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

a proposed rule, entitled ''Premarket Notification for a New Dietary Ingredient'' (hereinafter referred to as ''the September 1996 proposal''). FDA issued this proposal in response to section 8 of the DSHEA (Pub. L. 103–417). This section of the DSHEA amended the act by adding, among other provisions, section 201(ff) (21 U.S.C. 321(ff)), which defines a dietary supplement, and by adding section 413(a) (21 U.S.C. 350b(a)), which provides, among other things, for the notification of the Secretary of Health and Human Services (the Secretary) (and by delegation FDA) at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient. Section 413(a) of the act states that a dietary supplement that contains a new dietary ingredient shall be deemed adulterated unless it meets one of two requirements. One requirement is that ''the dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.'' The alternative requirement is that:

> [T]here is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

FDA published the September 1996 proposal to establish a procedure that would enable industry to comply with this notification requirement in an efficient manner. Adoption of this procedure will help to facilitate compliance with the notification required by section 413(a)(2) of the act. Interested persons were given until December 26, 1996, to comment on the proposal.

FDA received four letters each containing one or more comments from consumer groups, a trade association, and industry in response to the proposal. All of the comments generally supported the proposal. Several comments suggested modifications or revisions of various aspects of the proposal. A summary of the comments and the agency's responses follows.

II. New Dietary Ingredients Subject to Notification Requirements

1. Several comments expressed concern that proposed § 190(a), published in the September 1996 proposal, implied that any ''new dietary ingredient'' is subject to the notification requirements. The comments argued that the statutory requirement for notification under section 413(a)(2) of the act does not apply to those new dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered, as described in section 413(a)(1) of the act.

FDA agrees with the comments that the notification requirements of this regulation apply only to new dietary ingredients described in section 413(a)(2) of the act. Section 413(a)(1) of the act applies to dietary supplements that contain only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered, and the statute does not require that FDA be notified before these products are marketed. To make clear which new dietary ingredients are subject to the notification requirement in section 413(a)(2) of the act, FDA is modifying proposed § 190.6(a) by incorporating the phrase ''that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered'' to define which new dietary ingredients are subject to the notification requirement.

III. The Notification

2. One comment opposed the requirement in proposed § 190.6(b)(3)(i) that the notification include the level of the new dietary ingredient in the dietary supplement. The comment claimed that notices may be submitted by vendors who will not know the level of the new ingredient in the supplement and argued that these vendors should not be barred from the sale of these ingredients.

FDA does not agree that it would be appropriate to remove the requirement that the notification include the level of the new dietary ingredient in the dietary supplement. First, § 190.6(b)(3)(i) responds to section 413(a)(2) of the act that states that the manufacturer or the distributor is to provide the information on a dietary supplement that contains a new dietary ingredient. Both of these parties would have access to information on the level of the new dietary ingredient. If a vendor wants to stand in the position of a manufacturer or distributor, it needs to be able to provide the information that they can provide.

Second, section 413(a) of the act also states that a dietary supplement that contains a new dietary ingredient is adulterated unless there is a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, and that the notification must include the information on which the manufacturer or distributor has determined that the dietary supplement containing the dietary ingredient will meet this standard. It is not possible to have a reasonable expectation of safety without knowledge of the level of the new dietary ingredient in the supplement. The dietary ingredient may be safe under certain conditions of use, but it may be unsafe under other conditions of use. For example, the essential trace mineral selenium is safe when consumed in amounts necessary to meet a person's nutrient requirements, but it is toxic when consumed at high levels. Some dietary ingredients contain constituents that have potent pharmacologic actions that could cause the dietary ingredient to present a significant or unreasonable risk of injury or illness under the labeled conditions of use. The bark of *Pausinystalia yohimbe* (K. Schumann) (commonly called yohimbe) contains the indolalkylamine alkaloid yohimbine, which is a potent alpha-2-adrenergic antagonist that may be toxic when ingested in high doses.

Thus, if the notification does not contain the level of the dietary ingredient in the product, the notification would not contain a piece of information that is necessary if the manufacturer or distributor is to conclude that the dietary supplement will reasonably be expected to be safe under the conditions of use recommended or suggested in its labeling. Without this information, the dietary supplement would be adulterated under section 402(f)(1)(B) of the act (21 U.S.C. 342(f)(1)(B)). Therefore, FDA is not persuaded to remove or revise proposed § 190.6(b)(3)(i). This provision is necessary to ensure that a manufacturer has considered information that directly bears on the safety of the new dietary ingredient of interest.

3. One comment stated that FDA's proposed rule on the notification for a new dietary ingredient is a procedural regulation when what is needed is a substantive regulation that provides adequate guidance to the manufacturer

as to the quality and quantity of the information necessary to meet the requirements of section 413(a)(2) of the act. The comment disagreed with FDA's assertion that the manufacturer is only required to provide the basis on which it has concluded that the dietary supplement will reasonably to expected to be safe and that the manufacturer or distributor is not required to do a complete search of all available sources of information on the new dietary ingredient. The comment maintained that under the proposed regulation, manufacturers could knowingly market products with documented deleterious effects as long as they provide FDA with articles citing only a product's benefits.

The comment requested that FDA examine how the DSHEA amended section 402 of the act as well as section 413 of the act. Section 402(f)(1)(B) of the act states that a ''food shall be deemed to be adulterated if it is a dietary supplement or contains a dietary ingredient that is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.'' The comment argued that without a minimal safety data requirement, FDA risks that its interpretation of the DSHEA could cause a manufacturer to challenge the validity of the DSHEA on the grounds that the statute is void for vagueness because it does not provide fair warning to the manufacturer of what is expected. The comment requested that FDA issue regulations that elaborate on omissions in the statute by Congress.

The comment further suggested that FDA should require that a new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, be generally recognized as safe (GRAS); that is, that FDA apply to a new dietary ingredient the standard that there is general recognition that a dietary supplement containing the new dietary ingredient ''will reasonably be expected to be safe.'' The comment further suggested that FDA should provide industry with examples of publications that are acceptable as evidence of safety and a list of sources to search for evidence of adverse effects associated with a new dietary ingredient. Further, the comment maintained that manufacturers should be required to provide FDA with a summary of studies and scientific data, including known adverse effects. The comment stated that, in the absence of an appropriate scientific standard of evidence, manufacturers would be free to submit articles from questionable publications or unpublished materials to establish the safety of the new dietary ingredient. The comment argued that reliance on a GRAS standard would not be contrary to the statute or to congressional intent because it would still permit the marketing of dietary supplements without prior approval.

FDA disagrees with the comment that a substantive, rather than a procedural, regulation is necessary to respond to section 413(a)(2) of the act. The comment appears to be opposed to proposed § 190.6(b)(4), which sets out the substantive information that the notification must include. Significantly, § 190.6(b)(4) simply tracks the language of section 413(a)(2) of the act. It is appropriate that the regulation do so because, contrary to what the comment asserts, the manufacturer or distributor is not required to do a complete literature search. It is required only to provide ''the basis on which [it] has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe'' (section 413(a)(2) of the act). That is all that the regulation requires.

FDA agrees with the comment that sections 402(f)(1)(B) and 413 of the act are related in that they both relate to new dietary ingredients. FDA also acknowledges that Congress has provided in section 413(a) of the act that a failure to provide the information under section 413(a) of the act would render the dietary supplement adulterated under section 402(f) of the act. The agency, however, in deciding what information needs to be provided, is bound by the standard in the act. It is not free to rewrite the law, as the comment appears to suggest.

The fact that Congress did not create a minimal safety data requirement in section 413(a)(2) of the act does not render the DSHEA void for vagueness. The manufacturer's or distributor's obligation under section 413(a)(2) of the act is clear. It must make a showing as to why it considers that consumption of a new dietary ingredient will be safe.

FDA also does not agree that the GRAS concept has relevance here. The concept of GRAS was adopted by Congress in 1958, as a limitation on the scope of the ''food additive'' definition (section 201(s) of the act). Congress excluded from the definition of ''food additive'' substances that are generally recognized, among experts qualified by scientific training and experience to evaluate their safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food) to be safe under the conditions of their intended use. However, dietary ingredients, which are used in dietary supplements, are not food additives. Congress excluded them from the definition of a ''food additive'' in the DSHEA (section 201(s)(6) of the act, which was added by section 3(b) of the DSHEA). Thus, the concept of GRAS is not relevant to how dietary ingredients are regulated.

Furthermore, there is a fundamental difference between who is to make at least the initial judgment as to the safety of an ingredient under section 413(a)(2) of the act and whose judgment is relevant to a determination that an ingredient is GRAS. Whether an ingredient is GRAS is based on the judgment of ''experts qualified by scientific training and experience to evaluate'' the ingredient's safety. In contrast, the requirement in section 413(a)(2) of the act that a notification be made for a new dietary ingredient provides that the manufacturer or distributor is to determine whether a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. While this determination is subject to review by FDA, section 413(a) of the act does not specify that the manufacturer or distributor must rely on any specified third party in making its judgment. For these reasons, FDA is not requiring in § 190.6(b)(4) that the notification for a new dietary ingredient include information establishing that the new dietary ingredient is GRAS or the subject of any other type of general recognition.

Furthermore, FDA is not persuaded that it is necessary for the agency to provide examples of scientific publications that are adequate to provide the information that can be the basis on which the manufacturer or distributor has concluded that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. The agency also is not persuaded that the act requires that a manufacturer or distributor provide to FDA information on all known adverse effects attributable to the new dietary ingredient that is the subject of the submission. Section 413(a)(2) of the act requires only that the notification provide information ''which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe when used under the conditions recommended or suggested in the labeling.'' Thus, the statute does not specify or limit what evidence a manufacturer or distributor may rely on in determining whether the use of the

ingredient will reasonably be expected to be safe. Nonetheless, FDA expects that, in making a determination that a new dietary ingredient is reasonably expected to be safe and does not present a significant or unreasonable risk of illness or injury, a manufacturer or distributor will consider the evidence of safety that is available in the scientific literature and from examination of reports of adverse effects associated with the use of a new dietary ingredient.

FDA does not find that the statute requires that the agency determine the relative merit of different types of evidence of safety, and therefore, the agency is not modifying § 190.6 to specify specific safety requirements for new dietary ingredients or to establish standards that the evidence of safety must meet.

4. One comment opposed the proposed requirement in § 190.6(b)(4) that the premarket notification for a ''new dietary ingredient'' contain reprints or photostatic copies, including, if necessary, English translations of all references to published information offered in support of the notification. The comment stated that with FDA's diminished resources the handling, cataloging, and storage of such copies could place a substantial burden on the agency and that this requirement for submission of copies of cited articles would be expensive and cumbersome for the manufacturer. The comment suggested that the requirement for submission of copies of references should not become a part of the final rule on new dietary ingredient notifications because of the availability of scientific data through electronic data bases.

FDA is not persuaded to delete proposed § 190.6(b)(4). FDA finds that it would take significantly more agency resources to find and obtain copies of references than would be expended to managing them as a part of each notification. Furthermore, FDA has found in reviewing the notifications that have been received since the passage of the DSHEA that many of the references cited in the notifications are not readily available in the United States or are not easily obtained electronically. In some cases, English translations are not available unless provided by the party making the notification. On the other hand, the manufacturer or distributor, who has reviewed the published information in concluding that there is a reasonable expectation of safety, will have ready access to the articles and thus would be in a position to supply them to FDA.

Thus, FDA is not persuaded that the requirement that the new ingredient notification include copies of all references used to support the notification will impose an excessive or unnecessary burden on FDA or on manufacturers or distributors who make a notification. Consequently, it is not revising § 190.6(b)(4).

5. Several comments opposed the proposed § 190.6(b)(5) requirement that the premarket notification of the marketing of a new dietary ingredient include the signature of an authorized official of the manufacturer or distributor of the dietary supplement that contains the new dietary ingredient.

One comment asked that the regulation be changed to require the signature of the person who is directly responsible for assimilating and submitting the premarket notification. The comment stated that in its company, an ''authorized official'' usually means an officer of the company, but that the assimilation and submission of documents such as premarket notifications to FDA is the responsibility of someone who is not an officer of the company.

Another comment stated that it had no objection to the requirement in proposed § 190.6(b)(5) that the notification be signed by an authorized official of the manufacturer or distributor. The comment did state, however, that such a signature does not constitute a certification of the accuracy or completeness of the data set out in the notification. The comment argued that section 8 of the DSHEA is entirely silent with respect to the signature or certification of notices, and that the agency's proposal creates an administrative amendment to DSHEA and is, therefore, inappropriate.

In the preamble to the September 1996 proposal, FDA stated that it was ''including this provision to ensure that the individual that is responsible for the accuracy, completeness, and understandability of the notification is identified'' (61 FR 50774 at 50775). Section 8 of the DSHEA does not designate a specific employee or representative of a manufacturer or distributor who is to submit the notice on behalf of a manufacturer or distributor. FDA did not intend by its use of the word ''authorized'' to designate a particular person that the firm must assign the responsibility of preparing the notification required under section 413(a)(2) of the act. Instead, the agency only intended that § 190.6(b)(5) provide that the person who signs the notification be familiar with the information contained in it and be available to answer questions or provide additional information to FDA if questions about a notification arise. Therefore, FDA is modifying § 190.6(b)(5) by replacing the term ''authorized official'' with the word ''person.'' This change will make clear that a manufacturer or distributor may assign responsibility for the notification to a person without concern about that person's official capacity within the management structure of the firm.

The September 1996 proposal did not represent that the signature of the individual that is responsible for the accuracy, completeness, and understandability of the notification constitutes a ''certification.'' However, the person signing the notice, and the company on whose behalf he or she signs it, should recognize that there are significant consequences to their action, including potential liability under 18 U.S.C. 1001. The intent of section 413(a)(2) of the act is for the firm to provide to FDA the information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. A firm must have such information, or the dietary supplement may well be adulterated under section 402(f)(1)(B) of the act. The notification is intended to be the mechanism by which that information is made available to FDA, so that the agency is aware of the basis that a manufacturer or distributor has for concluding that there is reasonable assurance that a new dietary ingredient is safe. Consequently, the information in the notification must be a fair and accurate representation of the information that a firm used in developing its conclusion that a new dietary ingredient is safe. A notification that intentionally omitted information that would indicate that a new dietary ingredient presents a significant or unreasonable risk of illness or injury or that contained false or misleading information would be a knowing and willful submission of false information to the Federal Government and could subject the parties involved to criminal sanctions under 18 U.S.C. 1001.

However, the person who signs the notification need not certify the information in the notification. The signature is intended to identify the person to whom FDA may address questions to concerning the notification. However, such persons should be cognizant of their responsibility in providing this notification and of the consequences of submitting of false or misleading information to the Federal Government.

IV. Administrative Procedures

6. One comment requested that proposed § 190.6(c) be revised to state that FDA will send an acknowledgment of the receipt of the premarket notification of the marketing of a new dietary ingredient noting the filing date, so that manufacturers will know when the 75-day notice period expires.

FDA is persuaded to make this revision. However, the agency cautions that the acknowledgment of the receipt of the premarket notification of the marketing of a new dietary ingredient does not constitute a finding by FDA that the new dietary ingredient, or the dietary supplement that contains the new dietary ingredient, is safe, or that it is not adulterated under section 402 of the act. Therefore, FDA has required § 190.6(c) by adding the sentence: ''FDA will acknowledge the receipt of the notification made pursuant to section 412(a) of the act and will notify the submitter of the date of receipt of such a notification.''

7. One comment asked that proposed § 190.6(c) be revised by removing the last sentence which states: ''For 75 days after the filing date, the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient shall not introduce or deliver for introduction, into interstate commerce the dietary supplement that contains the new dietary ingredient.'' The comment stated that this language is not found in the act, and that the language is unnecessarily restrictive. The comment argued that if the agency completes its review and decides there is no concern, the manufacturer should not be prohibited from marketing the dietary supplement when such a determination by FDA is made prior to the 75th day after the notification was filed.

FDA does not agree that this sentence should be removed from the regulation. While the comment is correct that the language in the regulation is not stated in the law, section 413(a)(2) of the act states, as stated in the previous paragraph, that at least 75 days before introducing or delivering for introduction, a new dietary ingredient into interstate commerce, the manufacturer or distributor is to provide information that the dietary ingredient will reasonably be expected to be safe. The comment is based on a misunderstanding of the notification process. Because there is no requirement that the notification provide a comprehensive safety review of the new dietary ingredient, it is not likely to provide the agency with a basis to find that there is no concern. Rather, the process is more likely to identify those new dietary ingredients that do present a concern. Thus, it is the people who have provided a notice that raises concerns, rather than one that does not, who are likely to hear from the agency. Given this fact, and to ensure that the system runs smoothly, FDA is codifying its expectation based on the act that manufacturers and distributors that submit a notification to FDA will not market their product for 75 days from the date of submission of the notice. Consequently, FDA has not modified proposed § 190.6(c) as requested by this comment.

8. One comment asked that proposed § 190.6(d) be changed to state that:

> * * * if additional information is provided in support of the new ingredient notification, the agency will determine whether the additional information is a substantive amendment to the submission. If the agency determines that the new submission is a substantive amendment, FDA will assign a new filing date. FDA will acknowledge receipt of the additional information and, when applicable, notify the manufacturer of the new filing date, which is the date of receipt by FDA of the information that constitutes the substantive amendment.

The comment argued that proposed § 190.6(d) would require that any additional information, regardless of how significant (for example, a single response to an inquiry from the agency about a submission), would reset the 75-day period. Furthermore, the comment stated that its suggested language would provide flexibility for submitting additional information without unnecessarily prolonging the 75-day period.

FDA agrees with the substance of this comment that the agency should be flexible in its handling of the submission of additional materials. Therefore, FDA has revised § 190.6(d) to reflect that if it receives additional information, the agency will review all submissions pertaining to the notification in question, including responses made to inquires from the agency, to determine whether they are significant and whether they require that the 75-day period be reset.

V. Environmental Impact

The agency had 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, 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.

In the economic analysis of the proposed rule, FDA estimated the number of new ingredients to be 0 to 12 per year and the cost per notification to be $410, for an annual cost range of $0 to $4,920 per year. In the most recent year, the industry introduced six new ingredients for an estimated cost of $2,460. FDA received no comments on these estimates and consequently concludes that the actual costs of this rule will not be significant.

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 (Public Law 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.

FDA received no comments on the regulatory flexibility analysis of the proposed rule. As the agency stated in the analysis of the proposed rule, the dietary supplement industry does not have its own standard industrial classification code. The industry's products come closest to the industry groups Food Preparations (not elsewhere classified) (Standard Industrial Classification code 2099) and Medicinal Chemicals and Botanical Products (Standard Industrial Classification code 2833). The Small Business Administrations' (SBA) size standards for ''small'' are 500 or fewer employees for food preparations and 750 or fewer employees for medicinal and botanical products. The use of this size standard will cause the majority of

firms in the dietary supplement industry to be classified as small businesses.

Without further information on the identity of the businesses introducing new ingredients, FDA concludes that the total number of businesses affected by the proposed rule will be no more than the number of new ingredients (estimated to be 0 to 12 per year). Before the event, FDA cannot determine the sizes of firms that introduce new dietary ingredients. Small businesses could introduce all new ingredients or none. The annual number of small businesses potentially affected by the proposed rule will therefore be the same as the annual number of new ingredients, 0 to 12.

Whether the cost of notification, approximately $410 per submission, will be a substantial burden depends partly on the revenues of the smallest businesses in the dietary supplement industry. For the smallest businesses in the industry, the cost of notification considered alone could be a significant burden. This cost, however, cannot be considered in isolation from the total cost of introducing a new dietary ingredient. A dietary supplement firm introducing a new ingredient must first determine that the ingredient can reasonably be expected to be safe. Technical, legal, and marketing costs of introducing a new dietary ingredient and ensuring its safety will be much larger than the cost of providing the information required under this rule. The costs of notification are therefore not likely to be a substantial part of the total cost of introducing a new dietary ingredient. Small businesses capable of bearing the cost of introducing new ingredients, then, would be highly unlikely to find the additional cost imposed by the 75-day premarket notification procedure to be an economically significant burden.

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 Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities.

VII. 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 following title, description, and respondent description of the information collection provisions are shown 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: Dietary supplements; dietary ingredients; premarket notification.

Description: FDA is requiring, by regulation, the submission to the agency of information that is the basis on which a manufacturer or distributor of a new dietary ingredient or a dietary supplement containing a new dietary ingredient has concluded that the dietary supplement containing such dietary ingredient will reasonably be expected to be safe. This information must be submitted to the agency at least 75 days prior to the first commercial distribution of a dietary supplement containing a new dietary ingredient. FDA will review the submitted information to determine whether the submission meets the requirements of section 413 of the act. The agency is establishing § 190.6 as the procedural regulation for this program. This regulation provides details of the administrative procedures associated with the submission and identifies the information that must be included in the submission in order to meet the requirements of section 413 of the act and to show the basis on which a manufacturer or distributor of a new dietary ingredient or a dietary supplement containing a new dietary ingredient has concluded that the dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

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

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
190.6	6	1	6	20	120
Total					120

There are no capital or operating and maintenance costs associated with this collection of information.

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 0910–0330. This approval expires 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 190

Food ingredients, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, title 21 CFR chapter I is amended by adding new part 190 to read as follows:

PART 190—DIETARY SUPPLEMENTS

Subpart A—[Reserved]

Subpart B—New Dietary Ingredient Notification

Sec.

190.6 Requirement for premarket notification.

Authority: Secs. 201(ff), 301, 402, 413, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff), 331, 342, 350b, 371).

Subpart A—[Reserved]

Subpart B—New Dietary Ingredient Notification

§ 190.6 Requirement for premarket notification.

(a) At least 75 days before introducing or delivering for introduction into interstate commerce a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered, the manufacturer or distributor of that supplement, or of the new dietary ingredient, shall submit 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, information including any citation to published articles that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. An original and two copies of this notification shall be submitted.

(b) The notification required by paragraph (a) of this section shall include:

(1) The name and complete address of the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient;

(2) The name of the new dietary ingredient that is the subject of the premarket notification, including the Latin binomial name (including the author) of any herb or other botanical;

(3) A description of the dietary supplement or dietary supplements that contain the new dietary ingredient including:

(i) The level of the new dietary ingredient in the dietary supplement; and

(ii) The conditions of use recommended or suggested in the labeling of the dietary supplement, or if no conditions of use are recommended or suggested in the labeling of the dietary supplement, the ordinary conditions of use of the supplement;

(4) The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which the distributor or manufacturer of the dietary supplement that contains the new dietary ingredient has concluded that the new dietary supplement will reasonably be expected to be safe. Any reference to published information offered in support of the notification shall be accompanied by reprints or photostatic copies of such references. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation; and

(5) The signature of the person designated by the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient.

(c) FDA will acknowledge its receipt of a notification made under section 413 of the Federal Food, Drug, and Cosmetic Act (the act) and will notify the submitter of the date of receipt of such a notification. The date that the agency receives the notification submitted under paragraph (a) of this section is the filing date for the notification. For 75 days after the filing date, the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient shall not introduce, or deliver for introduction, into interstate commerce the dietary supplement that contains the new dietary ingredient.

(d) If the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient, provides additional information in support of the new dietary ingredient notification, the agency will review all submissions pertaining to that notification, including responses made to inquiries from the agency, to determine whether they are substantive and whether they require that the 75-day period be reset. If the agency determines that the new submission is a substantive amendment, FDA will assign a new filing date. FDA will acknowledge receipt of the additional information and, when applicable, notify the manufacturer of the new filing date, which is the date of receipt by FDA of the information that constitutes the substantive amendment.

(e) FDA will not disclose the existence of, or the information contained in, the new dietary ingredient notification for 90 days after the filing date of the notification. After the 90th day, all information in the notification will be placed on public display, except for any information that is trade secret or otherwise confidential commercial information.

(f) Failure of the agency to respond to a notification does not constitute a finding by the agency that the new dietary ingredient or the dietary supplement that contains the new dietary ingredient is safe or is not adulterated under section 402 of the act.

Dated: August 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–24737 Filed 9–22–97; 8:45 am]

BILLING CODE 4160–01–F