other nutrients or dietary ingredients, the label or labeling shall clearly identify which vitamin or mineral is described by the term ''high potency'' (e.g., ''Botanical 'X' with high potency vitamin E'').

(2) The term ''high potency'' may be used on the label or in the labeling of a multiingredient food product to describe the product if the product contains 100 percent or more of the RDI for at least two-thirds of the vitamins and minerals that are listed in § 101.9(c)(8)(iv) and that are present in the product at 2 percent or more of the RDI (e.g., ''High potency multivitamin, multimineral dietary supplement tablets'').

(3) Where compliance with paragraphs (f)(1)(i), (f)(1)(ii), or (f)(2) of this section is based on a nutrient that has been added to a food (other than a dietary supplement), that fortification shall be in accordance with the policy on fortification of foods in § 104.20 of this chapter.

(g) *Nutrient content claims using the term ''antioxidant.''* A nutrient content claim that characterizes the level of antioxidant nutrients present in a food may be used on the label or in the labeling of that food when:

(1) An RDI has been established for each of the nutrients;

(2) The nutrients that are the subject of the claim have recognized antioxidant activity; that is, when there exists scientific evidence that, following absorption from the gastrointestinal tract, the substance participates in physiological, biochemical, or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions;

(3) The level of each nutrient that is the subject of the claim is sufficient to qualify for the § 101.54(b), (c), or (e) claim (e.g., to bear the claim ''high in antioxidant vitamin C,'' the product must contain 20 percent or more of the RDI for vitamin C). Beta-carotene may be a subject of the claim when the level of vitamin A present as beta-carotene in the food that bears the claim is sufficient to qualify for the claim. For example, for the claim ''good source of antioxidant beta-carotene,'' 10 percent or more of the RDI for vitamin A must be present as beta-carotene per reference amount customarily consumed; and

(4) The names of the nutrients that are the subject of the claim are included as part of the claim (e.g., ''high in antioxidant vitamins C and E''). Alternatively, when used as part of a nutrient content claim, the term ''antioxidant'' or ''antioxidants'' (as in ''high in antioxidants'') may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of a product label followed by the name or names of the nutrients with recognized antioxidant activity. The list of nutrients shall appear in letters of a type size height no smaller than the larger of one-half of the type size of the largest nutrient content claim or 1/16 inch.

3. Section 101.60 is amended by revising paragraph (c)(1)(iii)(A) to read as follows:

§ 101.60 Nutrient content claims for the calorie content of foods.

* * * * *

(c) * * *

(1) * * *

(iii)(A) It is labeled ''low calorie'' or ''reduced calorie'' or bears a relative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section, or, if a dietary supplement, it meets the definition in paragraph (b)(2) of this section for ''low calorie'' but is prohibited by §§ 101.13(b)(5) and 101.60(a)(4) from bearing the claim; or

* * * * *

Dated: September 11, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–24732 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 96N–0094]

Uniform Compliance Date for Food Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to comments.

SUMMARY: The Food and Drug Administration (FDA) is responding to comments that were submitted in response to a final rule establishing January 1, 2000, as the uniform compliance date for food labeling regulations that the agency issues between January 1, 1997, and December 31, 1998. FDA received three comments in response to that final rule. The agency is not making any changes in the final rule in response to these comments. January 1, 2000, remains the uniform compliance date for food labeling regulations that are issued between January 1, 1997, and December 31, 1998.

EFFECTIVE DATE: December 27, 1996.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFS–150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4561.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has periodically announced uniform compliance dates for new food labeling requirements to minimize the economic impact of label changes. In 1992, FDA suspended this practice pending the issuance of regulations implementing the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). In the **Federal Register** of December 24, 1996 (61 FR 67710), FDA issued a final rule (hereinafter referred to as the December 24, 1996, final rule) establishing January 1, 1998, as its new uniform compliance date for all food labeling regulations that are issued after its publication and before January 1, 1997. FDA announced that it was reinstating its previous practice of periodically announcing, as final rules, uniform compliance dates for food labeling regulations. In the **Federal Register** of December 27, 1996 (61 FR 68145) (hereinafter referred to as the December 27, 1996, final rule), FDA established January 1, 2000, as the uniform compliance date for food labeling regulations that are issued between January 1, 1997, and December 31, 1998. Because FDA had already provided notice and opportunity for comment on the practice of establishing uniform compliance dates by issuance of a final rule announcing the date (see 61 FR 67710, December 24, 1996), the agency found any further rulemaking unnecessary. Nonetheless, under 21 CFR 10.40(e)(1), FDA provided an opportunity until March 13, 1997, for interested persons to comment on whether the uniform compliance date of January 1, 2000, should be modified or revoked. In the December 27, 1996, final rule, FDA advised that it would publish a notice setting out the agency's conclusions concerning any comments that it received in response to the final rule or initiate notice and comment rulemaking to modify or revoke the uniform compliance date that the final rule established.

FDA received three letters, each containing one or more comments, from trade associations in response to the December 27, 1996, final rule. A summary of these comments and the

agency's responses are provided as follows:

II. Comments

A. Dietary Supplements

One of the comments asked the agency to confirm that the final rule for a uniform compliance date of January 1, 2000, will apply to the proposed regulations for dietary supplement labels that FDA published in the **Federal Register** of December 28, 1995 (60 FR 67176 and 67194). The comment noted that the December 28, 1995, proposals specified a compliance date of December 31, 1996, and that obviously that date had come and gone and the final regulations had yet to be issued. The comment agreed with FDA's statements concerning the use of a uniform compliance date and stated that the uniform compliance date of January 1, 2000, should be applied to the final rule issued in response to the December 28, 1995, proposed regulations concerning dietary supplements. The comment explained that the dietary supplement labeling regulations will have a massive impact on the entire industry. It stated that every single dietary supplement label will need to be revised, and that many products that do not currently bear nutrition labeling will be required to do so. The comment concluded that, based on the passage of time and the need for the industry to have adequate time to reprint and replace label stock, the uniform compliance date of January 1, 2000, is the appropriate effective date for the final labeling regulations for dietary supplements.

As stated in the December 27, 1996, final rule, ''The new uniform compliance date will apply only to final FDA food labeling regulations that require changes in the labeling of food products and that publish after January 1, 1997, and before January 1, 1999'' (61 FR 68145). The Dietary Supplement Health and Education Act of 1994 (DSHEA) amended the Federal Food, Drug, and Cosmetic Act (the act) to establish a new definition for ''dietary supplement'' in section 201(ff) of the act (21 U.S.C. 321(ff)). The last sentence of section 201(ff) of the act states, ''Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act.'' Therefore, the agency confirms that the uniform compliance date will generally apply to regulations that establish requirements for the labeling of dietary supplements.

In the December 27, 1996, final rule (61 FR 68145 at 68146), however, FDA advised that if any food labeling regulation, including one concerning dietary supplements, involves special circumstances that justify a compliance date other than January 1, 2000, the agency will determine for that regulation an appropriate compliance date and will specify that compliance date in the final rule that resolves the proceeding. Elsewhere in this issue of the **Federal Register**, FDA is publishing final rules in response to proposals on dietary supplements that it published in the **Federal Register** of December 28, 1995. As discussed in those final rules, FDA has concluded that a compliance date of March 23, 1999, is responsive to the directives of DSHEA, and that extending the compliance date to January 1, 2000, for those final rules would not be appropriate. Therefore, FDA is adopting March 23, 1999, as the effective date for the final regulations for the labeling of dietary supplements, rather than January 1, 2000.

B. Bakery Industry

Although two letters from trade associations for the bakery industry agreed with the concept of a uniform compliance date, these letters disagreed with establishing January 1, 2000, as the uniform compliance date for regulations issued between January 1, 1997, and December 31, 1998. One comment stated that the uniform compliance date of January 1, 1998, should be extended to January 1, 1999, and that the uniform compliance date of January 1, 2000, should be extended to January 1, 2001. The comment stated that this extra year would allow firms to do laboratory analyses-reformulations, use existing inventory, and release new products and packaging to consumers. The comment explained that it is hard to foresee what types of new final regulations will materialize by December 31, 1998, and that 2 years would not be sufficient time for all of the changes needed. The comment suggested that all future uniform compliance dates allow a 3-year timeframe to make changes. The comment stated that, while some types of labeling changes may be more swiftly implemented than others, FDA should consider the more complicated cases like folic acid in establishing these dates.

The second comment stated that a compliance period of 1 year is not sufficient for the small and medium, mostly family owned, wholesale bakers that it represents to implement labeling changes in a manner that would minimize economic impact. The comment stated that the least amount of time needed for bakers to efficiently and effectively implement new labeling regulations would be 24 months. The comment expressed its concern that the rule would constrict a company's method of implementing FDA's rules, particularly for slow selling items, where labels are ordered for an extended length of time.

These two comments raise concerns similar to some that were raised in response to the uniform compliance date proposal of April 15, 1996 (61 FR 16422), and that were addressed in the December 24, 1996, final rule. In that proceeding, there were comments that objected to establishing January 1, 1998, as the uniform compliance date for food labeling regulations issued between January 1, 1995, and December 31, 1996, on the grounds that it resulted in a ''compliance period'' that at its shortest possible length would be only 12 months long. FDA disagreed with those comments, stating that a compliance period that is 18 months or 2 years at its shortest is too long. The agency pointed out that it must consider the costs and benefits to both the food producer and the consumer (61 FR 67710). A compliance period of 6 months would increase the benefit to the consumer but would result in even greater costs to the food producers than are caused by a compliance period of 12 months. Although a lengthier compliance period would reduce the costs to food producers, it would delay implementation of the labeling changes, thus decreasing the value of any benefits to the consumer.

As the agency pointed out in the December 24, 1996, final rule, the minimum compliance period of 1 year is the same compliance period that it has used for all of its uniform effective date final rules dating back to the 1970's, until it issued the labeling regulations that implemented the 1990 amendments. The agency is unaware of, nor has anyone submitted, including in the comments in this proceeding, any information to demonstrate any problems with respect to bringing labels into compliance with the various uniform effective dates that it had established over the period of approximately 20 years during which it has announced uniform compliance dates. While there have been instances where the agency has granted extensions beyond the uniform compliance date, generally firms have come into compliance with little complaint to the agency. The agency is merely reinstating its former practice.

The agency concludes that the comments on the December 27, 1996, final rule do not provide a basis on which to initiate rulemaking to revoke or modify the uniform compliance date

established therein. Therefore, FDA confirms that January 1, 2000, will be the uniform compliance date for food labeling regulations issued between January 1, 1997, and December 31, 1998.

Dated: September 11, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–24731 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 96N–0240]

Food Labeling; Notification Procedures for Statements on Dietary Supplements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to establish the notification procedures for manufacturers, packers, or distributors of dietary supplements who are marketing dietary supplement products that bear statements under a provision of the Federal Food, Drug, and Cosmetic Act (the act). The agency is adopting this procedure to ensure that notification is accomplished efficiently. FDA instituted this proceeding to help the industry comply with the Dietary Supplement Health and Education Act of 1994 (the DSHEA).

EFFECTIVE DATE: October 23, 1997.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4605.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 27, 1996 (61 FR 50771), FDA published a proposed rule entitled ''Food Labeling; Dietary Supplement; Nutritional Support Statement; Notification Procedure'' (hereinafter referred to as ''the September 1996 proposal''). FDA issued this proposal in response to section 6 of the DSHEA (Pub. L. 103–417). This section of the DSHEA amended the act by adding section 403(r)(6) (21 U.S.C. 343(r)(6)). This section of the act allows for statements to be made on the label or in the labeling of a dietary supplement that does the following:

(1) Claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States,

(2) describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans,

(3) characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or

(4) describes general well-being from consumption of a nutrient or dietary ingredient if the statements are made in accordance with certain requirements. The manufacturer of the dietary supplement must:

(1) Substantiate that the statement is truthful and not misleading;

(2) Include, prominently displayed and in boldface type, the following: ''This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease;'' and

(3) Notify the Secretary of Health and Human Services (the Secretary) (and by delegation FDA) no later than 30 days after the first marketing of a dietary supplement bearing such a statement that the statement is being made. The statement may not claim to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases.

In the September 1996 proposal, FDA outlined the procedure by which manufacturers would comply with the requirements that they notify the Secretary when they make a claim under section 403(r)(6) of the act. FDA received eight responses to the proposal. Each response contained one or more comments. Some comments supported the proposal generally or supported aspects of the proposal. Other comments addressed issues outside the scope of the proposal (e.g., guidelines differentiating health claims from structure/function claims, health information to consumers, types of claims that can be made, the form and amount of substantiation FDA will require, when the disclaimer should or should not be required, and the use of classical nutrient deficiency claims) and will not be addressed in this document. Several comments suggested modifications or revisions of various aspects of the proposal. A summary of the comments and the agency's responses to the comments follow.

II. Notification of ''Products'' or ''Brands''

1. One comment objected to proposed § 101.93(b)(4) (redesignated as § 101.93(a)(2)(iv)) requiring that the brand name of the product be included in the notification. The comment argued that providing this information would be unnecessarily burdensome, and that the DSHEA did not require this information. The comment cited the fact that a dietary supplement product, such as vitamin C 500 milligrams (mg), may be marketed under a variety of brand names, but that the product (i.e., the dietary supplement) could be the same from brand ABC to brand XYZ. The comment argued that if a notification has been made for a claim on one brand of this dietary supplement, it should not be necessary for every manufacturer of this type of supplement to file a notification.

FDA is not persuaded to modify the regulation in response to this comment. If a manufacturer makes a type of dietary supplement, such as a vitamin C supplement, under a number of different brand names, under § 101.93(a)(2)(iv), a manufacturer may list all of the brands on which the claim is to appear, and thus for which it is providing notification, in a single submission. The regulation does not require that a separate notice be submitted for each individual product or brand.

FDA finds that the brand name of a dietary supplement is a necessary part of the notification that a statement of nutritional support is being made on the label or in the labeling of the dietary supplement. Including the brand is necessary to efficiently enforce the act. If the notification does not include the relevant brand name, FDA will not know which products are in compliance with the notification requirement of section 403(r)(6) of the act. This is particularly important because there is no requirement that a manufacturer submit to FDA its substantiation that establishes that its claim is truthful and not misleading (section 403(r)(6)(B) of the act). Thus, it cannot be assumed that the first submission for a claim under section 403(r)(6) of the act establishes that adequate substantiation exists to support that claim for all products that may contain that substance. Each manufacturer must have its own substantiation that any statement it makes in the labeling of a dietary supplement product under section 403(r)(6) of the act is truthful and not misleading, and the manufacturer must submit a notice to FDA that attests to this fact.

III. Signature of Person Who Can Certify that Firm has Substantiation

2. Several comments objected to proposed § 101.93(c) (redesignated as