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:

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, and by adding section 413 (21 U.S.C. 350b), which, among other things, provides 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 contain only dietary ingredients that have been present in the food supply as articles used for food in a form in which they have not been chemically altered. Alternatively, the dietary supplement is not adulterated if there is a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the supplement's labeling, will reasonably be expected to be safe, and at least 75 days before the supplement is 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, 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.

FDA urges that, pending final action, manufacturers and distributors who file notices with FDA under section 413(a) of the act follow the procedures proposed in this document.

II. The Proposal

A. Notification Procedure

Proposed § 190.6(a) provides that at least 75 days before introducing or delivering for introduction into interstate commerce a dietary supplement that contains a new dietary ingredient, the manufacturer or distributor of that supplement, or of the new dietary ingredient, 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 the dietary supplement containing the new dietary ingredient will reasonably be expected to be safe. Proposed § 190.6(a) requires that the notification be submitted as an original and two copies. FDA tentatively concludes that the submission of this number of copies is necessary to ensure that there will be a copy for public display and copies for any agency employees who will need to review the notification.

Proposed § 190.6(b)(1) provides that the notification shall include the name and address of the manufacturer or distributor of the new dietary ingredient or of the dietary supplement that contains the new dietary ingredient. This information is necessary to identify the firm that is responsible for the notification and that intends to market the new dietary ingredient.

Proposed § 190.6(b)(2) provides that the new dietary ingredient notification contain 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. FDA tentatively concludes that this information is necessary so that the agency will know what ingredient is the subject of the notification and will be able to determine whether the information submitted is appropriate for making an evaluation of the safety of the new dietary ingredient.

Proposed § 190.6(b)(3) requires that the notification contain a description of the dietary supplement, or dietary supplements, that are to contain the new dietary ingredient. FDA is proposing that this description include the level of the new dietary ingredient in the dietary supplement (§ 190.6(b)(3)(i)) and 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 (§ 190.6(b)(3)(ii)). This information is necessary to facilitate the agency's review of the use of the new dietary ingredient and to determine whether there is any basis for concern about the safety of its use.

Proposed § 190.6(b)(4) provides that the new dietary ingredient notification shall also contain 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. Under proposed § 190.6(b)(4), this history of use or other evidence of safety must include citation to published articles or other evidence that is the basis on which the distributor or manufacturer of the dietary supplement has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. Proposed § 190.6(b)(4) reflects the requirements in section 413(a)(2) of the act. FDA is providing in proposed § 190.6(b)(4) that any reference to published information offered in support of the notification required by § 190.6(a) be accompanied by reprints or photostatic copies of such references, and that, if any part of the material submitted is in a foreign language, it be accompanied by an accurate and complete English translation. FDA tentatively concludes that submission of this material is necessary for efficient implementation of this provision of the act.

Proposed § 190.6(b)(5) provides that the new dietary ingredient notification contain the signature of an authorized official of the manufacturer or distributor of the dietary supplement that contains the new dietary ingredient. FDA is including this provision to ensure that the individual that is responsible for the accuracy, completeness, and understandability of the notification is identified.

B. Administrative Procedures

Proposed § 190.6(c) states that the date that the agency receives the notification submitted under § 190.6(a) is the filing date for the notification. Consistent with section 413(a)(2) of the act, proposed § 190.6(c) also provides that the manufacturer or distributor of the dietary supplement that contains the new dietary ingredient is not to introduce the dietary supplement, or deliver it for introduction, into interstate commerce for 75 days after the filing date. Congress provided for a 75-day notice so that the agency would have sufficient time to examine all of the material submitted and decide whether there is any basis for concern about the marketing of a dietary supplement that contains a new dietary ingredient.

Proposed § 190.6(d) states that if the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient, or of a new dietary ingredient, provides additional information in support of the new dietary ingredient notification, the date of receipt by FDA of the additional information in support of the new dietary ingredient notification will constitute the filing date of the notification. FDA tentatively concludes

that it is necessary to give a new filing date to the new dietary ingredient notification when additional information in support of the notification is received so that the agency has time to examine all of the material submitted and to determine whether there is any basis for concern about the marketing of the dietary supplement.

Consistent with section 413(a) of the act, proposed § 190.6(e) provides that the FDA will not disclose the existence of, or the information contained in, a new dietary ingredient notification for 90 days after the filing date of the notification. Proposed § 190.6(e) also provides that 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.

Proposed § 190.6(f) makes clear, however, that 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 that it is not adulterated under section 402 of the act (21 U.S.C. 342). This tentative position reflects the fact that the manufacturer or distributor of a new dietary ingredient or a dietary supplement that contains a new dietary ingredient is only required to provide the basis on which it has concluded that the dietary supplement will reasonably be expected to be safe. Since the manufacturer or distributor is not required to do a complete search of all available sources of information on the new dietary ingredient, the agency will not be in a position to make a determination that the supplement is safe, or that it is not adulterated under section 402 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. Analysis of Impacts

FDA has examined the economic impact 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 impact 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.

The rule sets out the information that must be included in a premarket notification for a new dietary ingredient. The information must show the basis for the manufacturer's conclusion that the ingredient is expected to be safe. Because the rule deals only with the filing of information, the compliance costs are all clerical. Technical and legal costs of introducing a new dietary ingredient and ensuring its safety will be borne regardless of the proposed rule.

In the section of the document dealing with the Paperwork Reduction Act, FDA estimates that the burden to industry will be approximately 20 hours per submission. The costs per hour are estimated to be $20.50 for labor, benefits, and overhead (mainly computer time and photocopying). The cost to industry per submission is therefore estimated to be $410. In the most recent year, six new dietary ingredients appeared, which would imply an annual cost to industry of $2,460. FDA assumes that the number of new ingredients will vary, but will not be greatly different from the past year. The plausible range is estimated to be 0 to 12 new ingredients per year, for a cost range of 0 to $4,920 per year. Because industry may take several years to adjust to the DSHEA, FDA expects the number of new ingredients (and annual costs) to be closer to the high end of the range in the next few years and closer to the low end after that.

FDA is not able to quantify the benefits of this rule. The rule increases the information available to FDA for implementing and enforcing rules dealing with the new dietary ingredient provisions of the DSHEA. The benefits are therefore derived from the benefits of FDA efforts to implement the DSHEA so as to ensure that dietary ingredients do not present a significant or unreasonable risk of illness or injury.

Under the Regulatory Flexibility Act, FDA must consider the effects of the proposed rule on small businesses. The Small Business Administration (SBA) does not define ''small'' for the dietary supplement industry. The industry's products, for the most part, come closest to being included in the Commerce Department's industry categories of Food Preparations N.E.C. (not elsewere classified) (Standard Industrial Classification code 2099) and Medicinal Chemicals and Botanical Products (Standard Industrial Classification code 2833). The SBA size standards for small are 500 or fewer employees for food preparations and 750 or fewer employees for medicinal and botanical products. According to either size standard, the majority of firms in the dietary supplement industry would be classified as small businesses. The total number of businesses affected by the proposed rule will be small—no more than the number of new ingredients (estimated to be 0 to 12 per year). FDA cannot determine, before the event, the sizes of firm 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. The effect, as shown above, will be small—approximately $410 per submission. FDA concludes that the 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 that are subject to review by the Office of Management and Budget (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 premarket notification.

FDA is interested in receiving comments that: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the

burden of the proposed collection of information; (3) evaluate the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Title: Dietary supplements; dietary ingredients; premarket notification.

Description: FDA is proposing a regulation requiring 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 before 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 proposing to establish 21 CFR part 190 as the procedural regulations for this program. This proposal 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 of a dietary supplement that contains 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	Hours per Response	Total Hours
190.6	6	1	20	120
Total	.....	.....	.....	120

The agency believes that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program, because the agency is requesting only that information that the manufacturer or distributor should already be developing to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the act. However, the agency estimates that extracting and summarizing the relevant information from the company's files, and presenting it in a format that will meet the requirements of section 413 of the act, will require a burden of approximately 20 hours 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. Comments

Interested persons may, on or before December 26, 1996, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, written comments regarding this proposal. Two copies of any comment 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 190

Food ingredients, Reporting and recordkeeping requirements.

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

PART 190—DIETARY SUPPLEMENTS

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

§ 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, 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 202004, information, including any citation to published articles, that is the basis on which the manufacturer or distributor has concluded that the dietary supplement 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 an authorized official of the manufacturer or distributor of the dietary supplement that contains the new dietary ingredient.

(c) 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 date of receipt by FDA of the additional information in support of the new dietary ingredient notification shall constitute the filling date.

(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: September 19, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–24752 Filed 9–26–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–209826–96]

RIN 1545–AU29

Application of the Grantor Trust Rules to Nonexempt Employees' Trusts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to the application of the grantor trust rules to nonexempt employees' trusts. The proposed regulations clarify that the grantor trust rules generally do not apply to domestic nonexempt employees' trusts, and clarify the interaction between the grantor trust rules, the rules generally governing the taxation of nonqualified deferred compensation arrangements, and the antideferral rules for United States persons holding interests in foreign entities. The proposed regulations affect nonexempt employees' trusts funding deferred compensation arrangements, as well as U.S. persons holding interests in certain foreign corporations and foreign partnerships with deferred compensation arrangements funded through foreign nonexempt employees' trusts. In addition, the proposed regulations affect U.S. persons that have deferred compensation arrangements funded through certain foreign nonexempt employees' trusts. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written comments must be received by December 26, 1996. Requests to speak (with outlines of oral comments to be discussed) at the public hearing scheduled for January 15, 1997, at 10:00 a.m. must be submitted by December 24, 1996.

ADDRESSES: Send submissions to: CC:DOM:CORP:R (REG–209826–96), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG–209826–96), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. The public hearing will be held in room 2615, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the ''Tax Regs'' option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at http://www.irs.ustreas.gov/prod/tax__regs/comments.html.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations, James A. Quinn, (202) 622–3060; Linda S. F. Marshall, (202) 622–6030; Kristine K. Schlaman (202) 622–3840; and M. Grace Fleeman (202) 622–3850; concerning submissions and the hearing, Michael Slaughter, (202) 622–7190 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, T:FP, Washington, DC 20224. Comments on the collection of information should be received by November 26, 1996. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in this proposed regulation is in § 1.671–1(h)(3)(iii). This information is required by the IRS to determine accurately the portion of certain foreign employees' trusts properly treated as owned by the employer. This information will be used to notify the Commissioner that certain