DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N–384H and 96P–0500]

RIN 0910–AA19

Food Labeling; Nutrient Content Claims, Definition of Sodium Levels for the 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, 2006, the partial stay of certain provisions of the nutrient content claim regulations pertaining to the use of the term ''healthy.'' This action is being taken to allow the agency to conduct rulemaking to consider amending the sodium content requirements for foods labeled ''healthy.'' A stay also will provide industry time to implement any changes resulting from the rulemaking.

DATES: Effective May 8, 2002, 21 CFR 101.65(d)(2)(ii)(C), (d)(3)(ii)(C), and (d)(4)(ii)(B) are stayed until January 1, 2006. Submit written or electronic comments by June 7, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Ellen M. Anderson, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–822), Harvey W. Wiley Federal Bldg., 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1798.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 10, 1994 (59 FR 24232), FDA published a final rule defining 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 individual foods and for meal and main dish products to be able to use the nutrient content claim ''healthy.'' Among other things, the final rule defined sequential timeframes (before January 1, 1998, and after January 1, 1998) in which different criteria for sodium content would be effective for foods labeled ''healthy'' or bearing another related term.

The final rule provided that before January 1, 1998, individual foods (including raw, single-ingredient seafood or game meat) could be labeled as ''healthy'' only if they contained no more than 480 milligrams (mg) of sodium: (1) Per reference amount customarily consumed per eating occasion (reference amount); (2) per serving size listed on the product label; 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) (§ 101.65(d)(2)(ii)(A) through (d)(2)(ii)(B) and (d)(3)(ii)(A) through (d)(3)(ii)(B)). Meal and main dish products could be labeled as ''healthy'' only if they contained no more than 600 mg of sodium per reference amount (§ 101.65(d)(4)(ii)(A)). After January 1, 1998, however, the sodium criteria for ''healthy'' foods were to become more stringent. For individual foods, the limit to qualify for a ''healthy'' claim was to become 360 mg sodium: (1) Per reference amount; (2) per serving size listed on the product label; and (3) per 50 g for products with small reference amounts (§ 101.65(d)(2)(ii)(C)(1) through (d)(2)(ii)(C)(2) and (d)(3)(ii)(C)(1) through (d)(3)(ii)(C)(2)). For meal and main dish products, the limit was to become 480 mg of sodium per reference amount (§ 101.65(d)(4)(ii)(B)). In the remainder of this document, the original, higher sodium levels will be referred to as the ''first-tier sodium levels''; the lower levels that were to go into effect on January 1, 1998, will be referred to as the ''second-tier sodium levels.''

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.'' 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 to reduce the sodium content of foods, and there is a better understanding of the relationship between sodium and hypertension.

FDA responded to ConAgra's petition by announcing a stay of the second-tier sodium levels until January 1, 2000 (62 FR 15390, April 1, 1997). This stay was intended to allow time for FDA to: (1) Reevaluate the second-tier sodium levels based on 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 may result from the agency's reevaluation.

In the **Federal Register** of 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 nutrient content claim regulations pertaining to use of the term ''healthy.'' In the ANPRM, FDA requested comments on whether it should propose to amend the definition of the term ''healthy'' relative to sodium requirements. Persons who supported changing the ''healthy'' definition were asked to address what the new definition should require to ensure that the term 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 consistent with dietary guidelines. Those who supported allowing the second-tier sodium levels to take effect were asked to provide data to demonstrate that those levels were not so restrictive as to effectively prevent use of the term (62 FR 67771 at 67772).

FDA received 22 responses to the ANPRM. The comments presented a variety of views on whether FDA should allow the second-tier sodium levels to take effect. They also contained a significant amount of data relating to the use of the term ''healthy'' in the marketplace.

In the **Federal Register** of March 16, 1999 (64 FR 12886), FDA further extended the stay of the second-tier sodium requirement for individual foods (§ 101.65(d)(2)(ii)(C)), for meal and main dish products (§ 101.65(d)(4)(ii)(B)), and for raw, single-ingredient seafood or game meat (§ 101.65(d)(3)(ii)(C)) until January 1, 2003.

FDA has decided that it is appropriate to further stay the second-tier sodium provisions of the final rule for the term ''healthy'' until January 1, 2006. Agency regulations at 21 CFR 10.35(a) provide that the Commissioner of Food and Drugs may at any time stay the effective date of an action. The agency finds that a further extension of the stay of the second-tier sodium provisions is in the public interest.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(3)(A). Alternatively, the agency's implementation of this action without opportunity for public comment,

effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(3)(B), (d)(3), and 21 CFR 10.40(e)(1). Under these provisions, FDA may issue a regulation without notice and comment when the agency determines that such procedures are impracticable, unnecessary, or contrary to the public interest. Seeking public comment before implementing this stay would be contrary to the public interest.

The current, second-tier sodium provisions are scheduled to take effect on January 1, 2003. To comply with this effective date, manufacturers would have to reformulate and/or relabel their products within a short timeframe, a process that could involve significant expense. As FDA is currently preparing to issue a proposed rule concerning ''healthy'' sodium levels, it would be contrary to the public interest to require manufacturers to comply with the second-tier sodium levels, even as the agency considers whether alternative levels may be more appropriate. Accordingly, a further stay of the second-tier sodium levels is warranted. This stay will give the agency time to issue its proposed rule, consider comments, and complete the rulemaking. The stay also will allow time for manufacturers to make changes necessitated by the rulemaking (e.g., reformulating or relabeling products and using up old label stock). Finally, the January 1, 2006, effective date should coincide with the uniform compliance dates for food labeling regulations. The next uniform compliance date is scheduled for January 1, 2004, and FDA typically sets these dates to occur every 2 years (see 65 FR 69666).

Although FDA has determined that it is in the public interest to issue this rule without prior public comment, interested persons are invited to submit comments on whether this extension of the stay of the second-tier sodium levels should be modified or revoked (see 21 CFR 10.40(e)(1)). 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.

FDA encourages manufacturers who can meet the second-tier sodium levels for particular foods and still produce an acceptable product to do so, even as the agency proceeds with rulemaking.

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, 2006.

Dated: April 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 4, 5, 7, 19, 20, 22, 24, 25, 26, 27, 70, and 251

[T.D. ATF—479]

RIN 1512–AC47

Importation of Distilled Spirits, Wines, and Beer; Recodification of Regulations (2000R–247P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Final rule (Treasury decision).

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms (ATF) is recodifying the regulations pertaining to the importation of distilled spirits, wines, and beer. The purpose of this recodification is to reissue the regulations in part 251 of title 27 of the Code of Federal Regulations (27 CFR part 251) as 27 CFR part 27. This change improves the organization of title 27.

DATES: This rule is effective on May 8, 2002.

FOR FURTHER INFORMATION CONTACT: Jennifer Berry, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 111 W. Huron Street, Room 219, Buffalo, New York, (716) 434–8039.

SUPPLEMENTARY INFORMATION:

Background

As a part of continuing efforts to reorganize the part numbering system of title 27 CFR, ATF is removing part 251, Importation of Distilled Spirits, Wines, and Beers, in its entirety, and is recodifying the regulations as 27 CFR part 27. This change improves the organization of title 27 CFR. ATF intends to update and clarify the regulations in this part, but believes that such revisions would be best undertaken at a later time through a notice of proposed rulemaking with public comment.

DERIVATION TABLE FOR PART 27

The requirements of sec.	Are derived from sec.
Subpart A	
27.1	251.1
27.2	251.2
27.3	251.3
Subpart B	
27.11	251.11
Subpart C	
27.30	251.30
27.31	251.31
Subpart D	
27.40	251.40
27.41	251.41
27.42	251.42
27.42a	251.42a
27.43	251.43
27.44	251.44
27.45	251.45
27.46	251.46
27.48	251.48
27.48a	251.48a
27.49	251.49
Subpart E	
27.55	251.55
27.56	251.56
27.57	251.57
27.58	251.58
27.59	251.59
27.60	251.60
27.61	251.61
27.62	251.62
27.74	251.74
27.75	251.75
27.76	251.76
27.77	251.77
Subparts F–G [Reserved]	
Subpart H	
27.120	251.120
27.121	251.121
Subpart I	
27.133	251.133
27.134	251.134
27.136	251.136
27.137	251.137
27.138	251.138
27.139	251.139
Subparts J–K [Reserved]	
Subpart L	
27.171	251.171
27.172	251.172
27.173	251.173
27.174	251.174
27.175	251.175
Subpart M	
27.181	251.181
27.182	251.182