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

§ 101.93(a)(3)), which requires that the notice be signed by a responsible individual or by the person authorized to certify that the information presented and contained in the notice is accurate. Other comments objected to proposed § 101.93(c) (redesignated as § 101.93(a)(3)) which requires that the individual certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading. These comments argued that the DSHEA does not require that the notification be signed by anyone, and that it does not require that an individual certify that the information contained in the notice is complete and accurate, or that the notifying firm have substantiation that the statement is truthful and not misleading.

One comment agreed that the company must have substantiation that statements made in accordance with section 403(r)(6)(B) of the act are truthful and not misleading. However, this comment maintained that section 403(r)(6)(B) of the act does not require, or provide any basis for requiring, signature and certification as part of the notification. Another comment stated that the DSHEA's requirement that manufacturers of dietary supplements have substantiation that such statements are truthful and not misleading is independent of the notification requirement.

Several comments also disagreed with FDA's explanation that the requirement for a signature will ensure that the statutory requirements have been met, and that the certification is necessary to provide assurance that a notifying firm has fully complied with the requirement of section 403(r)(6) of the act.

Several comments contended that neither the courts nor FDA have established procedures, guidelines, or standards for identifying the type and amount of evidence needed to support substantiation, and therefore, the manufacturer who is giving notification cannot know whether the evidence it has meets FDA's expectations and has no basis to provide certification. One comment stated that general dictionary definitions for ''substantiation'' are of no help because, in the relevant legal context, the question requires detailed legal analysis, which at best can only identify possible interpretations and does not even begin to predict what the agency's ultimate interpretation of ''substantiation'' might be. One comment stated that ''substantiation'' under the DSHEA might be interpreted by regulated supplement companies to mean a number of different things (e.g., near scientific certainty, significant scientific agreement, or reasonable basis). The comment requested that FDA acknowledge that it will not attempt to set a substantiation standard under the DSHEA comparable to new drug or health claims requirements, and that it will not adopt the Federal Trade Commission's ''reasonable basis'' standard that is currently applied in dietary supplement advertising cases.

Several comments maintained that the requirement that manufacturers certify that the notifying firm has substantiation that the statement is truthful and not misleading goes beyond the authority of the act because it imposes potential liability under the False Statements Act (18 U.S.C. 1001) if FDA does not agree that the substantiation relied upon by the person making the notification meets the requirements of the act. Another comment contended that the objective of § 101.93(a)(3) is accomplished by existing Federal statutes (i.e., 18 U.S.C. 1001) that prohibit the knowing and willful false representation of any statement to a Government agency. Another comment objected to the agency subjecting both a manufacturer and the person representing the company to potential criminal sanctions for making false statements, and this comment argued that, in doing so, FDA would be acting in a manner that is inconsistent with the intent of Congress.

FDA disagrees with these comments and finds that they are without merit. First, FDA does not agree that the requirement that manufacturers have substantiation that statements made in accordance with section 403(r)(6) of the act are truthful and not misleading is independent of the notification requirement. The last sentence of section 403(r)(6) of the act states that if a manufacturer of a dietary supplement proposes to make a ''statement described in the first sentence of this subparagraph,'' it is to notify the Secretary (that is, FDA). A ''statement described in the first sentence of [section 403(r)(6)]'' is one for which (among other things) ''the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading.'' In section 403(r)(6) of the act, thus, contrary to the assertion in the comment, there is a direct connection between the substantiation requirement and the notification requirement in section 403(r)(6) of the act.

Second, FDA also finds no merit to the argument made with respect to 18 U.S.C. 1001. Because the act on its face connects the notification requirement to the substantiation requirement, a manufacturer who submits a notification under section 402(r)(6) of the act without being in possession of substantiation that the claim that it intends to make, or is making, is truthful and not misleading is making a false statement to the Government, in violation of 18 U.S.C. 1001. This is true without regard to whether a responsible individual has signed a certification or not.

FDA is requiring that the notification be signed by a responsible individual, and that individual certify the accuracy of the information presented in the notice, for efficient enforcement of the act under sections 403(r)(6) and 701(a) of the act (21 U.S.C. 371(a)). The person signing the notice, and the company on whose behalf he or she signs it, must recognize that there are significant consequences to their action, including potential liability under 18 U.S.C. 1001. Signing a certification that the information in the notice is accurate will likely cause the person who is doing so to check the information in the notice. Such a check should minimize any problems under this section of the act and thus will contribute to its efficient enforcement.

Third, FDA finds no merit to the comments that claim that firms have no basis to determine what level of substantiation is necessary. In this regard, the act is clear on its face: The manufacturer must have substantiation that the statement is truthful and not misleading. If the manufacturer has any doubts as to whether it has substantiation to meet this standard, it should not make the statement in question on its label or in its labeling. Claims that manufacturers are unable to interpret this standard are belied by the fact that since the passage of the DSHEA, FDA has received literally hundreds of notices under section 403(r)(6) of the act. FDA assumes that these notifications have been made in good faith, and the submitters were confident that they were in possession of adequate substantiation. Thus, FDA finds no need for it to elaborate on the substantiation standard that appears in the act.

IV. Recommended Compliance With the Proposed Rule

3. One comment stated that FDA indicated in the preamble to the September 1996 proposal that it ''recommends'' that manufacturers follow the proposed regulation immediately. The comment requested that FDA make clear that failure to follow ''recommendations'' that are not final rules carries no penalty or sanction and generates no prejudice.

FDA made this recommendation in the September 1996 proposal because of the many requests from manufacturers to FDA asking for guidance on how to make a statement of nutritional support notification. However, the comment is correct that no penalty or sanction applies to manufacturers who do not make their notification according to these rules until the effective date of this regulation. It should, however, be noted that dietary supplement manufacturers do not have the option of not notifying FDA if they are making statements of nutritional support on the label or in the labeling of their products. The requirement to make the notification to FDA no later than 30 days after the first marketing of the dietary supplement that bears such a statement became effective with the signing into law of the DSHEA on October 25, 1994.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

A. 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 economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). 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; adversely affecting some sector of the economy in a material way; adversely affecting jobs or competition; or raising novel legal or policy issues.

In the economic analysis of the proposed rule, FDA stated that the costs of this regulation consisted of the costs of preparing and submitting notification to FDA regarding statements of nutritional support. FDA concluded that because the information should already have been gathered in order to prepare the nutritional support statement itself, the additional cost incurred for notification would be small and in many instances negligible. One comment said that the costs of notification could be burdensome for a manufacturer producing many different brands and products. FDA is not persuaded that this additional burden would be large, for the same reasons as stated in the economic analysis of the proposed rule—the notification cost will be negligible to manufacturers who have borne the labeling costs associated with nutritional support statements for several different brands or products. This final rule is procedural and implements the statutory notification requirement at minimal cost. Other requirements associated with nutritional support statements will be dealt with by other rules.

FDA finds that this final rule does not constitute a significant rule as defined by Executive Order 12866. Furthermore, it has been determined that this rule is not a major rule for the purpose of congressional review (Pub. L. 104–121).

B. Small Business Analysis

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities.

For purposes of defining industry size standards, the Small Business Administration (SBA) classifies industries according to four-digit Standard Industrial Classification (SIC) codes. SBA does not define ''small'' for the dietary supplement industry, because no SIC code corresponds to the industry—dietary supplements encompass a wide range of products. The industry's products come closest to the industry groups Food Preparations N.E.C. (SIC code 2099) and Medicinal Chemicals and Botanical Products (SIC code 2833). The SBA size standards for small businesses are 500 or fewer employees for food preparations and 750 or fewer employees for medicinal and botanical products. Under either employee-based size standard, virtually all firms in the dietary supplement industry could be classified as small, including some firms that are among the leaders in sales revenues.

For the dietary supplement industry, FDA is basing size classifications on sales revenue rather than employees. According to the *Nutrition Business Journal*, of the 850 firms manufacturing dietary supplements, 11 firms have total revenues over $100 million, accounting for 53 percent of total sales; 30 firms have sales revenues between $20 and $100 million, accounting for 28 percent of total sales; and 809 firms have sales under $20 million, accounting for 19 percent of total sales. The 809 firms in the under $20 million category have an average sales revenue of $800,000 and will be considered small businesses by FDA. Because the total includes some firms making functional foods that are not dietary supplements and other products, such as sports nutrition products, that are not considered dietary supplements, the estimate may overstate the number of small firms affected by this final rule.

The number of small businesses affected by this final rule could include all small businesses in the dietary supplement industry, if they choose to use nutritional support statements. As FDA concluded in the benefit-cost analysis, the additional costs imposed by the notification provisions will be negligible to small firms once the labeling provisions have been carried out. This final rule requires only that the manufacturer notify FDA within 30 days of marketing a supplement that bears a nutritional support statement on its label. The information required in the notification is either on the label itself (e.g., the text of the statement) or readily available (e.g., the name of the ingredient that is the subject of the statement).

FDA finds that this final rule will not have a significant economic impact on a substantial number of small entities. Accordingly, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that this final rule will not have a significant impact on a substantial number of small entities.

VII. The Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Food Labeling; Notification Procedures for Statements on Dietary Supplements.

Description: FDA is, by regulation, requiring manufacturers, packers, and distributors of dietary supplements to

notify FDA that they are marketing a dietary supplement product that bears on its label or in its labeling a statement provided for in section 403(r)(6) of the act. Section 403(r)(6) of the act requires that the agency be notified, with a submission about such statements, no later than 30 days after the first marketing of the dietary supplement. Information that is required in the submission includes: (1) The name and address of the manufacturer, packer, or distributor of the dietary supplement product; (2) the text of the statement that is being made; (3) the name of the dietary ingredient or supplement that is the subject of the statement; (4) the name of the dietary supplement (including the brand name); and (5) a signature of a responsible individual who can certify the accuracy of the information presented.

In § 101.93, the agency is establishing procedures for submitting required information. Section § 101.93 provides details of the procedures associated with the submission and identifies the information that must be included in the submission in order to meet the requirements of section 403 of the act.

Description of Respondents: Businesses or other for-profit organizations.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.93	420	1	420	0.5–1	210–420

(Through inadvertent error, the agency misreported the number of respondents and the annual frequency per response and omitted the total annual response in the proposal. Hours per response and total hours were reported correctly. In this final rule, FDA is correcting the inadvertent errors that it made in the proposal).

Individuals and organizations may submit comments on these burden estimates or on any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to the Office of Special Nutritionals (HFS–450), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

The information collection provisions in this final rule have been approved under OMB control number 0910–0331. This approval expires on October 31, 1999. An agency may not conduct or sponsor, and a person is not required, to respond to a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.93 is added to subpart F to read as follows:

§ 101.93 Notification procedures for certain types of statements on dietary supplements.

(a)(1) No later than 30 days after the first marketing of a dietary supplement that bears one of the statements listed in section 403(r)(6) or the Federal Food, Drug, and Cosmetic Act, the manufacturer, packer, or distributor of the dietary supplement shall notify the Office of Special Nutritionals (HFS–450), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, that it has included such a statement on the label or in the labeling of its product. An original and two copies of this notification shall be submitted.

(2) The notification shall include the following:

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement;

(ii) The text of the statement that is being made;

(iii) The name of the dietary ingredient or supplement that is the subject of the statement, if not provided in the text of the statement; and

(iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears.

(3) The notice shall be signed by a responsible individual or the person who can certify the accuracy of the information presented and contained in the notice. The individual shall certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

(b) through (e) [Reserved]

Dated: August 20, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–24738 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 190

[Docket No. 96N–0232]

Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing the procedure by which a manufacturer or distributor of dietary supplements or of a new dietary ingredient is to submit under the Federal Food, Drug, and Cosmetic Act (the act) the information on which it has concluded that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe. FDA is issuing this regulation to enable industry to comply with the requirements of the Dietary Supplement Health and Education Act of 1994 (the DSHEA).

EFFECTIVE DATE: October 23, 1997.

FOR FURTHER INFORMATION CONTACT: Carolyn W. Miles, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–401–9858.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 27, 1996 (61 FR 50774), FDA published