DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 96P–0500 and 91N–384H]

RIN 0910–AA19

Food Labeling; Nutrient Content Claims, Definition of Term: Healthy; Extension of Partial Stay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; extension of partial stay.

SUMMARY: The Food and Drug Administration (FDA) is extending until January 1, 2003, the partial stay of certain provisions of the nutrient content claim regulations pertaining to the use of the term ''healthy.'' This action is in response to a citizen's petition from ConAgra, Inc. (the petitioner), to amend the definition of this term.

DATES: Effective March 16, 1999; 21 CFR 101.65(d)(2)(ii)(C), (d)(3)(ii)(C), and (d)(4)(ii)(B) are stayed until January 1, 2003. Written comments by April 15, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857.

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: In the **Federal Register** of May 10, 1994 (59 FR 24232), FDA published a final rule to define the term ''healthy'' under section 403(r) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)). The final rule set up criteria for foods and for meals and main dishes to be able to use the nutrient content claim ''healthy.'' Among other things, it defined two separate timeframes in which different criteria for sodium content would be effective (i.e., before January 1, 1998, and after January 1, 1998) and specified the criteria for a food to qualify to be labeled with either the term ''healthy'' or another related term.

Among other things, before January 1, 1998, under § 101.65(d)(2)(ii)(A), (d)(2)(ii)(B), (d)(3)(ii)(A), and (d)(3)(ii)(B), for a food to qualify to bear the term ''healthy'' or a derivative of that term, the food could contain no more than 480 milligrams (mg) of sodium (first-tier sodium level): (1) Per reference amount customarily consumed (RACC) per eating occasion; (2) per serving size listed on the product label; and (3) per 50 grams (g) for products with small RACC's (i.e., less than 30 g or less than 2 tablespoons). After January 1, 1998 (§ 101.65(d)(2)(ii)(C) and (d)(3)(ii)(C)), the food could contain no more than 360 mg of sodium (second-tier sodium level) per RACC, per labeled serving size, and per 50 g for products with small RACC's. Under § 101.65(d)(4)(ii), main dish and meal products, to qualify to bear this or a related term, could contain no more than 600 mg of sodium per RACC before January 1, 1998 (§ 101.65(d)(4)(ii)(A)), and no more than 480 mg of sodium per RACC after January 1, 1998 (§ 101.65(d)(4)(ii)(B)).

On December 13, 1996, FDA received from ConAgra, Inc., a petition 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.'' As an alternative, 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 there is a better understanding of the relationship between sodium and hypertension.

In the **Federal Register** of April 1, 1997 (62 FR 15390), in response to this petition, FDA announced a stay until January 1, 2000, of the provisions in § 101.65(d)(2)(ii)(C) and (d)(4)(ii)(B). This stay was intended: (1) To allow time for FDA to reevaluate the standard, including the data contained in the petition and any additional data that the agency might receive; (2) to conduct any necessary rulemaking; and (3) to allow time for industry to respond to the rule or to any change in the rule that may result from the agency's reevaluation.

In the **Federal Register** of December 30, 1997 (62 FR 67771), FDA published an advanced notice of proposed rulemaking (ANPRM) announcing that it was considering whether to initiate rulemaking to reevaluate and possibly amend the nutrient content regulations pertaining to use of the term ''healthy.'' Among other things, FDA requested information on the current status of ''healthy'' labeling and on the impact of permitting the second-tier, more-restrictive sodium levels to become effective. The agency also asked that persons who support changing the definition should address what the new definition 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 consistent with dietary guidelines. The agency asked that those who support keeping the existing definition, including the second-tier sodium levels, should provide data showing that the second-tier sodium levels are not so restrictive as to effectively prevent use of the term.

FDA received 22 responses to the ANPRM. The comments responding to the ANPRM presented strong and opposing views on whether FDA should let the second-tier sodium levels take effect. They also contained a significant amount of data relating to use of the term ''healthy.''

FDA has reviewed the comments and also made an independent assessment of the number of foods labeled as ''healthy.'' Based on the information available, the agency tentatively concludes that, in some cases, the second-tier sodium levels may be overly restrictive, thereby eliminating a term that may potentially assist consumers in maintaining a healthy diet. The agency needs time to reevaluate the definition of the term ''healthy'' to consider options that preserve the public health intent while permitting manufacturers to use this term on foods that are consistent with dietary guidelines.

FDA has not completed its reevaluation in the time allowed by the April 1, 1997, partial stay due to: (1) Limited agency resources; (2) other agency priorities; and (3) the need to investigate independently the validity of the strong, opposing positions expressed in the comments. Because FDA needs additional time to consider whether proposing a change in the definition is necessary, the agency is extending the partial stay until January 1, 2003.

Under § 10.35(a) and (d)(1), the Commissioner of Food and Drugs (the Commissioner) may at any time stay or extend the effective date of a pending action if the Commissioner determines that it is in the public interest to do so. As discussed previously in the partial stay (62 FR 15390) and the ANPRM (62 FR 67771), the petition has raised significant issues that have public health implications.

FDA also recognizes, as mentioned in the petition, that manufacturers must begin very soon to revise the formulations and labeling if they have not already done so for those products that do not currently comply with the requirement that must be met after January 1, 2000, for a product to bear

the claim. FDA needs time to consider the supporting and opposing positions and to conduct any necessary rulemaking on the issues raised. Given these factors, the agency is persuaded that it is in the public interest to stay the provisions for the lower standards for sodium in the definition of ''healthy'' (§ 101.65).

Therefore, while the agency resolves these issues, FDA is staying until January 1, 2003, the provisions in § 101.65(d)(2)(ii)(C) for foods and in § 101.65(d)(4)(ii)(B) for meals and main dishes. The agency also is staying the provisions in § 101.65(d)(3)(ii)(C) for raw, single-ingredient seafood or game meat, a citation that was inadvertently omitted in the initial stay. This action is being taken to: (1) Allow FDA time to reevaluate the information that supports and opposes the petition, (2) conduct any necessary rulemaking on the sodium limits for the term ''healthy,'' and (3) provide time for companies to respond to any changes that may result from agency rulemaking.

Interested persons may submit comments regarding the appropriateness of the basis of this stay. In doing so, however, FDA encourages manufacturers who can meet the lower sodium levels for particular foods and still produce an acceptable product to do so even as the agency reevaluates the issues discussed.

Interested persons may, on or before April 15, 1999, submit to the Dockets Management Branch (address above) written comments regarding this document. 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.

This document is issued under the authority of 15 U.S.C. 1453, 1454, 1455, and 21 U.S.C. 321, 331, 342, 343, 348, 371.

For the reasons set forth in the preamble, 21 CFR 101.65(d)(2)(ii)(C), (d)(3)(ii)(C), and (d)(4)(ii)(B) are stayed until January 1, 2003.

Dated: March 8, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 94P–0240]

Food Labeling; Serving Sizes; Reference Amount for Baking Powder, Baking Soda, and Pectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the nutrition labeling regulations to change the reference amount customarily consumed per eating occasion for the food category ''Baking powder, baking soda, pectin'' from 1 gram (g) to 0.6 g to more accurately reflect the amount of these products that is customarily consumed. The agency is also including 1/8 teaspoon (tsp) as an additional allowable household measure, because it is a common household measure available to consumers. This action is being taken in response to a petition submitted by Church Dwight Co., Inc., on behalf of Arm & Hammer.

DATES: Effective January 1, 2002. Full compliance is required for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after January 1, 2002. Voluntary compliance may begin April 15, 1999.

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 the **Federal Register** of November 18, 1997 (62 FR 61476), FDA published a proposed rule to amend the nutrition labeling regulations to change the reference amount customarily consumed per eating occasion for the food category ''Baking powder, baking soda, pectin'' from 1 g to 0.6 g to more accurately reflect the amount of these products that is customarily consumed. The agency also proposed to include 1/8 tsp as an additional allowable household measure because it is a common household measure available to consumers. Interested persons were given until February 2, 1998, to comment on the proposal.

FDA had issued the proposal in response to a petition dated June 23, 1994, from Church Dwight Co., Inc., on behalf of Arm & Hammer (94P–0240). The petitioner requested that the agency amend Table 2 in § 101.12(b) (21 CFR 101.12(b)) under ''Miscellaneous Category: Baking powder, baking soda, pectin'' to create a separate subcategory for baking soda with a reference amount of ''500 milligrams (mg)'' and to permit a corresponding serving size of ''1/8 tsp (500 mg)'' (which would require amending § 101.9(b)(5)(i) (21 CFR 101.9(b)(5)(i)).

II. Final Action

The agency received no comments in response to the proposal. Therefore, FDA concludes that, for the reasons set out in the proposal, it is appropriate to amend §§ 101.9(b)(5)(i) and 101.12(b) as proposed to better reflect the amounts customarily consumed for these products. Thus, in the final rule set forth below, FDA is revising its food labeling regulations to: (1) Amend § 101.12(b) by changing the reference amount for ''Baking powder, baking soda, pectin'' from ''1 g'' to ''0.6 g'' (the weight of 1/8 tsp of baking powder and baking soda, and close to the weight of 1/8 tsp of pectin); (2) amend § 101.9(b)(5)(i) by including 1/8 tsp as an additional allowable household measure; and (3) reorganize § 101.9(b)(5)(i) to simplify the options for teaspoon and tablespoon measures and to improve clarity.

III. Effective and Compliance Dates

Voluntary compliance with this final regulation, including any required labeling changes, may begin April 15, 1999, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after January 1, 2002, shall fully comply.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (62 FR 61476 at 61479). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Benefit—Cost Analysis

FDA has examined the economic implications of this final rule as required by 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