Interested persons may, on or before February 13, 1998, submit written comments on the data developed under Study B to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and labeled ''ATTN: Study B, OTC Drug Labeling Data Collection.'' The data, frequency tabulations, and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic format of the data are available on the internet at: www.fda.gov/CDER/ or can be obtained in electronic form from the Dockets Management Branch at the address listed above.

Dated: December 19, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–33803 Filed 12–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 91N–384H and 96P–0500]

RIN 0910–AA19

Food Labeling: Nutrient Content Claims, Definition of Term: Healthy

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is considering whether to institute rulemaking to reevaluate and possibly amend certain provisions of the nutrient content claims regulations pertaining to the use of the term ''healthy.'' This action is in response to a citizen petition from ConAgra, Inc., to amend the definition of this term. The petitioner has raised important issues regarding both the technological feasibility of reductions in sodium levels in foods that currently meet FDA's definition for the term ''healthy'' and the safety of at least some of these foods if there are reductions in their sodium levels. The agency is requesting that data be submitted relative to these issues. In addition, FDA is responding to comments that it received in response to a stay of certain provisions pertaining to the use of the term ''healthy.''

DATES: Written comments by March 16, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5483.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 10, 1994 (59 FR 24232), FDA published a final rule to establish a definition of the term ''healthy'' under section 403(r) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)). In that final rule, FDA stated that 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 (59 FR 24232 at 24233). In its consideration of comments relative to the proposed qualifying level of sodium to be incorporated into the definition of the term ''healthy,'' the agency rejected comments that suggested that the food should meet the requirements for ''low sodium'' (59 FR 24232 at 24239). The agency stated that such a definition was too restrictive, and that many foods that would otherwise meet the definition of ''healthy'' would be disqualified by a ''low sodium'' requirement. The agency stated that for the claim to be useful, foods that are able to bear the term should be of a sufficient number and variety to help consumers achieve a total diet that is consistent with current dietary recommendations (59 FR 24232 at 24239).

The agency explained that sodium plays an important role in consumer acceptance of a product, and that many products that qualify to bear a claim for ''healthy'' may lose their appeal to consumers because of an unacceptable flavor profile if, in addition to being low in fat and saturated fat, the foods were low in sodium. FDA stated that, if consumers abandon products or add salt to taste at the table, foods bearing the term would lose their usefulness in assisting consumers to achieve dietary recommendations with respect to sodium intake (59 FR 24232 at 24239).

Based on the comments to the proposed rule for ''healthy'' relative to specific sodium levels, the agency adopted qualifying criteria of 360 milligrams (mg) of sodium per reference amount customarily consumed (RACC) in individual foods and 480 mg sodium per RACC in main dish and meal products (59 FR 24232 at 24240). In addition, the agency established a transition period to allow time for industry to reformulate products to meet the new qualifying sodium levels. The agency determined that levels of 480 mg of sodium in individual foods, single ingredient seafood, and game meat, and of 600 mg of sodium in main dishes and meal products, were appropriate levels during the transition period, but that after January 1, 1998 (essentially 3-1/2 years from the date of publication of the final rule), these foods would have to meet the lower sodium qualifying levels to bear the claim ''healthy'' (59 FR 24232 at 24241 and 24245 and see § 101.65(d)(2)(ii), (d)(3)(ii), and (d)(4)(ii) (21 CFR 101.65(d)(2)(ii), (d)(3)(ii), and (d)(4)(ii))).

On December 13, 1996, FDA received a petition from ConAgra, Inc. (the petitioner), 888 17th St. NW., suite 300, Washington, DC 20006, requesting that § 101.65(d) be amended 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'' (Docket 96P–0500, CP–1, p. 1). Alternatively, the petitioner requested that the effective date of January 1, 1998, in § 101.65(d)(2) through (d)(4) be delayed until such time as food technology catches up with FDA's goals to reduce the sodium content of foods, and until there is a better understanding of the relationship between sodium and hypertension.

The agency was persuaded by the petition that it is in the public interest to stay the effect of the lower standards for sodium in the definition of ''healthy'' in § 101.65 while the agency endeavors to resolve the issues raised by the petition. Therefore, in the **Federal Register** of April 1, 1997 (62 FR 15390), FDA published a final rule that stayed, until January 1, 2000, the effective date of January 1, 1998, in § 101.65(d)(2)(ii) and (d)(4)(ii) for when foods must achieve the lower sodium levels (the ''second tier levels'') to qualify to bear the term ''healthy.'' The agency said that it was issuing the stay to allow itself time to reevaluate the standard, and to evaluate the data contained in the petition and any additional data that it may receive; to conduct any subsequent notice-and-comment rulemaking that it finds is necessary; and to allow ample time for implementation of the rule or of any changes in the rule that may result from the agency's reevaluation.

Accordingly, FDA announced that interested persons may submit comments regarding the appropriateness of the basis for the stay and the feasibility of further lowering the sodium level in foods while maintaining consumer acceptability.

FDA is issuing this advance notice of proposed rulemaking (ANPRM) to respond to the comments that it received in response to the stay and to solicit comments and additional information on whether it should propose to amend the definition of the term ''healthy'' relative to the sodium requirements. Those interested persons that believe that the agency should amend the ''healthy'' definition should address what the amended regulation should require to ensure that the term can appear on a significant number of foods but is not so broadly defined as to lose its value in highlighting foods that are useful in constructing a diet that is consistent with dietary guidelines. Those who believe that the current definition is appropriate and should not be changed should provide data that demonstrate that the definition, with the sodium levels that were scheduled to take effect in January of 1998, is not so restrictive as to effectively preclude use of the term.

II. FDA's Response to Comments on the Stay of Certain Provisions in the Definition of ''Healthy''

FDA received eight comments in response to the stay of the sodium provisions in § 101.65(d)(2)(ii) and (d)(4)(ii) from industry, trade associations, a health care association, and a Federal Government agency. Most of the comments agreed with the agency's decision to stay these provisions until January 1, 2000, to allow the agency time to reevaluate the standard on the basis of available data, including the data contained in the petition and any additional data that the agency may receive.

Three comments disagreed with the agency's decision to stay the regulations. Two of the comments asserted that to stay the sodium level is a disadvantage to those companies that are ready to produce products that qualify to bear the term ''healthy'' under the stayed provisions. One comment stated that the consumer benefits if companies are prepared and allowed to respond to the opportunity to be one of a few or of several to offer and label foods as ''healthy.'' The other comment stated that many companies have demonstrated their ability and willingness to manufacture products that meet the lower second-tier sodium levels in § 101.65(d)(2)(ii) and (d)(4)(ii). The comment stated that reducing sodium intake is one component of a comprehensive nutritional approach to blood pressure lowering that would benefit many Americans.

One comment stated that FDA's decision to stay the lower sodium requirements conflicts with the agency's findings in adopting the ''healthy'' final rule in 1994. The comment noted that, in the final ''healthy'' regulation, FDA arrived at the final sodium criteria based on four key findings: (1) The levels will assist consumers in constructing a diet consistent with dietary guidelines; (2) they provide for a reasonable amount of sodium that enables a wide variety of foods to use the ''healthy'' claim without compromising the appeal of the food; (3) the levels are not so restrictive that they are likely to disqualify many foods that are recommended to be included in a healthy diet; and (4) the level ensures consistency with the U.S. Department of Agriculture (USDA). The comment stated that FDA seems willing to ignore its stated public health goals out of concern that certain foods may not be commercially viable at the levels of sodium determined by FDA to be appropriate.

FDA recognizes that some companies will have reformulated their products to meet the second tier sodium levels in § 101.65(d)(2)(ii) and (d)(4)(ii) by 1998, but it disagrees with the comments that stated that the stay will put these companies at a disadvantage. These companies will be able to make comparative claims that highlight their achievement (e.g., ''25 percent less sodium than Brand X''). As stated in the final rule of April 1, 1997, FDA encourages manufacturers who can meet the lower sodium levels for particular foods to do so even as the agency reevaluates the issues discussed in the petition (62 FR 15390 at 15391).

The agency also disagrees that it is ignoring the basis on which it established the sodium criteria out of concern that certain foods may not be commercially viable at the second-tier sodium levels. The petitioner raised significant questions, based on work that it did after publication of the ''healthy'' final rule, relative to the second of the four key findings noted previously; namely, whether there will be a wide variety of foods that will qualify to use the term ''healthy'' at the second-tier sodium levels that are also acceptable to consumers. Given this fact, but given that the scientific evidence indicates further reductions in fat and sodium intakes will result in meaningful public health gains (62 FR 15390), the agency is staying the second tier levels until it resolves this issue. The agency is concerned that if the technology does not yet exist that permits manufacturers to produce, by January 1, 1998, certain types of reduced sodium foods that are acceptable to consumers, the possibility exits that the term ''healthy'' will disappear from the market. FDA will evaluate the data that it receives on whether the technological barriers to reducing the sodium content to the lower levels required in § 101.65(d)(2)(ii) and (d)(4)(ii), and likewise for § 101.65(d)(3)(ii), are insurmountable or not. The burden is on interested persons to provide convincing evidence to show why the lower sodium levels are not attainable. If they fail to do so, the lower sodium levels will become effective on January 1, 2000.

III. Petition to Amend the Definition of ''Healthy'' and the Agency Response

A. The Petition

The petitioner cited as grounds to amend the definition of ''healthy'': (1) A lack of scientific basis supporting the Daily Reference Value for sodium and the allowable levels of sodium in § 101.65(d); (2) a lack of consumer acceptance of products containing low sodium levels; (3) a lack of acceptable sodium substitutes and the difficulties in manufacturing whole lines of food products at low sodium levels; and (4) FDA's failure to provide notice and comment on the second tier sodium levels in the ''healthy'' definition, to follow directives of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), and to consider recent scientific studies that raise concerns if too little sodium is consumed (Docket 96P–0500, CP–1, p. 3).–

Relative to the efforts of industry to lower the sodium level of foods, the petitioner stated that the technology does not yet exist to manufacture certain low fat products that both contain the levels of sodium necessary to satisfy the second tier requirements in the ''healthy'' definition and are acceptable to consumers (Docket 96P–0500, CP–1, p. 24). The petitioner argued that there is no adequate substitute for sodium chloride as a provider of a salty taste (Docket 96P–0500, CP–1, p. 36). In addition, the petitioner stated that salt enhances or modifies all flavors of food, and that flavors are dulled or become harsh when salt is reduced.

The petitioner submitted the results of a consumer survey that examined consumer acceptance of three products (hot dogs, macaroni and cheese, and chicken soup) with different sodium

levels (600 mg, 480 mg, and 360 mg sodium per serving) (Docket 96P–0500, CP–1, pp. 25 to 28 and exhibit 161). While the results of the survey show reductions in consumer acceptance at levels of 480 mg sodium, a much greater, i.e., a statistically significant, reduction occurred at levels of 360 mg sodium per serving. As stated by the petitioner, ''If the sodium is so low in a product as to render the product tasteless or even bad tasting, consumers will not eat the product or will reach for the table salt. This is counter productive to the intent of the 1990 amendments and will not result in the goal Congress envisioned; i.e., to improve the eating habits of the American public, but instead could result in even more salt intake—not less'' (Docket 96P–0500, CP–1, p.28).

The petitioner also delineated several technological concerns associated with lowering the sodium levels in foods related to the functional role of salt. For example, the petitioner described the effects of such reductions on the microbial stability of perishable products, on product texture and water binding capacity, on the flavor characteristics of certain ingredients, and on total electrolyte levels, which, the petitioner asserted, play a critical role in product safety (Docket 96P–0500, CP–1, pp. 28 to 30).

The petitioner explained that a number of novel, proprietary, and known technological approaches to replace or potentiate sodium have been evaluated, but that, to date, none have been found to have suitable consumer acceptance. The petitioner stated that potassium chloride, often cited as capable of increasing salty taste, is also known for leaving a bitter aftertaste and has not gained widespread, satisfactory consumer acceptance (Docket 96P–0500, CP–1, p. 41). The petitioner suggested that to achieve the second-tier sodium levels as defined for ''healthy'' will require the ''invention, development, and commercialization of ingredients or components that do not exist today'' (Docket 96P–0500, CP–1, p. 41).

B. The Agency Response

FDA finds that some of the issues raised in the petition regarding the second tier sodium levels appear to have merit. Others do not.

The agency does not find merit in the petition's questions regarding the lack of scientific basis for the usefulness of lowered sodium levels in the diet of the general population. There is significant scientific agreement that lower dietary sodium levels reduce the risk of hypertension (Refs. 1 to 7). The overwhelming majority of experts and of authoritative bodies still favors making recommendations for the general public to moderate sodium intake. This consensus is reflected in the Dietary Guidelines for Americans (Ref. 8).

FDA also finds the petitioner's argument that the agency failed to provide notice and comment on the second tier sodium levels in the ''healthy'' definition to be without merit. The revisions in the sodium requirements for individual foods and main dishes and meal products that were adopted in the ''healthy'' final rule were a logical outgrowth of the proposal (59 FR 24232 at 24241). In the proposal, the agency asked for comments for evaluating whether the definition of ''healthy'' that it had proposed (i.e., foods that do not exceed the disclosure level for sodium or cholesterol and are ''low'' in fat and saturated fat) was appropriate (58 FR 2944 at 2947). FDA acknowledged that its proposed definition of the term ''healthy'' differed from the definition for ''healthy'' that was proposed by USDA (i.e., meat or poultry that contain less than 10 grams (g) of fat, less than 4 g of saturated fat, less than 95 mg of cholesterol, and less than 480 mg of sodium per 100 g and per reference amount customarily consumed for individual foods, and per 100 g and labeled serving for meal-type products) (58 FR 688); and FDA asked for comments on whether it was necessary that FDA and USDA provide uniform criteria for use of this term, or whether different definitions would be appropriate (58 FR 2944 at 2948). As stated previously, the agency received comments that argued that FDA should adopt levels both lower and higher than those that it proposed and those that it adopted (see 59 FR 24232 at 24238 and 24239). FDA considered the information submitted in the comments in arriving at the final levels (see 59 FR 24232 at 24239 to 24241). Thus, the agency provided full and adequate notice of its intent to adopt sodium levels, and the levels that it adopted were the logical outgrowth of the proposal. See *Small Refiner Lead Phase-Down Task Force* v. *USEPA*, 70S F.2d 506, 548–550 (D.C. Cir. 1983).

However, the agency does find that the issues relative to technological and safety concerns of reduced sodium foods present important questions that merit further consideration.

FDA has defined the term ''healthy'' to serve as a means to help consumers to identify food products that will help them meet the guidelines for a healthy diet. Consumers understand the significance of this term, and thus many make purchasing decisions based on its presence on a food label. Because of this fact, manufacturers have an incentive to produce foods that qualify to bear this term. If the petitioner is correct that the technology does not yet exist that will permit manufacturers, by January 1, 1998, to produce certain types of low fat foods at the lower levels of sodium required in § 101.65(d) that are still acceptable to, and safe for, consumers, then the possibility exists that ''healthy'' will disappear from the market for such foods. This result would force consumers who are interested in foods with restricted fat and sodium levels to choose among foods in which an effort has been made to lower the level of one or the other of these nutrients but not necessarily both. If this situation comes to pass, FDA will have squandered a significant opportunity. Therefore, the agency has decided that, before allowing the new sodium levels for ''healthy'' to go into effect, it needs to explore whether it has created an unattainable standard for many types of foods.

Accordingly, FDA is considering whether to institute rulemaking to resolve the issues raised by the petition and to reevaluate the sodium provisions of the nutrient content claims regulations pertaining to the use of the term ''healthy.'' In this notice, the agency is asking for data or evidence on what will happen to the use of the term ''healthy'' in the market if the second-tier sodium levels were in effect. How many products that bear the term ''healthy'' would be eliminated? Would there be other impacts on the number of consumer choices?

The agency is also asking for: (1) Data regarding the technological feasibility of reducing the sodium content of individual foods (including single ingredient seafood and game meats) to 360 mg per RACC and of reducing the sodium content of meals and main dishes to 480 mg sodium per labeled serving, and (2) additional information or views on consumer acceptance of foods with such sodium levels.

With regard to technological feasibility, the agency is asking for 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 sodium levels on the shelf-life stability and the safety of the food. Are there certain types of foods for which it is not possible to reach the second tier levels of sodium? If so, what are these foods? Should FDA make special exemptions for them, or should FDA exclude them from bearing the term ''healthy?''

The agency is also asking for comments on other approaches to

reduce the amount of sodium in foods labeled ''healthy.'' It is important that consumers seeking to eat a health-promoting diet have food choices available that enable them to reduce the amount of sodium in their diet.

If the comments reveal that agreement exists that there are technological hurdles that cannot be overcome at this time for all foods, or certain types of food, the agency is interested in exploring options for maximizing the public health gains that would come from reducing dietary sodium levels. To this end, the agency has identified the following four options that seem to represent the available alternatives.

One, the agency may make no changes to the stayed rule, and the second tier sodium levels in § 101.65(d)(2)(ii) and (d)(4)(ii) will become effective on January 1, 2000. This is the default option should the industry fail to provide evidence, data, or arguments that support amendment of these sections. Adequate support for these levels existed at the time FDA published the May 10, 1994, final rule; and the agency will not hesitate to reconfirm them in the event that the industry fails to provide evidence to persuade FDA to do otherwise.

Two, FDA can propose to amend the definition of ''healthy'' in § 101.65(d)(2)(ii) and (d)(4)(ii) as requested in the petition, and, at the same time, propose to amend § 101.65(d)(3)(ii), to make the current sodium levels for individual foods, single ingredient seafood and game meats, main dishes, and meal products the qualifying levels and to delete § 101.65(d)(2)(ii)(C)(*1*) and (d)(2)(ii)(C)(*2*), (d)(3)(ii)(C)(*1*) and (d)(3)(ii)(C)(*2*), and (d)(4)(ii)(B) in their entirety. FDA is likely to propose this option should the evidence submitted in response to this ANPRM demonstrate that it is technologically impossible to find salt substitutes for use in any type of food that would satisfactorily meet the requirements for taste, texture, safety, and consumer acceptance. However, persons who support this course would have to provide evidence on the efforts that they or others have made to comply with the second tier sodium levels, and they would have to provide a persuasive explanation as to why these reductions in sodium levels are not attainable.

Three, if data and information submitted in response to this ANPRM suggest that technological advancements could be made but would require more time than provided in the stay of the effective date for the tier two sodium reductions (i.e., January 1, 2000, see 62 FR 15390), the agency would consider continuing the stay of the effective date of § 101.65(d)(2) and (d)(4) for an appropriate period of time. To support this option, FDA would expect to receive information demonstrating that progress is being made in the reformulation of ''healthy'' products, as well as information that provides an estimate of how much additional time is needed and that establishes the reasonableness of this estimate.–

Four, the agency could reconsider the sodium levels that it has established as the second tier of the ''healthy'' definition. For example, one possibility might be that an individual food would have to contain 360 mg sodium or less per RACC, or at least 25 percent less sodium per RACC than a market basket norm, so long as the final sodium level does not exceed 480 mg per RACC. For both main dish and meal products, the agency might consider the use of a percent reduction from the disclosure level for main dishes (720 mg sodium) or a percent reduction from the market basket norm. If a 25 percent reduction from the disclosure level of 720 mg were applied, the sodium level per labeled serving for main dishes and meals would be 540 mg (720 mg times 0.25 equals 180, and 720 mg minus 180 mg equals 540 mg).

If the definition is set at the reasonably achievable level of a 25 percent reduction from the disclosure level or from the market basket norm, more foods are likely to be available, and consumers will be able to select from more and different foods to meet dietary guidelines. Furthermore, market competition may spur some manufacturers to exceed this minimal reduction, thereby resulting in foods with even greater reductions. On the other hand, the question that must be considered is whether a 25 percent reduction from the disclosure level or market basket norm is of adequate dietary significance to warrant use of the term ''healthy.''

Based on the foregoing, the agency requests comments on whether it should institute rulemaking to reevaluate the sodium provisions of the nutrient content claims regulations pertaining to the use of the term ''healthy'' and on the other issues raised by the petition.

IV. Executive Order 12866 Analysis

If any rulemaking is proposed as a result of comments received to this ANPRM, FDA will examine the economic implications of the proposed rule as required by Executive Order 12866, which directs agencies to assess all costs and benefits of available regulatory alternatives. 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, or if it raises novel legal or policy issues.

If FDA institutes rulemaking, the agency will examine the potential costs of the proposed rule, including but not limited to label redesign costs, product reformulation costs, and potential loss of product or product name. FDA will also examine potential benefits including improved access to information regarding the health effects of particular foods. FDA requests information that would aid the agency in responding to the Executive Order.

V. Regulatory Flexibility Analysis

If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to analyze options that would minimize the economic impact of that rule on small entities. According to the Regulatory Flexibility Act, the definition of a small entity is a business independently owned and operated and not dominant in its field. The Small Business Administration (SBA) has set size standards for most business categories through use of four-digit Standard Industrial Classification codes. For most processed foods, SBA considers any entity with fewer than 500 employees to be small. FDA requests information on the number of small entities that use the term ''healthy'' in the labeling of their products. FDA also requests information regarding the impact on small entities of the four options which FDA has identified and described in section III.B of this document. Specifically, FDA is interested in how each option may impact on a small entity's viability.

VI. Comments

Interested persons may, on or before March 16, 1998, submit to the Dockets Management Branch (address above) written comments regarding this ANPRM. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons

between 9 a.m. and 4 p.m., Monday through Friday.

1. DHHS, Public Health Service (PHS), ''The Surgeon General's Report on Nutrition and Health,'' U.S. Government Printing Office, Washington, DC, pp. 139 to 143, 157 to 161, 165, and 167 to 174, 1988.

2. FNB/NAS, *Diet and Health*, National Academy Press, Washington, DC, pp. 355 to 356, 549 to 553 and 556 to 561, 1989.

3. Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure, ''The Fifth Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure,'' *Archives of Internal Medicine*, 153:154 to 183, 1993.

4. Nutrition Committee, American Heart Association, ''Dietary Guidelines for Healthy American Adults—A Statement for Health Professionals from the Nutrition Committee, American Heart Association,'' *Circulation*, 94:1795 to 1800, 1996.

5. LSRO, ''Evaluation of Publicly Available Scientific Evidence Regarding Certain Nutrient-Disease Relationships, 4. Sodium and Hypertension,'' Bethesda, MD, December 1991.

6. FNB, National Research Council, ''Recommended Dietary Allowances,'' 10th ed., National Academy Press, Washington, DC, pp. 247–261, 1989.

7. USDA, DHHS, ''Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans,'' USDA, Washington, DC, 1995.

8. USDA, DHHS, ''Nutrition and Your Health: Dietary Guidelines for Americans,'' 4th ed., Home and Garden Bulletin No. 232, 1995.

Dated: December 10, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–33921 Filed 12–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 94P–0168]

Food Labeling; Serving Sizes; Reference Amount and Serving Size Declaration for Hard Candies, Breath Mints

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the nutrition labeling regulations to change the label serving size for the product category ''Hard candies, breath mints'' to one unit. This action is in response to a petition to provide a serving size for breath mints that more accurately reflects the amount customarily consumed per eating occasion. In a related issue, FDA is proposing to allow the declaration of caloric amounts of less than 5 calories in the nutrition label.

DATES: Submit written comments by March 16, 1998. Submit written comments on the information collection provisions by January 29, 1998. See Section V of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Ellen M. Anderson, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5662.

SUPPLEMENTARY INFORMATION:

I. Background

In response to the Nutrition Labeling and Education Act (hereinafter referred to as ''the 1990 amendments''), FDA, among other actions, issued a proposal on serving sizes (56 FR 60394, November 27, 1991). FDA proposed a reference amount customarily consumed per eating occasion (hereinafter referred to as ''reference amount'') of 15 grams (g) for ''Baking candies * * * and hard candies'' but no separate reference amount for breath mints (56 FR 60394 at 60419).

The agency received several comments from hard candy manufacturers opposing the uniform 15-g reference amount for hard candies (58 FR 2229 at 2266, January 6, 1993). The comments stated that the 15-g reference amount would result in the serving size of breath mints being the entire package, and that, therefore, breath mints should have a separate smaller reference amount. Most comments recommended a reference amount of one piece. One comment disagreed, however, arguing that several pieces may be consumed during one eating occasion. None of the comments that requested a reference amount based on pieces included any data to support their request.

One comment submitted data from a home use mail survey that supported 2 g as the customarily consumed amount for large breath mints. FDA carefully examined the data from this survey and noted that it only tested the manufacturer's own brands of candies and breath mints. However, in the final rule for serving sizes, because these data were the only breath mint data available to FDA, the agency created a separate product category for ''Hard candies, breath mints'' with a reference amount of ''2 g'' (58 FR 2229 at 2297). The 2 g reflected the weight of one breath mint (Ref. 1).

II. The Petition and Other Communications

FDA received a petition dated April 20, 1994 (Docket No. 94P–0168), from Ferrero USA, Inc., requesting that the agency amend the product category for ''Sugars and Sweets: Hard candies, breath mints'' to create a separate product category with a 0.5-g reference amount for small breath mints (weighing 0.5 g or less) that fulfill the same breath-freshening function as a larger mint. The manufacturer submitted study data not only on small breath mints but also on five large breath mint products. The manufacturer asserted that the data establish that their small breath mints (0.38 g each) are consumed one mint at a time, and that the majority of consumers never eat 2 g of small breath mints, equivalent to five mints, during an entire day.

The company also stated that consumers chose the small breath mints for their breath freshening ability and lower caloric content. The manufacturer stated that their trademarked slogan has been ''The 1 1/2 calorie breath mint,'' based on a serving size of ''1 mint,'' and that changing this slogan would result in an economic hardship. The petitioner concluded that the serving size for small breath mints should be ''1 mint'' and requested that FDA create a separate product category for small breath mints with a reference amount of 0.5 g.

The agency received correspondence opposed to, and in support of, this petition. The opposing comments (Docket No. 94P–0168, comments 1 and 2) stated: (1) That the facts presented in the petition did not support the 0.5 g (one mint) reference amount because nearly half of the users surveyed consumed two or more mints per occasion; (2) that the attempt to establish such an extremely narrow reference category to accommodate a single product runs counter to one of the principal objectives of the 1990 amendments, to provide consistency in labeled serving sizes among comparable and interchangeable products; (3) that ''breath-freshening function'' is not the