a final rule to provide immediate temporary relief to reporters in the aftermath of Hurricanes Katrina and Rita. The final rule provides an extension to pay royalties owed on Federal oil and gas leases and report corresponding royalty and production reports. On August 29, 2005, Hurricane Katrina struck the Gulf of Mexico coast of the United States. Subsequently, in late September 2005, Hurricane Rita struck the Gulf Coast. Both hurricanes caused extensive damage to areas in which a number of Federal oil and gas lessees, particularly lessees of offshore leases, have their offices and principal operations. This final rule extends the due date for monthly royalty payments and reports and monthly operations reports for Federal oil and gas lessees, royalty payors, and operators whose operations have been disrupted by one or both of the hurricanes to the extent that the lessee, payor, or operator is prevented from submitting accurate payments or accurate reports. Extending the due date for royalty payments means that late payment interest will not accrue for the period between the original due date and the new due date established by this rule.

DATES: Effective date: September 29, 2005.

FOR FURTHER INFORMATION CONTACT: Sharron L. Gebhardt, Lead Regulatory Specialist, Minerals Revenue Management (MRM), Minerals Management Service, P.O. Box 25165, MS 302B2, Denver, Colorado 80225; telephone (303) 231–3211; FAX (303) 231–3781; e-mail *sharron.gebhardt@mms.gov.* The principal authors of this final rule are Geoffrey Heath of the Office of the Solicitor and Robert Prael of MRM, MMS, U.S. Department of the Interior.

SUPPLEMENTARY INFORMATION:

I. Background

A. Lease Royalty Reporting, Royalty Payment and Production Reporting Obligations

Applicable regulations and the terms of Federal oil and gas leases prescribe the dates by which lessees must pay royalty and by which they must submit required royalty reports. Specifically, 30 CFR 218.50(a) requires:

Royalty payments are due at the end of the month following the month during which the oil and gas is produced and sold except when the last day of the month falls on a weekend or holiday. In such cases, payments are due on the first business day of the succeeding month. * * *

The terms of almost all onshore and offshore Federal oil and gas leases likewise provide that royalty is due at the end of the month following the month of production.

Section 111(a) of the Federal Oil and Gas Royalty Management Act of 1982 (FOGRMA), 30 U.S.C. 1721(a), prescribes that lessees must pay interest on royalty payments received after the due date. Section 1721(a) provides in relevant part:

(a) In the case of oil and gas leases where royalty payments are not received by the Secretary *on the date that such payments are due*, or are less than the amount due, the Secretary shall charge interest on such *late payments* or underpayments at the rate applicable under section 6621 of the Internal Revenue Code * * *. (Emphasis added.)

Implementing MMS regulations at 30 CFR 218.54 prescribe in relevant part:

(a) An interest charge shall be assessed on unpaid and underpaid amounts *from the date the amounts are due.*

* * * * *

(c) Interest will be charged only on the amount of the payment not received. *Interest will be charged only for the number of days a payment is late.* (Emphasis added.)

Title 30 CFR 210.52 prescribes similar requirements for the reports that accompany royalty payments. It provides in relevant part:

(a) You must submit a completed Form MMS–2014 (Report of Sales and Royalty Remittance) to MMS with:

(1) All royalty payments * * *

* * * * *

(c) Completed Forms MMS–2014 for royalty payments are due by the end of the month following the production month.

Thus, for all Federal oil and gas leases onshore and on the Outer Continental Shelf, both royalty payments and royalty reports are due at the end of the month following the month of production.

Title 30 CFR 216.53 prescribes similar requirements for production reporting. It provides in relevant part:

(a) You must file an Oil and Gas Operations Report [OGOR], Form MMS–4054, if you operate one of the following that contains one or more wells that are not permanently plugged or abandoned:

(1) An OCS lease or federally-approved agreement; or

(2) An onshore Federal or Indian lease or federally-approved agreement for which you elected to report on a Form MMS–4054 instead of a Form MMS–3160.

* * * * *

(c) * * *