that: (1) ''[T]he language of the notice is outdated and appears to have been intended for a labeling transition that took place during 1977–1978,'' (2) ''specific requirements of the regulation are outdated,'' and (3) ''the regulation is one that should be deleted per President Clinton's request for a list of regulations that the agency plans to eliminate.''

Subsequently, on April 1, 1996, the President signed into law Pub. L. 104–124 to amend the act by repealing section 403(p) of the act. In discussing the provisions of H. R. 1787, which was enacted as Pub. L. 104–124, the House report reflected on the intent of the SSLA provision for a store placard and the intent of Pub. L. 104–124 that the placard no longer be required:

> The redundant store notice warning requirement was included as a stop-gap measure to provide the warning prior to the time that warning labels would begin to appear on foods containing saccharin. Now that warning labels appear on all products, this requirement is no longer necessary. Eliminating the store warning notice will reduce a burden on retail establishments including ''mom and pop'' grocery stores, neighborhood supermarkets, pharmacies, and convenience stores.

H. Rept. 104–386, page 2 (December 6, 1995).

In view of the revocation of section 403(p) of the act by Pub. L. 104–124 and the fact that section 403(o) of the act, which was also added to the act by the SSLA, requires that all food products containing saccharin include on their labeling a warning statement (see Statement of final guidelines for labeling of food products containing saccharin (42 FR 62209, December 9, 1977)), the agency tentatively finds that § 101.11 is no longer necessary and should be revoked. This action responds to the request in the Calorie Control Council's citizen petition. This action is also consistent with the Administration's ''Reinventing Government'' initiative which seeks to ease burdens on regulated industry and consumers.

FDA has determined that this proposed rule is not a significant regulatory action for the purposes of Executive Order 12866. This proposed rule is expected to reduce the burden on small businesses. Therefore, the agency certifies that this proposed rule will not have a significant adverse impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*)

The agency has determined under 21 CFR 25.24(a)(11) 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.

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is intended to minimize the reporting and recordkeeping burden on the regulated community, as well as to minimize the cost of Federal information collection and dissemination. In general, the Paperwork Reduction Act of 1995 requires that information requests and recordkeeping requirements affecting 10 or more non-Federal respondents be approved by the Office of Management and Budget. Because this proposed rule would remove an existing regulation and would not establish or modify any information or recordkeeping requirements, it is not subject to the requirements of the Paperwork Reduction Act of 1995.

Interested persons may, on or before December 11, 1996 submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

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).

§ 101.11 [Removed]

2. Section 101.11 *Saccharin and its salts; retail establishment notice* is removed from subpart A.

Dated: September 19, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–24754 Filed 9–26–96; 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; Dietary Supplement; Nutritional Support Statement; Notification Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to establish the procedure by which manufacturers, packers, and distributors of dietary supplements who are marketing a dietary supplement product that bears on its label or in its labeling one of the types of statements provided for in the Federal Food, Drug, and Cosmetic Act (the act) are to notify FDA of that fact. FDA is issuing this proposal in response to the Dietary Supplement Health and Education Act of 1994 (the DSHEA) and to inquiries from the dietary supplement industry.

DATES: Written comments by December 26, 1996.

ADDRESSES: Written comments may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

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, 202–205–5372.

SUPPLEMENTARY INFORMATION:

I. Background

On October 25, 1994, the DSHEA (Pub. L. 103–417) was signed into law. The DSHEA, among other things, amended the act by adding section 201(ff) (21 U.S.C. 321(ff)), which defines a ''dietary supplement,'' by adding section 403(r)(6) (21 U.S.C. 343(r)(6)), which provides for the use of certain types of statements on the labels and in the labeling of dietary supplements, and by amending section 201(g)(1), which defines ''drug,'' to state: ''A food, dietary ingredient, or dietary supplement for which a truthful and nonmisleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.''

Section 403(r)(6) states that a statement for a dietary supplement may be made if:

> [T]he statement claims a benefit related to a classical nutrient deficiency disease and

discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient * * *

(section 403(r)(6)(A) of the act) and certain other conditions are met. These other conditions include that the manufacturer of the dietary supplement have substantiation that the statement is truthful and not misleading (section 403(r)(6)(B)); that the statement prominently contain the disclaimer: ''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'' (section 403(r)(6)(C)); and that the manufacturer notify FDA no later than 30 days after the first marketing of a dietary supplement product that bears such a statement on its label or in its labeling.

While section 403(r)(6) of the act became effective immediately upon the signing of the DSHEA by the President, FDA has tentatively concluded that certain elaborations and clarifications of its provisions will facilitate implementation of this section. Although some manufacturers have already submitted notifications to the agency under section 403(r)(6), others have made inquiries that reflect uncertainty about what must be done to notify the agency about a statement of this type for a dietary supplement product. In addition, the Nutritional Health Alliance, in a petition dated March 20, 1995 (petition number 95P–0079/CP 1), requested, among other things, that FDA issue regulations implementing section 403(r)(6) of the act, including regulations on the procedure to notify the agency about such statements. Therefore, the agency is issuing this proposal to facilitate manufacturers' preparation and submission of the notice required under section 403(r)(6) of the act. In this proposal, FDA has sought to set out those steps necessary to ensure that notification is accomplished as efficiently as possible but with the least possible burden on the industry.

FDA recommends that pending final action on this proposal, manufacturers, packers, or distributors who file notices with FDA under section 403(r)(6) of the act follow the procedures proposed below.

II. The Proposal

Proposed § 101.93(a) provides that a manufacturer, packer, or distributor of a dietary supplement who wishes to take advantage of section 403(r)(6) of the act, 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, within 30 days after first marketing, that it is marketing a dietary supplement that bears one of the statements listed in section 403(r)(6) of the act. This provision reflects the basic requirement of the act. Proposed § 101.93(a) provides that the notification be submitted as an original and two copies to ensure that the agency receives the number of copies necessary for the maintenance of records to demonstrate that the manufacturer has complied with the requirements of the act.

Proposed § 101.93(b)(1) provides that the name and address of the manufacturer, packer, or distributor of the dietary supplement product that bears such a statement be included in the notification. This information is necessary to identify the firm responsible for the claim.

Proposed § 101.93(b)(2) provides that the text of the statement that is being made be included in the notification. FDA tentatively finds that this information is necessary to enable the agency to determine whether the statement is of the type that can appropriately be made under section 403(r)(6) of the act. For example, FDA has already received notifications for numerous statements that evidence an intent to cure, treat, mitigate, diagnose, or prevent disease. FDA has advised the submitters of these notices of this fact and of the fact that such statements are not authorized under section 403(r)(6) of the act, and that if the company continues to market the product, it risks regulatory action by the agency.

Proposed § 101.93(b)(3) provides that firms are to include in the notification the name of the dietary ingredient or supplement that is the subject of a statement if it is not provided in the text of the statement. It would not be possible for FDA or the manufacturer to know with certainty whether a notification has been submitted for a statement on the labeling of a specific product or a product containing a specific dietary ingredient, or whether the claim was being made in compliance with the requirements of the act, without this information.

Proposed § 101.93(b)(4) provides that firms are to include in the notification the name of the dietary supplement (including the brand name) if not provided in response to proposed § 101.93(b)(3). A claim may be made for a dietary ingredient, in which case the claim that is the subject of the notification would likely not identify the product labeled with the claim. If the notification did not include the name of the dietary supplement product, FDA could not determine whether a product whose label bears the claim is in compliance with section 403(r)(6). Therefore, the agency tentatively concludes that it is necessary for the notification to contain the name of the dietary supplement, as well as of the dietary ingredient.

Proposed § 101.93(c) provides that the notice be signed by a responsible individual or the person who can certify the accuracy of the information presented and contained in the notice. This provision will ensure that a responsible person at the firm, qualified to determine that the statutory requirements have been met, has reviewed and certified that the notification is complete and accurate. Proposed § 101.93(c) also 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. This certification is necessary to provide assurance that the firm has fully complied with the requirements of section 403(r)(6) of the act.

III. 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.

IV. Economic Impact

FDA has examined the economic implications of the proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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, safety, distributive, and equity effects). 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. If a rule has a significant economic effect on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic impact of the rule on small entities. FDA finds that the proposed rule does not constitute a significant rule as defined by Executive Order 12866, and finds that under the Regulatory Flexibility Act, the proposed rule will not have a significant impact on a substantial number of small entities. Finally, the agency, in conjunction with the Administrator of the Office of Management and Budget (OMB), finds that this proposed rule is not a major rule for the purpose of congressional review (Pub. L. 104–121).

The proposed rule deals only with notification of nutritional support statements. The costs and benefits associated with the nutritional support statements themselves were analyzed in the Federal Register on December 28, 1995 (60 FR 67176). Because the proposed rule covers only the procedures for notification, not the rules governing the nutritional support statements themselves, this regulatory impact analysis will be restricted to the costs and benefits of the notification procedure.

The costs of this regulation are the costs of preparing and submitting notification to FDA regarding statements of nutritional support. The size of these costs will depend on the amount and type of information contained in the support statements. The greater the amount of information, the greater will be the cost of notification. Because the information should already have been gathered in order to prepare the nutritional support statement itself, the additional cost incurred for notification will be small and in many instances negligible. The benefits of this regulation are that the information will enable FDA to enforce the rules governing the use of nutritional support statements for dietary supplements.

Under the Regulatory Flexibility Act, FDA must consider the effects of the proposed rule on small businesses. 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, for the most part, 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 proposes to base size classifications on sales revenue rather than employees. According to Nutrition Business Journal (August 1996), the industry includes 850 manufacturing companies and more than 100 large multilevel marketing firms that sell mostly dietary supplements. The journal divides the 850 manufacturing firms into the following three groups: 11 firms with total revenues over $100 million, accounting for 53 percent of total sales; 30 firms with sales revenues between $20 and $100 million, accounting for 28 percent of total sales; and 809 firms with 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. The SBA sales revenue standard for businesses that cannot be classified into a specific industry is $5 million; the 29 independent firms (one manufacturer in the category is a division of conglomerate) with sales between $20 and $100 million will therefore not be classified as small. FDA concludes that at least 809 firms in the dietary supplement industry should be considered small businesses.

The number of small businesses affected by this proposed rule could include all 809 small manufacturing firms in the industry, but the additional costs imposed by the notification provisions will be negligible to small. FDA therefore finds that this proposed rule will not have a significant economic effect on a substantial number of small businesses.

V. Paperwork Reduction Act

This proposed rule contains information collections which are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). Therefore, in accordance with 5 CFR 1320, the title, description, and respondent description of the proposed collection of information requirements are shown below with an estimate of the annual collection and information burden. Included in the estimate is the time for assembling existing data sources, gathering necessary information, and completing and submitting the notification.

Title: Food Labeling; Section 403(r)(6) Statements; Notification Procedure.

Description: FDA is proposing a 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.

The agency is proposing that § 101.93 establish procedures for submitting required information. Proposed § 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.

DESCRIPTION OF RESPONDENTS: BUSINESSES OR OTHER FOR-PROFIT ORGANIZATIONS

21 CFR Section	Annual No. of Respondents	Annual Frequency per Response	Average Burden Hours per Response	Annual Burden Total Hours
101.93	Variable	20	0.5–1 hr	210–420 hrs
Total				210–420 hrs

The agency believes that there will be minimal burden on the industry to generate information to meet the requirements of section 403 of the act in submitting information regarding section 403(r)(6) of the act statements on labels or labeling of dietary supplements. The agency is requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. The agency estimates that listing the information required by section 403 of the act, and presenting it in a format that will meet the proposed procedures of § 101.93, will require a burden of approximately 0.5 to 1 hour of work per submission.

The agency has submitted to OMB copies of this proposed rule for its review of this information collection requirement. Interested persons are requested to submit comments regarding the collection of information requirements to FDA's Dockets Management Branch (address above), and to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503. Attn: FDA Desk Officer.

VI. Effective Date

FDA is proposing to make these regulations effective 30 days after date of publication of a final rule in the Federal Register.

VII. Comments

Interested persons may, on or before December 26, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

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.New § 101.93 is added to subpart F to read as follows:

§ 101.93 Statements under section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

(a) 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) of 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 notice shall be submitted.

(b) The notification shall include the following:

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

(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, if not provided in the text of the statement; and

(4) The name of the dietary supplement (including brand name), if not provided in response to the preceding subparagraph, on whose label, or in whose labeling, the statement appears.

(c) 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.

Dated: September 19, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–24751 Filed 9–26–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 190

[Docket No. 96N–0232]

Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to establish 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 setting out those steps that it has tentatively concluded are necessary to ensure that notification is accomplished efficiently but with the least burden possible on the industry. FDA is issuing this proposal in response to the Dietary Supplement Health and Education Act of 1994 (the DSHEA).

DATES: Written comments by December 26, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 301–245–1064.

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, 202–205–5372.

SUPPLEMENTARY INFORMATION: