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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 91N–384H and 96P–0500]

RIN 0910–AC49

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulation for sodium levels for foods that use the nutrient content claim "healthy." The agency is proposing that a previously established, but not yet implemented, more restrictive, second-tier sodium level would be permitted to take effect as a criterion that individual foods must meet to qualify to bear the term "healthy." The agency is proposing to retain the current first-tier sodium level for meal and main dish products because implementing the second-tier sodium level could result in the substantial elimination of meal and main dish products bearing the claim "healthy" from the marketplace. After evaluating data from various sources, the agency believes that the proposed sodium levels will help consumers achieve a total diet that is consistent with current dietary recommendations, as the proposed levels will give consumers a reasonable number of "healthy" products from which to choose. The agency has also revised the regulatory text for the definition of

"healthy" to clarify the scope of the regulation and conform to the Presidential Memorandum instructing Federal agencies to use plain language.

DATES: Submit written or electronic comments by [*insert date 75 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Ellen M. Anderson, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1798.

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 final rule defined criteria for use of the implied nutrient content claim "healthy," or a related term (e.g., "health," "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).

Before January 1, 1998, under § 101.65(d)(2)(ii)(A) and (d)(2)(ii)(B), for an individual food to qualify to bear the term "healthy" or a related term, the

food could contain no more than 480 milligrams (mg) of sodium (first-tier sodium level): (1) Per reference amount customarily consumed per eating occasion (reference amount); (2) per serving size listed on the product label (serving size); and (3) per 50 grams (g) for products with small reference amounts (i.e., less than or equal to 30 g or less than or equal to 2 tablespoons). After January 1, 1998 (§ 101.65(d)(2)(ii)(C)), an individual food bearing the term "healthy," or a related term, could contain no more than 360 mg of sodium (second-tier sodium level) per reference amount, per serving size, and per 50 g for products with small reference amounts. 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]

To qualify to bear "healthy" or a related term, meal and main dish products could contain no more than 600 mg of sodium (first-tier sodium level) per serving size before January 1, 1998 (§ 101.65(d)(4)(ii)(A)), and no more than 480 mg of sodium (second-tier sodium level) per serving size after January 1, 1998 (§ 101.65(d)(4)(ii)(B)). The agency selected the 480 mg 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 sodium; and because comments suggesting other levels did not provide supporting data (59 FR 24232 at 24240). Higher levels of sodium were

[1] Under § 101.13(h)(1) (21 CFR 101.13(h)(1)), individual foods containing more than 480 mg sodium per reference amount, per labeled serving size, or per 50 g (if the reference amount is 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 nutrient disclosures are required when a food contains more than certain amounts of total fat, saturated fat, sodium, and cholesterol and that food bears a nutrient content claim. *id.*, 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).

rejected in the earlier rulemaking (59 FR 24232 at 24239) because the agency determined higher levels would not be useful to consumers wanting to use foods labeled "healthy" to limit their sodium intake 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. This stay was intended to allow time for FDA to: (1) Reevaluate the second-tier sodium levels based on the data contained in the petition and any additional data that the agency might receive; (2) conduct any necessary rulemaking; and (3) give industry an opportunity to respond to the rule or to any change 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 regulations pertaining to use of the term "healthy." FDA requested

comments on whether it should propose to amend the sodium levels for the term "healthy." Comments suggesting that the agency should amend the "healthy" definition were asked to address what the amended regulation should require to ensure that the term "healthy" could appear on a significant number of foods, without being "so broadly defined as to lose its value in highlighting foods that are useful in constructing a diet that is consistent with dietary guidelines" (62 FR 67771 at 67772). FDA asked those who believed the second-tier sodium requirements were appropriate and should not be changed to provide data demonstrating that the second-tier "healthy" definition was not so restrictive as to effectively preclude the use of the term.

In the ANPRM, FDA requested data or evidence on what would happen to the use of the term "healthy" in the marketplace if the second-tier sodium levels were to take effect. In addition, the agency asked how many "healthy" products would be eliminated if the second-tier sodium levels were to take effect and whether there would be other impacts on the number of consumer choices. The agency also asked for data regarding the technological feasibility of reducing the sodium content of individual foods, including raw, single-ingredient seafood and game meats, to 360 mg per reference amount and of reducing the sodium content of meals and main dishes to 480 mg sodium per serving size.

FDA also requested information and views on consumer acceptance of foods at the second-tier sodium levels. The agency further requested information about the availability or lack of availability of acceptable sodium substitutes, the difficulties in manufacturing different lines of food products with lowered sodium levels, and the impact of these lower sodium levels on the shelf-life stability and safety of the food. FDA also requested comments

on other approaches to reducing the amount of sodium in foods that bear the term "healthy" (62 FR 67771 at 67773 and 67774).

If comments responding to the ANPRM revealed agreement that there were technological hurdles that could not be overcome for all foods or certain types of food, the agency stated that it would be interested in exploring different options for maximizing the public health gains expected from reducing dietary sodium levels. The agency identified four options. First, the agency could make no changes in the stayed rule, and the second-tier sodium levels in § 101.65(d)(2)(ii) and (d)(4)(ii) would become effective at the end of the stay period. This was identified as the default option if industry failed to provide evidence, data, or arguments that supported amending the rule. Second, as requested by the petitioner, FDA could propose to amend the definition of "healthy" to make the first-tier sodium levels the qualifying levels for all food products, and to delete in their entirety the second-tier sodium levels. Third, the agency could continue the stay based on data and information submitted in response to the ANPRM suggesting technological advancements could be made but would require more time. Fourth, the agency could reconsider the second-tier sodium levels and create new levels based on other factors such as percentile reductions based on market basket norms (62 FR 67771 at 67774).

In response to requests for an extension to coincide with the end of the comment period for the U.S. Department of Agriculture's (USDA's) interim final rule on the use of "healthy" on the label or labeling of meat and poultry products (63 FR 7279, February 13, 1998), FDA extended the closing date of the comment period for the ANPRM, from March 16, 1998, to May 19, 1998 (63 FR 13154, March 18, 1998).

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: (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, USDA and the Department of Health and Human Services jointly published the "Dietary Guidelines for Americans 2000" (dietary guidelines) (Ref. 1). This report provides recommendations for nutrition and dietary guidelines for the general public and suggests a diet with a 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).

II. Summary of Comments From the ANPRM

FDA received 22 responses, each containing one or more comments, to the December 30, 1997, ANPRM.

Most of the comments stated that the requirements for the use of the term "healthy" should be amended and presented evidence to persuade the agency to change the sodium levels. The comments provided information that a large number of meal and main dish products currently labeled as "healthy" would not be able to meet the "healthy" definition should the second-tier sodium

levels take effect. The comments also stated that technological advances have not yet yielded an acceptable salt substitute.

Several comments discussed the possibility of the agency engaging in rulemaking to set new sodium levels. For instance, a few comments suggested using a sodium level based on a percentile reduction from the market-basket norm (e.g., 25 percent less sodium than otherwise comparable products that are currently on the market). The levels could be established for each food category or for those particular food items having difficulty meeting the second-tier sodium levels. One comment objected to "relaxing" the standards and suggested even tighter regulation in the interest of public health (200 mg for individual foods and 400 mg for meal products).

A few comments stated that the second-tier sodium levels were reasonable and should no longer be delayed. Evidence presented in these comments consisted of: (1) Information suggesting that manufacturers could conform to the second-tier sodium levels without presenting food safety concerns, and (2) summary lists of products that would remain in the marketplace if the second-tier sodium levels took effect.

The remaining comments did not directly address the issue of whether FDA should amend the sodium levels, but, rather, provided general information or opinions regarding sodium levels. For example, one such comment stated that there are health risks associated with a low-sodium diet.

FDA used information provided in the comments, along with information the agency gathered through an independent data analysis, to determine its proposed action.

III. Proposed Action

A. Introduction

The agency established a definition for the term "healthy" as an implied nutrient content claim (59 FR 24232). The fundamental purpose of a "healthy" claim is to highlight those foods that, based on their nutrient levels, are particularly useful in constructing a diet that conforms to current dietary guidelines, which suggest that daily sodium intake not exceed 2,400 mg (Ref. 1). To assist consumers in constructing such a diet, a reasonable number of "healthy" foods should be available in the marketplace.

FDA stated in the ANPRM that its 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," and not so broadly defined as to cause the term to lose its value in identifying useful products for constructing a healthy diet (62 FR 67771 at 67772).

To assess the number of "healthy" products in the marketplace, FDA conducted a marketplace data analysis (Ref. 2) using information from the Information Resources, Inc. (IRI) InfoScan database. The IRI InfoScan database contains dollar and 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 the database contains sales data for all products in these retail stores that are scanned (i.e., sold) at check out. 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. Using the IRI

InfoScan database, FDA estimated the number of "healthy" brands and "healthy" products in the marketplace during 1993 to 1999.

In the following discussion of the marketplace data analysis, the term "brands" refers to brand names (not manufacturers) in the IRI InfoScan database (e.g., Healthy Choice, Health Valley, Healthline), while the term "products" refers to the different items (i.e., separate Universal Product Codes) sold under that brand name (e.g., raisin bran versus corn flakes; 12-ounces (oz) package versus 16-oz package) (Ref. 2).

B. Individual Foods

1. Conventional Foods

In the marketplace data analysis of "healthy" individual foods, the agency estimated the total number of "healthy" products and brands available in 1993, in 1999, and any time in the timeframe from 1993 to 1999. The agency also estimated the number of "healthy" individual foods for specific food categories. FDA does not have any data to determine either the number of "healthy" products or the pace of increase in the availability of "healthy" products prior to 1993. When compiling the marketplace data analysis, the agency considered all conventional foods that did not meet the meal or main dish definition in § 101.13(l) and (m) (including soups, salads (e.g., precut in a bag, prepared refrigerated salads), and single-ingredient seafood and game meats) to be individual foods. FDA considered dietary supplements separately using a different database. Dietary supplements are discussed in section III. B.2 of this document.

FDA estimated that in 1999 the marketplace had 872 "healthy" individual food products available to the consumer, compared to 842 such products available in 1993 (Ref. 2). There was also an increase in the number of

"healthy" brands for individual foods in the marketplace from 1993 to 1999. In 1993, only 50 brands carried a "healthy" product, while 69 brands were available in 1999.

Considering that the 1993 figures are representative of the marketplace prior to the 1994 final rule defining "healthy," the increase in "healthy" products shows that, in addition to manufacturers being able to comply with the definition established in 1994, they have also been able to develop additional "healthy" products. Manufacturers have increased the number of available "healthy" brands as well as the number of available "healthy" products at or below the first-tier sodium level.

There has been an increase in the number of "healthy" individual food products in many of the specific food categories defined by IRI (Ref. 2). For example, in the IRI category of "Salty Snacks" (e.g., pretzels, potato chips), there were 18 available "healthy" products in 1993 and 46 in 1999, with 3 "healthy" brands available in 1993 and 5 in 1999. For popcorn products identified in the IRI category of "Popcorn/Popcorn Oil," no "healthy" products existed in 1993, but in 1999 there were 10 "healthy" products and 2 "healthy" brands in the marketplace. Similarly, in the IRI category "Fresh Breads & Rolls," 21 "healthy" products and 5 "healthy" brands were on the market in 1993, while in 1999, 64 "healthy" products and 9 brands were available. Increases can also be seen in the IRI category of "FZ [Frozen] Seafood"; 14 "healthy" products were available in 1993, while 22 were available to consumers in 1999, with 3 "healthy" brands in both 1993 and 1999. These are only a few examples of increases in the number of "healthy" individual food products available to the consumer.

Not all food categories, however, had an increase in the number of "healthy" products from 1993 to 1999. For instance, foods in the IRI categories "Cold Cereal," "Cookies," Dried Fruit," "Salad Dressings—SS" (where SS stands for shelf stable), "Sauce," and "Carbonated Beverages" saw a drop in the number of "healthy" products available from 1993 to 1999 (Ref. 2). For food categories such as cold cereal, salad dressing, and sauces, sodium may have been a factor in the decrease in the number of products available from 1993 to 1999 because the sodium levels in these products cover a very wide range, and some exceed the first-tier requirement for products labeled as "healthy" (Ref. 3). However, based on typical sodium levels for other food categories, such as cookies, dried fruit, and carbonated beverages, it is unlikely that sodium was responsible for the decrease in the number of these "healthy" products in the marketplace because typical sodium levels are below both the first- and second-tier sodium levels (Ref. 3).

In addition, certain food categories generally contain little sodium. Foods such as fish, fruit juices, hot cereals, rice, vegetables, pastas, and yogurt typically have considerably less than 360 mg sodium per reference amount and per serving size (Ref. 3). For most of these foods, there was an increase or no change in the number of brands and products available in 1999 compared to 1993 (Ref. 2). There was a decrease in the number of vegetable and pasta products labeled "healthy;" however, there is no reason to believe that this decrease was due to the sodium content. Because these categories of food generally contain little sodium, the proposed second-tier sodium level is unlikely to have an impact on the number of "healthy" products in the marketplace.

The agency also evaluated data from the 1997 Food Label and Package Survey (FLAPS) (Ref. 4), which represents data collected in 1997 from a limited number of product brands in specific food categories. The agency reviewed this database because it includes data that were not available in the marketplace data analysis, including information on claims and other information included on product labels. For example, FDA found a number of "healthy" claims on individual foods (Ref. 4), such as "Healthy real egg product" and "Apple sauce is a delicious and healthy fruit product, which contains no fat, very low sodium, and no cholesterol." Such statements are implied nutrient content claims for "healthy" that the marketplace data analysis did not identify because the term "healthy" was not part of the brand name of the product. This leads FDA to believe that there are individual foods in the market place bearing "healthy" claims in addition to those identified in the marketplace data analysis. As some "healthy" claims are not part of the brand name of the product and, therefore, were not captured in the marketplace data analysis, it is likely that the number of "healthy" individual foods included in that analysis underestimates the number of individual food products bearing "healthy" claims.

The agency notes that individual foods with reference amounts on the lower end of the scale are also less likely to be affected by adoption of the second-tier sodium level because they are able to claim the same 360 mg sodium level for a "healthy" product as other individual foods with larger reference amounts. For example, bread or rolls have a reference amount of 50 g (§ 101.12(b) (21 CFR 101.12(b)), table 2, "Bakery products: Breads (excluding sweet quick type), rolls"). A 50 g serving of bread or rolls typically contains less than 360 mg sodium (Ref. 3) and would meet the second-tier criterion.

Contrast that with individual foods such as pasta or potato salad, which have a reference amount of 140 g (§ 101.12(b), table 2 "Salads: Pasta or potato salad"). Assuming other aspects of the "healthy" definition are met, 140 g of pasta or potato salad must contain no more than 360 mg sodium to be considered "healthy," although the reference amount for pasta or potato salad (140 g) is almost three times that of bread or rolls (50 g). Many other individual foods are similar to the bread and rolls, having a reference amount on the lower end of the scale, which allows those products more flexibility in their sodium level.

Additionally, the agency believes that some individual foods may be close to meeting the second-tier sodium level. If the second-tier sodium level goes into effect, manufacturers may choose to reformulate such products in order to retain a "healthy" claim.

The ConAgra petition and other comments identified a few specific categories of individual foods for which the ability to make "healthy" claims could be negatively affected by permitting the second-tier sodium levels to take effect (e.g., soups, cheeses, frankfurters, and luncheon meats). FDA examined the marketplace data analysis for these specific food categories (Ref. 2).

The total number of "healthy" wet and dry soup products available in the marketplace increased during 1993 through 1999. In 1993, 104 "healthy" soup products were on the market. In 1999, over 20 more products were available, for a total of 126 "healthy" soup products in 1999. The number of "healthy" brands remained steady at six in both 1993 and 1999.

The petitioner indicated that its "healthy" soup products would not be able to meet the second-tier sodium level. The petitioner stated that it had expended numerous resources (e.g., consulting with experts in the field of food

technology and conducting research and development programs with flavor companies) and was not able to find a satisfactory salt replacement for its "healthy" line of soups.

On the other hand, a comment by a major manufacturer of soups claimed that it has been able to reduce the sodium levels in its "healthy" soups and is currently able to meet the second-tier sodium level for "healthy" individual foods. The comment from this major soup manufacturer indicated that it was able to reformulate its "healthy" soup product line by modifying the flavor system with ingredient changes on a product by product basis. The comment also noted that reducing sodium in a product is technically difficult but not unsolvable and that the flavor profile of a product can be manipulated so that it maintains consumer appeal.

Because one major soup manufacturer has been able to develop a "healthy" soup line that meets the second-tier sodium level for "healthy" individual foods, FDA tentatively concludes that it is technologically feasible to produce a "healthy" soup product that meets the second-tier sodium level and is palatable to consumers. The petitioner also stated that cheese might not be able to meet the second-tier "healthy" sodium requirement because salt is required in the manufacturing process and cannot be reduced without jeopardizing taste and texture. The petitioner also contended that if FDA permits the second-tier sodium level to take effect for individual foods, there will be no "healthy" version of cheese in the marketplace.

Another comment stated that if it is not possible to manufacture a "healthy" cheese, then no exception should be made, and cheese products should be removed from the "healthy" marketplace until manufacturers are capable of producing a cheese that meets the "healthy" definition.

The petitioner's comments regarding cheese are reinforced by the trend seen by FDA in its marketplace data analysis (Ref. 2). For example, there has been a general decline in the number of "healthy" cheeses in the marketplace. In 1993, before the final rule defining "healthy" was issued, there were a total of 60 "healthy" cheese products with 3 different brands on the market; however, in 1999, the numbers dropped to 32 products with only 1 brand in the marketplace. Furthermore, in Spring 2001, FDA staff made an informal telephone inquiry to the customer service center of the only manufacturer of "healthy" cheese identified in the marketplace data analysis for 1999 (Ref. 5). The manufacturer indicated that its "healthy" line of cheese had been discontinued. To the best of the agency's knowledge, no new manufacturer has entered the "healthy" cheese market.

FDA agrees that cheese generally requires salt in the manufacturing process. Cheese is made from the coagulation of milk into curds and whey. The whey is drained off and salt (sodium chloride) is typically added to the curd to control microbial growth and enzyme activity, assist in curd synthesis (whey expression), and directly cause changes in cheese proteins that will influence cheese texture (Ref. 6). The agency requests comments on whether salt is the limiting element in achieving a "healthy" cheese and whether salt can be removed from the cheese-making process.

FDA notes that "healthy" cheeses may have been removed from the marketplace for reasons other than the sodium requirement. Some "healthy" cheeses (e.g., light mozzarella cheeses) were able to meet the proposed second-tier sodium level for "healthy" individual foods; nonetheless, those products were removed from the marketplace (Ref. 5). In addition to sodium, cheese also typically contains fat and saturated fat, which have been identified as

nutrients to limit when constructing a "healthy" diet (Ref. 1). Because the "healthy" claim sets limits on all three nutrients, the multiple requirements may be the reason why "healthy" cheeses are no longer in the marketplace. FDA requests comments that would help clarify whether it is the sodium limit, the fat or saturated fat limits, the combination of limits, or some other factor or factors that have resulted in manufacturers discontinuing the manufacture and marketing of "healthy" cheeses.

Further, the agency is not persuaded that it is necessary to provide for "healthy" cheese since the lack of a "healthy" cheese product is not likely to prevent consumers from constructing a diet consistent with dietary guidelines. Although cheese contributes calcium to the diet (Ref. 1), consumers can obtain their reference daily intake (RDI) of calcium from many other sources such as low-fat milk, yogurt, and dark-green leafy vegetables, to name a few.

For consumers who choose to eat cheese, there are alternative cheese products such as "reduced fat" or "reduced sodium" cheeses. These claims accurately describe the specific attributes of the product without claiming that it conforms to the requirements for "healthy."

FDA also is concerned that treating cheese differently from other foods could be misleading to consumers trying to construct a healthy diet. Cheese has a small reference amount (30 g) (§ 101.12(b), table 2, "Dairy Products and Substitutes: Cheese, all others except those listed as separate categories—includes cream cheese and cheese spread"), and therefore, more than one serving can be consumed easily. In general, approximately 32 g to 46 g of cheese is consumed per eating occasion (Ref. 7). Because the actual amount consumed is typically larger than the reference amount (30 g), it appears that

consumers will be better served if the second-tier sodium level applies to all foods, including cheese. Applying the second-tier sodium level to cheese will help maintain a reasonable sodium intake even for those people who consume larger amounts of cheese.

However, FDA invites comments on whether having no "healthy" cheeses may have a negative impact on consumers, and if so, whether the agency could establish a reasonable alternative sodium requirement for "healthy" cheese. Alternative methods might include: (1) Leaving cheese at the current first-tier sodium level for "healthy" individual foods (480 mg) or (2) establishing "healthy" sodium levels based on a percent reduction of market-basket norms.

The first alternative of leaving cheese at the current first-tier sodium level for "healthy" individual foods may encourage cheese manufacturers to reenter the marketplace, since they would no longer have to face uncertainty as to whether the sodium level would be reduced to the second-tier level. The marketplace data analysis showed that there were 32 "healthy" cheese products in 1999, demonstrating that manufacturers were capable of producing a "healthy" cheese at the current first-tier sodium level.

The second alternative of establishing a "healthy" sodium level based on a market-basket norm may not be practical for all individual foods but may be appropriate for cheese because of its special manufacturing process. To consider both alternatives, it would be helpful to have additional information, such as: (1) The sodium levels for various cheeses currently in the marketplace that do not bear the term "healthy" (i.e., the current market-basket norm) and what might be an achievable percent reduction for sodium from that market-basket norm; (2) the impact that exempting cheese, not exempting cheese, or establishing an alternative sodium level would have on diets; (3) the minimum

levels of sodium that can be achieved in the production of an acceptable cheese product; (4) the technology available to reduce sodium levels in cheese products; and (5) the extent to which salt (sodium chloride) is required in the cheese-making process.

Comments received in response to the ANPRM also indicated that frankfurters and luncheon meat may have difficulty meeting the second-tier sodium level of the "healthy" definition. However, those products fall outside FDA's jurisdiction, as they are regulated by USDA; therefore, they are not addressed in this proposal.

Another issue raised by the petitioner was the role of salt as a preservative in refrigerated foods, particularly meat and poultry products, because the petitioner contended that refrigeration alone cannot be relied upon to ensure food safety. However, a comment stated that the difference between the first-tier (480 mg) and the second-tier (360 mg) sodium levels is insignificant with respect to food safety. The comment noted that sodium does not protect against microbiological contamination in processed meats and that no one factor is responsible for product safety.

Again, since meat and poultry fall outside FDA's jurisdiction, they will not be addressed in this rulemaking. The agency requests comments on whether sodium levels of 360 to 480 mg are protective and play a role in food safety for foods that FDA regulates; whether changing from the first- to the second-tier sodium level would negatively impact food safety; and what other preservation methods could be used to ensure food safety in conjunction with lower sodium levels.

Based on the data summarized, it appears that: (1) A reasonable number of "healthy" individual food products were available in the marketplace from

1993 through 1999; (2) in many food categories there has been an increase in the number of "healthy" products and brands; and (3) many "healthy" individual foods, such as those with reference amounts at the lower end of the scale or those that typically contain limited amounts of sodium, would remain unaffected by the proposed change to the second-tier sodium level for individual foods. Therefore, with the possible exception of cheeses, the overall impact of permitting the second-tier sodium level to take effect for individual foods appears to be limited to minor reductions in the number of "healthy" products in some food categories.

Accordingly, the agency tentatively concludes that the second-tier sodium level is the appropriate sodium requirement for the "healthy" definition for individual foods. The agency believes the second-tier sodium level provides a meaningful definition of "healthy" that will enable consumers to construct a diet that is consistent with current dietary guidelines but is not so narrowly defined as to disqualify many foods that are recommended to be in the diet (59 FR 24232 at 24240).

Therefore, the agency is proposing not to amend the second-tier "healthy" sodium level of 360 mg for individual foods in current § 101.65(d)(2)(ii)(C)(*1*) and (d)(2)(ii)(C)(*2*), and (d)(3)(ii)(C)(*1*) and (d)(3)(ii)(C)(*2*). These paragraphs are being revised in format, however, as discussed in section III. F of this document. The second-tier sodium level for individual foods is to take effect at the end of the stay period, January 1, 2006 (67 FR 30795).

The agency is requesting comments and information on the potential impact of the second-tier sodium level on specific individual food categories. In particular, FDA is seeking information on the range of sodium content in

food categories and the proportion of products that contain sodium at or below the first- and second-tier levels of current § 101.65.

2. Dietary Supplements

Dietary supplements, like other individual foods, must meet all of the requirements in § 101.65(d)(2) to make "healthy" claims. FDA has evaluated data for dietary supplements and tentatively concludes that permitting the second-tier sodium level to go into effect is unlikely to reduce the availability of "healthy" dietary supplements. The agency assessed the prevalence of dietary supplement products that contain salt or sodium and are labeled as "healthy." The agency used a database developed by Research Triangle Institute (RTI) (Ref. 8), which includes detailed information on approximately 3,000 dietary supplement products collected between November 1999 and February 2000, including information from labels of products purchased from retail establishments and information taken from mail-order catalogs and Internet sites. In selecting dietary supplement products, RTI used the definition of "dietary supplement" from the Dietary Supplement Health and Education Act of 1994 (Public Law 103–417), which includes, among other things, vitamins, minerals, herbs and other botanicals, and amino acids (section 201(ff) of the act (21 U.S.C. 321(ff))). RTI included only information available to consumers at the point-of-sale.

The RTI sampling procedure was designed to include the maximum number of different products and different ingredients, which led to a relatively greater variety of products than would be representative of consumer purchase patterns. In order to get as many products as possible with different characteristics, RTI over-sampled health food stores. This led to an over-sample of herbals and botanicals, which, according to the database, are more likely

to contain sodium. Thus, the design of the survey (e.g., how the products were sampled) would be likely to lead to an overestimate of the percentage of dietary supplements that contain sodium.

FDA recognizes that the RTI database cannot be used to make precise, quantitative estimates of dietary supplement characteristics; nevertheless, in the absence of other available data, FDA used these data to estimate the proportion of dietary supplement products that might be affected by permitting the second-tier sodium requirements to take effect for the term "healthy." FDA found these data useful as they allow for a conservative estimate of the impact of the proposed rule on dietary supplement products, because it is likely that a smaller proportion of products will be impacted than the proportion calculated under this assessment. FDA requests comments on this assessment of dietary supplement products that may contain sodium and welcomes any additional available data concerning dietary supplements.

To estimate the proportion of dietary supplement products in this dataset that contain sodium, FDA reviewed the ingredient information in the RTI database, which includes information on the first 30 ingredients contained in the product. The agency searched for ingredients containing either the term "salt" (sodium chloride), the most common source of sodium in foods, or the term "sodium" (e.g., sodium benzoate). This process would not have identified ingredients containing other sources of sodium (i.e., ingredients that include sodium-containing components that do not include sodium in their name). FDA identified 133 dietary supplement products in this dataset (4 percent) containing the terms "sodium" or "salt" in one or more of the first 30 ingredients.

To estimate the proportion of dietary supplement products in this dataset that may contain sodium and also bear a claim for "healthy," FDA reviewed the database for brand names, product names, and claims on the 133 dietary supplement products. The agency found 1 product with the term "health" in the brand name, 1 product with the term "health" in the product name and also in the product claim, and 32 products with claims containing the terms "health" or "healthy." Most of the claims on the products were structure/function claims under 21 CFR 101.93(f) (e.g., "Helps promote bone health") or health claims under 21 CFR 101.14 (e.g., "Enough calcium helps maintain good bone health and reduce the risk of osteoporosis"); such claims would not be considered "healthy" claims under § 101.65(d). FDA did, however, identify 11 products in this dataset (0.4 percent) bearing "healthy" claims under § 101.65(d) either as part of the brand or product name or as a separate claim on the product (Ref. 8). Since this dataset over-sampled products that are more likely to contain sodium, it is likely that less than one percent of dietary supplement products would potentially be affected by requiring individual foods bearing the claim "healthy" to meet the proposed, second-tier sodium requirement.

In addition to the relatively small proportion of dietary supplement products overall that contain sodium and bear "healthy" claims, judging from our sample of 11 products in this dataset, the amount of sodium contained in these dietary supplement products is probably quite limited for a variety of reasons. Since ingredients are listed on product labels in descending order of predominance by weight (21 CFR 101.4), the amount of sodium in dietary supplement products is likely to be small because the sodium-containing ingredients tend to be minor ingredients (Ref. 8). Furthermore, dietary

supplement products tend to have small serving sizes (e.g., pills, capsules, packets, teaspoons).

In addition, only a small proportion of most sodium-containing dietary supplement ingredients is actually sodium. For example, salt (sodium chloride) is the ingredient with the highest proportion of sodium, about 40 percent. The agency calculated the percentage of sodium for the other sodium-containing ingredients about which the agency had sufficient information, and these other ingredients contain a significantly smaller proportion of sodium, varying from around 12 to 27 percent (Ref. 8). Thus, dietary supplements are likely to contain limited amounts of sodium because the sodium-containing ingredients themselves contain limited amounts of sodium.

An example may help to illustrate how the two factors discussed work in tandem to limit the amount of sodium in dietary supplement products. Only one of the 11 products bearing a healthy claim listed salt as an ingredient. This product lists salt as the 14th ingredient in order of predominance. Thus, the amount of sodium in that particular dietary supplement product is likely to be small since it is only 40 percent of a very minor ingredient.

Also, unlike conventional food products that use salt to improve taste, dietary supplement products are taken to supplement the diet and are not generally consumed for their taste. Most dietary supplement products are in pill, tablet, or capsule form (Ref. 8) and are swallowed without chewing. Therefore, since taste is not a factor for most of these products, manufacturers selecting ingredients for their dietary supplement products can easily avoid sodium-containing ingredients if they are trying to limit the sodium content in order to make "healthy" claims.

Thus, given the foregoing information and observations based on the RTI data sample, FDA does not anticipate that the sodium content of dietary supplement products will have an impact on their ability to qualify for "healthy" claims. Furthermore, the agency received no comments to the ANPRM from dietary supplement manufacturers indicating that dietary supplement products currently making "healthy" claims would be affected. Thus, FDA does not believe that changing the sodium content requirement for individual foods bearing "healthy" claims will adversely affect dietary supplement manufacturers wishing to make such claims. The agency requests comments on whether its assessment regarding dietary supplement products is accurate and whether or not the availability of dietary supplement products bearing a "healthy" claim would be adversely affected by this rulemaking. FDA requests specific information on such products, including the numbers and types of products affected, the current level of sodium in the products, and the types of "healthy" claims that are being made.

C. Meal and Main Dish Products

For purposes of this section, meal and main dish products, which are defined separately in § 101.13(l) and (m), will be considered together. This is consistent with earlier treatment in the proposed rule, the final rule, the partial stays, and the ANPRM.

To assess the status of meal and main dish products, the agency separated the data on meal and main dish products from the data on other products in the marketplace data analysis. When determining the number of products and brands that fall within the meal and main dish category, the agency included chili with meal or main dish products. In performing this assessment, the agency considered three categories: (1) Frozen meals and main dishes, (2)

refrigerated and shelf-stable meals and main dishes, and (3) chili. FDA identified 148 meal and main dish products labeled "healthy" among 10 brands in the IRI analysis (Ref. 2). The 1997 FLAPS did not identify any meals or main dishes that used a "healthy" claim but were not from a "healthy" brand (Ref. 4).

The petitioner stated that a number of "healthy" meal and main dish products would "disappear" if the second-tier sodium levels were to take effect for meal and main dish products. The petitioner further indicated that it would not be able to produce many meal or main dish products that meet the second-tier sodium level and that are palatable. The petitioner also commented that some weight-control meal and main dish products are substantially higher in sodium than the second-tier level established for "healthy" meal and main dish products.

The petitioner provided the agency with data regarding how the current first-tier sodium levels for the "healthy" definition aid the consumer in achieving a diet that is consistent with dietary guidelines. The data included a sample menu of an average adult's daily consumption of "healthy" individual foods and meal and main dish products at the current first-tier sodium levels (Ref. 9). The sample menu demonstrated that an adult using "healthy" as a guidepost could obtain a diet with a sodium level close to the recommended daily sodium intake (Ref. 1).

In contrast, another comment supported permitting the second-tier sodium level for "healthy" meal and main dish products to take effect and claimed that the lower sodium level is attainable. However, that comment did not come from a firm that produces "healthy" meal or main dish products. In addition, the comment did not provide any basis for concluding that a reasonable

number of "healthy" meal and main dish products would remain in the marketplace if the second-tier sodium levels were to take effect for meal and main dish products.

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 (Ref. 2).

The number of "healthy" frozen meals and main dishes decreased from 177 products in 1993 to 119 products in 1999. During 1993 through 1999, 272 "healthy" frozen meal and main dish products were placed on the market, with less than half surviving until 1999. Similarly, the number of "healthy" frozen meal or main dish product brands has also decreased. In 1993, there were nine "healthy" brands available, and only six brands remained in 1999.

The number of "healthy" shelf-stable or refrigerated meal and main dish products also has decreased, with 23 products available in 1993 and only 11 products in 1999 (Ref. 2). During 1993 through 1999, 33 "healthy" shelf-stable and refrigerated meals and main dish products were introduced into the market, with only 30 percent of those products surviving in 1999. The number of brands marketing a "healthy" shelf-stable or refrigerated meal or main dish product has dropped slightly, with five brands available in 1993, and four brands in 1999. Only "healthy" chili products have increased in number from 10 in 1993 to 18 in 1999, and from 1 to 2 brands in that same timeframe.

Overall, the number of available meal and main dish products (including frozen, shelf-stable, refrigerated, and chili products) decreased by 30 percent, from 210 products in 1993 to 148 products in 1999 (Ref. 2). 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. 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. "Healthy" meal and main dish products, in addition to meeting the sodium limit, also meet the definition of "low" for fat and saturated fat; contain no more than 90 mg of cholesterol per serving size, and contain at least 10 percent of the RDI or daily reference value per serving size of two (for main dish products) or three (for meal products) of the following nutrients: Vitamin A, vitamin C, calcium, iron, protein, and fiber (§ 101.65(d)).

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 for "healthy" meal and main dish products and brands 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. In 1999, most

of the meal and main dish products available were frozen dinners and entrées. There were only 6 "healthy" brands of frozen meal and main dish products, and 5 of the brands comprised only 16 percent of the products available (Ref. 2). The remaining 84 percent of "healthy" meal and main dish products were manufactured by the petitioner. Between 1993 and 1999, there were 10 brands marketed by firms other than the petitioner. Five brands that were available for sale in 1993 had completely disappeared from the market by 1999; two brands had significantly fewer products for sale; two brands that were not available in 1993 offered only a few products in 1999; and one brand had more products for sale in 1999 than in 1993. The petitioner also had more "healthy" products for sale in 1999 than in 1993. 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 sodium content of the sample menu provided by the petitioner in support of retaining the first-tier sodium levels is close to the recommended daily sodium intake set forth in the dietary guidelines (Ref. 9). FDA believes that minor adjustments, such as the lower sodium level the agency is proposing for "healthy" individual foods, would be sufficient to bring such a menu within dietary guidelines.

The 1997 FLAPS data (Ref. 4) did not contain any additional "healthy" claims for meal and main dish products that were not already identified in the marketplace data analysis. This further supports the contention that there are a limited number of "healthy" meal and main dish products in the marketplace.

Meal and main dish products make a major contribution to the total daily diet, and FDA believes that sodium requirements for these products should reflect this contribution, while remaining consistent with current dietary guidelines. For example, under § 101.13(l), a meal is defined as weighing at least 10 oz per labeled serving and containing not less than three-40 g portions of food, or combinations of foods, from two or more of the four food groups: (1) Bread, cereal, rice, and pasta; (2) fruits and vegetables; (3) milk, yogurt, and cheese; and (4) meat, poultry, fish, dry beans, eggs, and nuts. Under the first-tier sodium requirement, a "healthy" meal must fall within the 600 mg sodium level per serving size of not less than 10 oz (282 g), or approximately 2.1 mg sodium per g of food. A "healthy" main dish, under § 101.13(m), must contain not less than 40 g of food, or combinations of foods, from each of at least two of the four food groups, and must contain 600 mg or less sodium per serving size of 6 oz (170 g), or approximately 3.5 mg sodium per g of food.

By contrast, the first-tier sodium level for "healthy" meal and main dish products is more stringent than the sodium level of a meal consisting of "healthy" individual foods at the second-tier sodium level. For example, both fresh or frozen vegetables and cooked fish/shellfish have reference amounts of 85 g (§ 101.12(b), table 2, "Vegetables: All other vegetables without sauce: fresh, canned, or frozen" and "Fish, Shellfish, Game Meats, and Meat or Poultry Substitutes: Entrees without sauce, e.g., plain or fried fish and shellfish, fish and shellfish cake"). Prepared fried potatoes have a reference amount of 70 g (§ 101.12(b), table 2, "Potatoes and Sweet Potatoes/Yams: French fries, hash browns, skins, or pancakes"). Under the second-tier sodium definition of "healthy," individual foods are limited to 360 mg sodium per reference amount and per serving size. The sodium levels under these

requirements would be approximately 4.2 mg sodium per g of fish or vegetables and approximately 5.1 mg sodium per g of potato. These levels are more than 200 percent higher than the sodium level that "healthy" meals are required to meet at the first-tier sodium level (2.1 mg sodium per g of food) and 120 percent higher than the first-tier sodium level for "healthy" main dish products (3.5 mg sodium per g of food). These examples demonstrate that the first-tier sodium level for "healthy" meal and main dish products is already more stringent than the second-tier sodium level proposed for "healthy" individual foods typically included in such meals and main dishes.

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 (Ref. 1) and allows for flexibility in the rest of the daily diet (i.e., the snack).

A number of comments to the ANPRM addressed whether there is an acceptable salt substitute that could be used to replace salt in meal and main dish products. Most of those comments indicated that currently it is not technologically feasible to manufacture a "healthy" meal or main dish product that uses a salt substitute to help meet the second-tier sodium level. Many

flavor manufacturers stated that although they have been working towards a flavor profile to replicate salt, an acceptable salt substitute is not yet available. The comments stated that some of the salt substitutes currently available are ammonium salt and potassium chloride. The comments further stated that these are not effective salt substitutes because they leave an off or bitter aftertaste and require a masking of that aftertaste that is not always successful. One flavor manufacturer asserted that it is not necessary to change the sodium requirements for the definition of "healthy" because this manufacturer had created a salt substitute that is acceptable for use in most processed foods. However, the petitioner described working with that manufacturer and using that salt substitute to try to reduce sodium in their products (e.g., frozen entrées) without success.

It appears that technological advances have not yet yielded an acceptable salt substitute that would allow meal and main dish products to meet the second-tier sodium level for the definition of "healthy." Furthermore, the second-tier sodium levels have been stayed several times to give manufacturers more time to develop alternatives. Because of the apparent difficulty of producing an acceptable salt substitute, FDA is no longer convinced that providing additional time will lead to the development in the near future of a salt substitute that is acceptable to manufacturers and palatable to consumers.

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. Accordingly, the agency is proposing to eliminate the second-tier sodium level of 480 mg for meal and main dish products and to make the first-tier sodium level permanent for those products.

D. Conclusion

FDA is proposing to permit the previously-established, second-tier sodium level to take effect for "healthy" individual foods and to retain the first-tier sodium level for "healthy" meal and main dish products. FDA believes that this combination of actions is necessary to provide for a reasonable number of "healthy" products in the marketplace. The marketplace data analysis indicated that the number of "healthy" individual foods has been increasing while the number of "healthy" meal and main dish products has been decreasing. Further, the first-tier sodium level for "healthy" meal and main dish products provides a lower sodium intake than the amount that would be consumed if a meal or main dish product consisted of "healthy" individual foods at the second-tier sodium level. The agency believes that the proposed sodium requirements represent levels that are achievable by manufacturers but sufficiently restrictive to provide consumers with a meaningful definition of the term "healthy" that will assist them in constructing a diet consistent with dietary guidelines. Thus, FDA tentatively concludes that the second-tier sodium level is appropriate for individual foods, and the first-tier sodium level is appropriate for "healthy" meal and main dish products.

E. Clarification

To clarify the scope of implied nutrient content claims under § 101.65(d), FDA is modifying § 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. This change makes the regulatory text consistent with the preamble discussions in both the proposed and final rules (58 FR 2944 at 2945, January 6, 1993; 59 FR 24232 at 24235, May 10, 1994), where FDA made clear that claims made in association with an implied claim or statement about a nutrient would be covered by the regulation. Thus, the regulation now states that a claim that suggests that a food, because of its nutrient content, may help consumers maintain healthy dietary practices, is an implied nutrient content claim if it is made in connection with an explicit or implicit claim or statement about a nutrient.

F. Plain Language

By January 1, 1999, Federal agencies were to use plain language in all proposed and final rulemaking documents published in the **Federal Register** (Ref. 10). FDA is therefore proposing to revise the format in § 101.65(d) for all nutrient requirements for the term "healthy." The codified language is currently in a text-based format. FDA is proposing a summary table format. This new format should aid the reader in comprehending and following these regulations.

Finally, FDA is proposing several minor changes in the wording of § 101.65(d) to make the regulation more concise and easier to understand. These changes are not intended to affect the meaning of the regulation.

IV. Environmental Impact

The agency tentatively concludes 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 Economic Impacts

A. Preliminary Regulatory Impact Analysis

FDA has examined the economic impacts of the proposed rule under Executive Order 12866. 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, public 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 proposed rule is a significant regulatory action under Executive Order 12866, although it is not economically significant.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). This proposed

rule is not expected to result in any 1-year expenditure that would exceed $100 million, adjusted for inflation. The current inflation-adjusted statutory threshold is $115 million.

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 serving size (usually the entire meal) in the first-tier compliance period, and sodium levels no higher than 480 mg per serving size 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 in the first-tier compliance period, and sodium levels no higher than the second-tier 360 mg per serving size 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), and more recently until January 1, 2006 (67 FR 30795, May 8, 2002).

In December 1996, ConAgra petitioned FDA to eliminate the second-tier, lower sodium levels. The petitioner claimed that these levels were too difficult to meet, and therefore would force the removal from the market of many products that were still healthy and contained less sodium than their direct competitors.

This proposal modifies the definition of the term "healthy" in only one respect: It makes the first-tier sodium level of 600 mg permanent for meals

and main dishes. "Healthy" individual foods still would have to comply with the second-tier limit of 360 mg per serving once that limit goes into effect.

2. Regulatory Options

FDA identified several options in the ANPRM: (1) Make no change to the current rule, i.e. allow the second-tier sodium levels to go into effect; (2) amend the definition of "healthy" as requested in the petition, i.e. eliminate the second-tier sodium levels; (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 very difficult to predict. FDA views any technological change as mitigating the eventual cost of this rule, but requests comments as to how to quantify this effect.

Also, analyzing alternative second-tier sodium limits in terms of net benefits (option 4) is not feasible in this analysis. The optimum sodium level for individual foods, meals, and main dishes balances the health benefits of limiting sodium intake with the cost to industry and of making food product preparation more complicated and the cost to consumers of limiting product choice. In the analysis that follows, we argue that the first-tier sodium level strikes that balance better than the second-tier level for meals and main dishes, but that the second-tier level strikes the balance better for individual foods. Other sodium levels may perform well in this type of analysis, but FDA has no way of differentiating health effects or manufacturing costs due to marginal differences in the allowable sodium content of "healthy" food products.

Therefore, the options we consider for this analysis are option 1 (allow second-tier levels to take effect) and option 2 (eliminate second-tier levels),

split into separate categories for individual foods (2a) and meals and main dishes (2b). The proposed rule would adopt 2b, but not 2a.

1. Implement the current rule 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 "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 cost of the other options is the negative health impact due to a net increase in sodium intake under options 2a, 2b, and 2c.

Option 2a: Retain the First-Tier Sodium Level for Individual "Healthy" Foods. FDA considers the current rule's second-tier sodium level for "healthy" appropriate for individual foods. Although this analysis does not quantify in detail the net benefit associated with lower sodium levels in food, the costs associated with option 2a in all likelihood outweigh the benefits. The agency does not have the information necessary to calculate the effects on the market of the 870 foods that use a "healthy" claim, but FDA invites comments regarding how to quantify the qualitative effects summarized here.

Benefits of Option 2a. The benefits 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. In the market analysis, FDA identified 870 individual food products among 69 brands that make a "healthy" claim (Ref. 2). The FLAPS survey also identified several additional individual foods that make a "healthy" claim but are not from a "healthy" brand (Ref. 4). However, according to the comments on the ANPRM 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 the three food product categories that FDA tentatively concludes are impacted by this option, sodium levels for "healthy" meats are regulated by USDA and therefore are not part of this analysis. Discussions on cheese and soup categories follow.

Other individual foods in other categories may have costs associated with meeting the second-tier sodium level, but FDA has no information concerning costs for those other individual foods. FDA invites comments on the costs that may be incurred by other "healthy" individual foods, including dietary supplements, in meeting the second-tier sodium level.

Cheese. Reformulating cheeses to meet the second-tier sodium level would be difficult. However, FDA believes that, as of May 2001, every "healthy" cheese product had already 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. 2). In an informal telephone inquiry, FDA confirmed that by May 2001, there were no longer "healthy" cheeses produced under this brand (Ref. 5).

Having no products to analyze prevents FDA from performing a detailed analysis of the potential impact of the second-tier sodium level on cheese. "Healthy" cheeses could have been taken off the market for several reasons.

First, an aspect of the product unrelated to sodium content (e.g. lower fat requirements) could have been responsible for low product demand. If so, option 2a would not lead to any societal benefits through influencing the market for cheese. Second, firms may not be able to create an acceptable "healthy" cheese product even under the first-tier sodium level for individual foods. This means that 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 re-introduce "healthy" cheese products.

In this case, FDA believes it likely that sodium content was not the primary factor in the decision to take "healthy" cheeses off the market. Many light mozzarella cheeses currently have a sodium content lower than second-tier sodium levels—between 167 and 357 mg per 50 g serving in our examples from Washington, DC, area grocery stores (Ref. 5)—and the "healthy" version of this cheese was among the most popular sellers among all "healthy" cheeses but was still pulled from the market (Ref. 2).

Soups. Costs associated with the current rule, and therefore benefits of avoiding these costs under option 2a, would be small for soups. "Healthy" soups had about a 7 percent market share by sales in 1999, but a major producer of "healthy" soups supports the second-tier sodium level; this is persuasive evidence that the private benefits to producers of preserving "healthy" as a high-quality health signal can be as valuable as the private cost of reformulation. This producer states in its comments to the ANPRM that, for most major varieties of its brand of "healthy" soup, it was able to achieve

taste parity under the second-tier sodium level. However, another major soup producer does not support the second-tier level.

Costs of Option 2a. The principal costs of this option are all associated with the deterioration of "healthy" as a signal of a truly healthy individual food.

Based on the comments to the ANPRM, over 90 percent of "healthy" individual foods could meet the second-tier sodium limit without material adverse changes in taste or texture. Cheeses and soups represent a small percentage of all "healthy" individual foods. Retaining the first-tier sodium level for all individual foods would diminish the effectiveness of the "healthy" low sodium signal substantially, compared to the current rule. Alternatively, if FDA retained the first-tier "healthy" sodium level only for soups and cheeses, FDA believes this inconsistency would also diminish the usefulness of the term "healthy" as a low sodium signal.

In addition, the current and proposed rule's second-tier level for individual foods is more consistent with the "healthy" definition for meals and main dishes. As explained in detail in section III of this document, the first-tier sodium level for combinations of "healthy" individual foods allows significantly more sodium than when those same foods are combined into meals and main dishes. "Healthy" meal and main dish products must contain at least two noncondiment food groups, and still can only contain 600 mg sodium per meal or main dish under the first-tier sodium level. In 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, or 40 percent of the RDI. The current and proposed rule's second-tier level for individual foods is fairly consistent with the meal

and main dish first-tier sodium level, but the first-tier difference of up to 360 mg sodium between a meal and two individual foods is substantial and could have a health effect if consumers are using "healthy" specifically as a low sodium signal. FDA believes this inconsistency in the labeling claim "healthy" could lead to higher sodium intake, if the first-tier sodium level were to remain in effect for individual foods.

FDA believes that the major cost of option 2a is the increased health risk caused by higher sodium intake due to retaining the higher first-tier sodium level for individual foods. FDA further believes that the costs of this option outweigh the benefits of adopting as permanent the first-tier sodium limit for all or particular individual foods.

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

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 adopting option 2b will not significantly affect the average amount of sodium consumed in an overall diet. The net increase in sodium intake under the proposed rule 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.

In the original analysis of the regulation defining the "healthy" claim, FDA referred to the many benefits of improved nutrition labeling, including decreased rates of cancer, coronary heart disease, obesity, hypertension, and allergic reactions to food. FDA also considered "healthy" claims an important contributor to the $4.4 billion to $26.5 billion benefit of improved food labels

over the 20 years following the rule (59 FR 24232 at 24247 and 24248). Several comments on the 1997 ANPRM expressed concern that "healthy" claims at the first-tier sodium level may undermine consumer attempts to improve their diets and health, as these meals are not truly healthy. An inaccurate "healthy" claim is not a useful signal that a product is indeed healthy.

In order to get a rough estimate of the difference in sodium intake between the current and proposed rule, we took a sample of 106 frozen meals and main dishes from a Washington, DC area grocery store (Ref. 5). The agency believes this sample is 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 (Ref. 5).

According to the Washington, DC grocery store sample, the current 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 dishes such as organic goods. Many of these products prominently display fat and calorie information on the front of the package; these brands clearly use nutritional content as a marketing tool.

According to our analysis (Ref. 5), 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 explore several possible consumer and producer responses to option 2b—retaining the first-tier sodium level for meals and main dishes—as compared to option 1—allowing the second-tier sodium level to go into effect—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. Among the "healthy" brands, producers would have the option of either reformulating their products to meet the second-tier level, or relabeling 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 independent comments to the ANPRM expressed concern that lowering the sodium requirement to the second-tier level could encourage a consumer to switch to higher sodium alternatives.

The scenarios are summarized in table 1 of this document. 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 are the

result of analysis explained in a technical memo (Ref. 5). 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 1 of this document represent the normal and bargain market segments previously described. We assume that the three "claims" brands in this analysis are a reasonable approximation to the "claims" market segment as previously described in this document. 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 + .52 +.03) equal to 1.

TABLE 1.—SODIUM CONSUMPTION SCENARIO ANALYSIS FOR SAMPLE 1 MEALS AND MAIN DISHES

Scenario	Healthy Brand Sodium mg (Market Share)	Claims Brand 1 Sodium mg (Market Share)	Claims Brand 2 Sodium mg (Market Share)	Other Sodium mg (Market Share)	Average Sodium mg
(1) Present market	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 claims competitors (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 total response to option 1.	480 (.45 - .113)	593 (.52 + .056)	722 (.03 + .056)	856 (0)	566
(6b) Combined total response to option 2b.	580 (.45 + .04)	593 (.52 - .02)	722 (.03 - .02)	856 (0)	588
(6) 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 the current rule (option 1) and the

proposed rule (option 2b) affect the average amount of sodium consumed. Scenarios 6a and 6b combine the responses in the previous scenarios in an attempt to capture the total effect of the proposed rule. The last row, in the last column, is the total change in sodium when comparing the proposed rule (6b) to the option 1 (6a) (scenario 6—"total effect").

Scenario 1: The Present Market. The first-tier sodium level applies until 2006, but firms may be trying to prepare for the second-tier sodium level, causing the average amount of sodium in the "healthy" brand to be lower than it would be under the proposed rule. The average "claims" segment meal, as reported in the last column of table 1 of this document, contains 579 mg sodium, the average "healthy" brand meal contains 551 mg sodium, and several "healthy" brand meals in this sample are 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 + 593*.52 + 722*.03) under option 1. The difference between this and the current market is 1.5 percent of the RDI of 2400 mg/day.

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"

product 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 "claims" products. 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" product 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 current rule 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 that only the current belief 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 the proposed rule, every "healthy" meal and main dish would contain 600 mg of sodium per meal. These meals and main dishes would no longer be the low sodium products in the market, but they would still be the second lowest sodium products among major producers, with "claims" brand 1 slightly lower. 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. 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 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" product and two-thirds will switch to non-"healthy" products. 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 for taste reasons. 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 is the best estimate of the "sodium cost" of the proposed rule, which is only 22 mg per meal.

FDA's technical memo (Ref. 5) repeats the basic parts of this analysis for a second sample of products pulled from the Web sites of a producer of "healthy" products and a "claims" segment producer, which we performed

as a stress test of the first sample conclusions. The result from this somewhat different sample of meal products is quite close to the 22 mg "sodium cost" calculated in scenario 6 of table 1 of this document.

According to our analysis, the sodium increase under option 2b, the proposed rule, 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 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 due to this proposed rule 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 1 of this document and in the results of the second sample (Ref. 5). However, FDA does not make this linear assumption. FDA believes that the health effects from this low level of sodium increase are negligible.

Benefits of Option 2b. The benefits of avoiding reformulation and relabeling costs under this option are substantial. As discussed in section III. C of this document, FDA identified 148 meal and main dish products labeled "healthy" among 10 brands.

Producers would have to expend resources to reformulate their meals 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 the current rule. If producers could reformulate perfectly, without altering any property other than sodium content, then reformulation would be the total cost of the rule. But if they could not replicate the desirable characteristics of their product, consumers would also suffer the utility loss of a market with fewer meal choices. This is a concern, since some dieticians recommend "healthy" claim products for their lower sodium content.

In the product samples used for the scenario analyses regarding the cost of the second-tier sodium level on 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 are above the second-tier sodium levels. If this is representative of 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 56 percent reformulation, or 83 of the 148 products on the market (see scenario 6a, in table 1 of this document).

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 has begun investigating possible reformulation—are well over $1 million, but we do not have detailed reformulation cost estimates for meals and main dishes. The following reformulation cost estimations are based on a detailed example of tortilla chip reformulation, but the steps are typical of food reformulation in general. FDA requests information on any reformulation processes for the meal and main dish industry that are different from those described here.

The reformulation process typically starts in a laboratory, where researchers develop a new lower sodium formula for their meals. Then the company investigates availability and price of new ingredients (herbs, for example) and new equipment. If the reformulated meal passes these obstacles, it moves to the test kitchen, where researchers produce the product in small batches. If approved at this level, the meal 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 a meal, 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 an existing product, we assume no 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. This cost would be incurred in the first year or two after the introduction of the rule. 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.

Regardless of the relative costs of reformulation, FDA believes 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 has already happened 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.

In this case, 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 to the manufacturer, they are most likely substantial.

However, the market may put a premium on "healthy" brands. This premium is a good measure of 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 this "willingness to pay" premium, and this investment would now be worthless if the product is unable to use the "healthy" claim. If the new definition of "healthy" with the second-tier sodium level is no more useful a health signal than the old definition, as we argue, this lost investment is a cost to society. In the original analysis of the regulation defining "healthy" (59 FR 24232 at 24247), which was issued in 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 oz equivalent. FDA used the Washington, DC store sample of 106 meals and main dishes referred to earlier to reestimate this premium for 2000, with similar results.

According to the analysis in FDA's technical memorandum (Ref. 5), the "healthy" brand competitor has 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. Excluding the specialty organic products, the "healthy" brand is the highest priced product on the market in our sample. FDA believes $0.32 to be a reasonable estimate of the market premium for the "healthy" brand. At average serving sizes of 10 oz, this translates into a $0.51 premium per 16 oz, which is very close to the $0.57 premium estimated in 1994.

In the 1994 analysis, the total value of each brand was based on this premium and average sales volumes. Sales of the brands still in the market were approximately 1.3 million units per product in 1999 (Ref. 2). Under the assumption of 19 percent rebranding in order for meals and main dishes to comply with the second-tier sodium level (scenario 6a), 28 products would be changed, 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 to the reformulation costs of the 83 products yields a total cost estimate of $29,908,000 for years one and two, and a residual of the lost premium of $11,648,000 for what would have been the rest of the normal life cycle of the lost "healthy" brand. Clearly, these costs are very large for a rule which would lead to little or no health benefit for the population, and avoiding these costs represents a large benefit of option 2b, the proposed rule.

Option 2c: Retain the First-Tier Sodium Levels for "Healthy" Meals and Main Dishes and Individual "healthy" Foods. The benefits and costs of option 2c are very close to the sum of the benefits and costs associated with options 2a and 2b. However, as stated in the discussion of option 2a previously in this document, retaining the first tier sodium levels for "healthy" individual foods would significantly decrease the consistency between sodium levels in "healthy" meals and main dishes and the sodium levels in meals put together

by combining "healthy" individual foods. The less consistent the sodium levels in "healthy" meals and individual foods, the less consistent, and therefore less useful, is the low sodium signal conveyed by the "healthy" label.

Costs of Option 2c. The cost of this proposed amendment, 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" low sodium signal. 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 discussed previously in detail in this document, the average increased sodium intake occurring under option 2b is insubstantial (roughly 22 mg per meal) and the health effects from this low level of sodium increase are negligible. As stated previously, 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 tier-2 levels would be less than 1. Furthermore, the effectiveness of the "healthy" low sodium signal would not be diminished since tier-1 levels of sodium for meals and main dishes allow for even less sodium than would appear in a meal composed of tier-2 individual "healthy" ingredients.

However, the potential increase in sodium intake, as discussed in detail under option 2a, due to relaxing the current level of sodium allowable in individual "healthy" foods, as well as the costs associated with the deterioration of the "healthy" signal, is significant.

Therefore, FDA believes the costs of option 2c, due to the reduced effectiveness of the "healthy" low sodium signal and the health risks due to

increased sodium intake are significant, but only negligibly higher than those costs described for option 2a.

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.

FDA estimates, as discussed in the benefits section of option 2a, that the benefits of avoiding reformulation and relabeling costs associated by retaining the first-tier sodium levels for individual "healthy" foods are small.

As discussed in the benefits section of option 2b, the benefits of avoiding reformulation, rebranding, and relabeling costs by retaining first-tier sodium levels for "healthy" meals and main dishes are substantial. FDA estimates the total cost of reformulation and relabeling avoided in option 2b is $29,908,000 for years one and two, and $11,648,000 per year thereafter.

Therefore, FDA believes the benefits of option 2c, due to the avoided reformulation and relabeling costs associated with implementing the tier-2 sodium levels for both "healthy" meal and main dishes and "healthy" individual foods, are substantial but only slightly higher than those benefits described for option 2b.

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

The net benefits of option 2a, retaining the first-tier level of sodium for individual "healthy" foods are negative. The costs due to the health risk associated with increased sodium intake and the lost consistency and meaning

of the "healthy" low sodium signal outweigh the benefits due to avoided reformulation, rebranding, and relabeling costs.

The net benefits of option 2b, retaining the first-tier level of sodium for "healthy" meals and main dishes are positive. The benefits in avoided reformulation, rebranding and relabeling costs substantially outweigh the negligible costs due to a very small potential increase in average daily sodium intake.

Since the net benefits of retaining the first-tier sodium level for "healthy" meals and main dishes are so substantial, FDA believes the net benefits of 2c, roughly the sum of the net benefits associated with 2a and 2b, are positive, but lower than the net benefits of the proposed rule, which would adopt as permanent the first-tier sodium limits for meals and main dishes only.

3. Net Benefits of the Proposed Rule

This analysis attempts to take limited data to illustrate in some detail what would actually take place in the market under the proposed rule. First, the costs to the "healthy" signal's meaning and consistency outweigh the benefits of retaining the first-tier sodium level for individual foods. However, the meal and main dish analysis 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 quite insubstantial or nonexistent. Therefore, the net benefits of the proposed rule, which would allow the second-tier sodium level to go into effect for individual foods but would adopt as permanent the first-tier sodium level for meals and main dishes, are positive.

B. Small Entity Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the economic effect of the rule on small entities. FDA finds that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This proposed rule would make permanent the less restrictive fist-tier sodium level that meals and main dishes must meet to make a "healthy" claim. Without this proposed rule, the more restrictive second-tier sodium level would raise the costs of making a "healthy" claim on such products. If a small business were to market a "healthy" meal or main dish, it would be able to do so at lower cost under the proposed rule than if FDA left the current rule unmodified.

This proposed rule does not modify the current rule for the sodium content of "healthy" individual foods, under which the second-tier sodium level for those foods will take effect in 2006. Although the proposed rule does not impose a cost on small businesses over and above the rule that would otherwise be in place, FDA could lower the cost to small businesses of making a "healthy" claim by adopting as permanent the first-tier sodium level for individual foods.

As stated in the preliminary regulatory impact analysis discussed earlier, manufacturers of "healthy" foods in three categories—cheeses, soups, and some meats—are likely to be affected by the implementation of the second-tier sodium level. These foods are discussed in this document. As FDA has

no information concerning costs for other individual foods and has received no comments indicating that manufacturers of these other foods would have difficulty meeting the second-tier sodium level, the agency tentatively concludes that the impact on small entities producing other types of "healthy" individual foods is not significant. FDA invites comments regarding small entities producing other "healthy" individual foods that may be adversely impacted by this proposed rule.

Of the affected individual food categories, meat is regulated by the USDA and is not part of this analysis. The Small Business Administration (SBA) considers a cheese manufacturer small if it employs 500 or fewer workers, but no small or large business currently produces "healthy" cheese. The SBA considers a miscellaneous food manufacturer (neither SBA nor the Census Bureau specifically tracks soup producers) small if it employs 500 or fewer employees. According to the 1999 survey of foods used for this analysis, six companies produce "healthy" soups (Ref. 2), but none of these companies qualifies as a small business according to the standard SBA criteria. According to the 1999 Statistics for Businesses from the United States Census Bureau, over 90 percent of food manufacturers are small by the standard SBA criteria, so new entries into this industry in the future are likely to be small businesses. FDA tentatively concludes that this proposed rule will not have a significant impact on small entities.

VI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed 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 proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has tentatively 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 tentatively 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. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) 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. Anderson, Ellen M., memorandum to file, September 3, 2002.

3. Kim, Heili, memorandum to file, July 16, 2001.

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

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

6. *Cheese: Chemistry, Physics and Microbiology*, edited by P.F. Fox Chapman & Hall, 2d ed.

7. Kim, Heili, memorandum to file, May 15, 2001.

8. Anderson, Ellen M., memorandum to file, August 19, 2002.

9. Kim, Heili, memorandum to file, May 15, 2001.

10. National Partnership for Reinventing Government, Plain Language Action Network, Presidential Memorandum on Plain Language (www.plainlanguage.gov/cites/memo.htm).

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, it is proposed that 21 CFR part 101 be 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	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	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) fat per RA[1] and per 100 g	Less than 2 g saturated fat per RA and per 100 g	Less than 95 milligrams (mg) cholesterol per RA and per 100 g	At least 10 percent of the RDI[2] or the DRV[3] 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)	90 mg or less cholesterol per SS[4]	At least 10 percent of the RDI or the DRV per SS of two nutrients (for a main dish) or of three nutrients (for a meal) of the following six nutrients—vitamin A, vitamin C, calcium, iron, protein, or fiber
(F) A food not specifically listed in this document	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)	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] RA means Reference Amount Customarily Consumed per Eating Occasion (§ 101.12(b)).
[2] RDI means Reference Daily Intake (§ 101.9(c)(8)(iv)).

[3] DRV means Daily Reference Value (§ 101 9(c)(9)).
[4] SS means Serving Size Listed on the Label (§ 101 9(b)), also referred to as Labeled Serving Size

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

If the food is.	The sodium level must be .
(A) A food with a RA[1] that is *greater* than 30 g or 2 tablespoons (tbsp)	360 mg or less sodium per RA and per SS[2]
(B) A food with a RA that is *equal to or less than* 30 g or 2 tbsp	360 mg or less sodium per 50 g[3]
(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 SS

[1] RA means Reference Amount Customarily Consumed per Eating Occasion (§ 101.12(b))
[2] SS means Serving Size Listed on the Label (§ 101 9(b)), also referred to as Labeled Serving Size.
[3] 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 part 101 of this chapter for any specific nutrient content claim used in labeling the food;

(iv) For foods in paragraph (d)(2)(i)(B) of this section, you may add ingredients that do not change the nutrient profile;

(v) Enriched cereal-grain products in paragraph (d)(2)(i)(C) of this section must conform to a standard of identity in part 136, 137, or 139 of this chapter; and

(vi) If you add a nutrient to the foods in paragraph (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 consistent with the fortification policy for foods in § 104.20 of this chapter.

Dated: February 13, 2003

William Hubbard

William K. Hubbard
Associate Commissioner for Policy ~~and Planning~~ and Planning

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