

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 May 6, 2003.

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 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

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).