foreign air carriers may apply to the Department for a waiver or modification of the requirements contained in part 221 (Tariffs). An application processing fee for such waiver or modification is warranted since the applicant seeks the special benefit of the Department's approval for relief from provisions of the requirements regulating tariffs.

No applications under this schedule item were processed during the cost-collection period, and we have no other basis to propose a change in the current fee or to assume that fee costs have changed. Accordingly, the current fee of $12 per Application is retained.

Schedule Item 69. Application for provision of certified copies of tariff material upon request (with DOT seal). Section 389.15 of the regulations provides that certified copies of tariffs filed with the Department will be provided upon request. Certification of these data are required in civil cases in order for parties to formally submit air carrier tariff provisions involving charges and conditions of carriage in international air transportation officially filed with the Department. A fee for providing this service is warranted because of the special benefit to the applicant of having certified copies of officially filed tariff material for use in legal proceedings.

The basis of our proposed fee is as follows:

Direct Labor	$807.58
Overhead	646.30
Total Cost	1,453.88
Applications processed	6
Cost per application	242.31
Proposed fee, Item 69: per application	240.00

Other Exemptions and Authorizations: Schedule Items 70–76

Schedule Item 70. Application for an exemption for slots at a slot-controlled airport. Under section 41714 of the Statute, an air carrier may apply to the Department for an exemption from 14 CFR Part 93, Subparts K and S (the High Density Rule), in order for the carrier to increase its number of operations (takeoff or landing ''slots'') at JFK, La Guardia, and/or O'Hare airports (Reagan National also is slot controlled, but is excluded from the exemption). Recognizing that air carriers may be restrained from entering markets as consequence of slot restrictions, the Congress provided the exemption mechanism as a way to increase air carrier access at three of the four slot-controlled airports. A processing fee for a slot exemption application is justified since the applicant is seeking the special benefit of the Department's authorization enabling access to takeoff and landing rights that otherwise would not be available.

Our proposed fee for this item is based on the following:

Direct Labor	$11,155.93
Overhead	6,211.62
Total Cost	17,367.55
Applications processed	4
Cost per application	4,341.89
Proposed fee, Item 70: per application	4,340.00

Schedule Item 71. Motion for confidential treatment of documents. Section 302.39 of the Department's Procedural Regulations sets forth the procedures that an applicant or other party must follow in seeking the Department's concurrence to withhold certain information from public disclosure in the context of a Departmental proceeding. A processing fee for this item is justified since the applicant is seeking the special benefit of the Department's approval to withhold sensitive information.

Our proposed fee for this item is determined as follows:

Direct Labor	$499.57
Overhead	253.37
Total Cost	752.94
Applications processed	2
Cost per application	376.47
Proposed fee, Item 71: per application	380.00

Schedule Item 72. Application for approval of and antitrust immunity for inter-carrier agreements. Under sections 41308 and 41309 of the Statute, air carriers and foreign air carriers may seek approval of antitrust immunity for agreements and activities with common business objectives. Applicants seek the benefit of this immunity in order to protect themselves from lawsuits alleging behavior normally not permitted under the antitrust laws. A processing fee is warranted since the applicant is seeking the special benefit of the Department's approval of immunity from antitrust enforcement.

No applications under this schedule item were concluded during the cost-collection period, and we have no other basis to propose a change in the current fee or to assume that fee costs have changed. Accordingly, the current fee of $1,080 per Application is retained.

Schedule Item 73. [Reserved.]

Schedule Item 74. [Reserved.]

Schedule Item 75. Petition for a change in mail rates. Section 41901 of the Statute provides that the United States Postal Service or a certificated air carrier may file a petition with the Department to change the mail rates set by the Department to be paid by the Postal Service to U.S. air carriers for the carriage of U.S. mail between the United States and foreign countries and/or within the State of Alaska. A fee for processing a petition is warranted since the petitioner is seeking the special benefit of the Department's approval to change existing mail rates.

No applications under this schedule item were processed during the cost-collection period, and we have no other basis to propose a change in the current fee or to assume that fee costs have changed. Accordingly, the current fee of $420 per Application is retained.

Schedule Item 76. Application for overseas military personnel charter operator authority. Under Part 372 of the Department's regulations, any U.S. citizen desiring to operate as an overseas military personnel charter operator may apply to the Department for operating authority. If granted this authority, the operator is relieved from provisions of section 41102 of the Statute for the purpose of enabling the operator to provide overseas military personnel charters utilizing aircraft chartered from direct air carriers or foreign air carriers. A processing fee is warranted since the applicant is seeking the special benefit of the Department's permission to advertise, organize, provide, sell and/or offer to sell overseas military personnel charters.

No applications under this schedule item were processed during the cost-collection period, nor has the Department had occasion to process any such applications for several years. Absent evidence of a cost change, the current fee of $665 per Application is retained.

[FR Doc. 99–1233 Filed 1–20–99; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98N–0826]

Food Labeling: Use on Dietary Supplements of Health Claims Based on Authoritative Statements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to permit the use on dietary supplements

of health claims based on authoritative statements under the notification procedures in the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDAMA permits nutrient content claims based on authoritative statements for both conventional foods and dietary supplements. FDAMA also permits health claims based on authoritative statements for conventional foods; however, FDAMA does not provide for the use of health claims based on authoritative statements for dietary supplements. FDA believes that, for health claims, conventional foods and dietary supplements should be subject to the same standards and procedures, including the notification procedure provided by FDAMA.

DATES: Submit written comments on the proposed rule by April 6, 1999. Submit written comments on the information collection provisions by February 22, 1999.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Constance B. Henry, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. The FDA Modernization Act of 1997

On November 21, 1997, the President signed FDAMA into law (Pub. L. 105–115), which amended the Federal Food, Drug, and Cosmetic Act (the act). Sections 303 and 304 of FDAMA amended section 403(r)(3) and (r)(2) of the act (21 U.S.C. 343(r)(3) and (r)(2)). Specifically, FDAMA added new section 403(r)(2)(G), (r)(2)(H), (r)(3)(C), and (r)(3)(D), which provides for the use in food labeling of nutrient content claims and health claims based on authoritative statements. FDAMA requires that a notification of a prospective nutrient content claim or a prospective health claim be submitted to FDA at least 120 days before a food bearing the claim may be introduced into interstate commerce.

The notification must include specific information including: (1) The exact wording of the prospective nutrient content claim or health claim; (2) a concise description of the basis upon which the petitioner relied for determining that the requirements of section 403(r)(2)(G)(i) of the act for nutrient content claims or section 403(r)(3)(C)(i) of the act for health claims have been satisfied; (3) a copy of the authoritative statement upon which the person relied in making the claim; and (4) a balanced representation of the scientific literature relating to the nutrient level for a prospective nutrient content claim or relating to the relationship between the nutrient and the disease or health-related condition for a prospective health claim. For a prospective nutrient content claim, the authoritative statement must identify the nutrient level to which the claim refers. For a prospective health claim, the authoritative statement must be a statement about the relationship between a nutrient and a disease or health-related condition to which the claim refers. For both types of claims, the authoritative statement must be currently in effect and it must have been published either by a scientific body of the U.S. Government that has official responsibility for public health protection or research directly relating to human nutrition (e.g., the National Institutes of Health or the Centers for Disease Control and Prevention) or by the National Academy of Sciences or any of its subdivisions (hereinafter referred to as a ''scientific body'').

Under new section 403(r)(2)(H) and (r)(3)(D) of the act, such a claim may be made until: (1) FDA has issued an effective regulation that prohibits or modifies the claim; (2) FDA has issued a regulation finding that the requirements under section 403(r)(2)(G) of the act for a prospective nutrient content claim or under section 403(r)(3)(C) of the act for a prospective health claim have not been met; or (3) a District Court of the United States in an enforcement proceeding under chapter III of the act has determined that the requirements under section 403(r)(2)(G) of the act for a prospective nutrient content claim or under section 403(r)(3)(C) of the act for a prospective health claim have not been met. During the 120 days following submission of a notification and before the claim may appear on a food, the agency may notify any person who is making the claim that the notification did not include all of the required information.

Section 304 of FDAMA permits nutrient content claims based on authoritative statements for both conventional foods and dietary supplements because section 304 amended section 403(r)(2) of the act, which provides for nutrient content claims on both conventional foods and dietary supplements. Section 303 of FDAMA, however, does not provide for health claims for dietary supplements based on authoritative statements. In particular, section 403(r)(5)(D) of the act specifies that health claims for dietary supplements shall not be subject to section 403(r)(3) of the act, but rather to a procedure and standard that FDA establishes by regulation. In section 303 of FDAMA, Congress amended section 403(r)(3) of the act, which provides for procedures and standards for health claims for conventional foods, to allow for health claims based on authoritative statements for conventional foods, but Congress did not amend section 403(r)(5)(D) of the act. Therefore, FDA believes that section 403(r)(3)(C) of the act provides only for use of a health claim based on an authoritative statement on any conventional food that provides an appropriate level of the nutrient that is the subject of the health claim, but that does not exceed the disqualifying nutrient levels identified in § 101.14(a)(5) (21 CFR 101.14(a)(5)), provided that the food and the claim otherwise comply with section 403(r)(3)(C) of the act and all other provisions of the act.

II. The Proposal

FDA believes that, for health claims, conventional foods and dietary supplements should be subject to the same standards and procedures, including the notification procedure provided by FDAMA. This approach is consistent with the agency's final rule that makes dietary supplements subject to the same general requirements that apply to conventional foods with respect to health claims (59 FR 395, January 4, 1994). This approach is also consistent with the guidance of the Commission on Dietary Supplement Labels. Although the commission did not discuss the provisions of FDAMA as enacted, it did state in its 1997 report (Ref. 1) that the process for the approval of health claims should remain the same for dietary supplements and conventional foods.

Therefore, FDA is proposing to add a new section to subpart E of part 101 (21 CFR part 101) to provide for the use of health claims based on authoritative statements on dietary supplements. The agency intends this rule to provide for the same process and standard for the use on dietary supplements of health claims based on authoritative statements as provided by section 403(r)(3)(C) of the act for conventional foods.

This proposed regulation tracks the language of FDAMA section 303 and it

would place dietary supplements on equal footing with conventional foods with respect to health claims. The agency notes that it has issued a document entitled ''Guidance for Industry—Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body'' ((Internet) ''http://www.cfsan.fda.gov/~dms/guidance.html'') (Ref. 2), as well as nine interim final rules in response to notifications of health claims based on authoritative statements (63 FR 34084, 34092, 34097, 34101, 34104, 34107, 34110, 34112, and 34115, June 22, 1998). FDA has received comments on the nine interim final rules, several of which take issue with the process and principles outlined in sections I.A and I.B of the ''Food Labeling: Health Claims; Antioxidant Vitamins C and E and the Risk in Adults of Atherosclerosis, Coronary Heart Disease, Certain Cancers, and Cataracts'' interim final rule (63 FR 34084 at 34085 through 34087). FDA will respond to those comments in proposing implementing regulations for sections 303 and 304 of FDAMA, and when it completes those nine rulemakings. At this time, however, FDA advises that the process and principles in the guidance and the nine interim final rules reflect the agency's current thinking with respect to implementation of sections 303 and 304 of FDAMA. The agency also advises that, in proposing regulations to implement sections 303 and 304 of FDAMA, it will provide further detail on how the notification procedures will be implemented with respect to the use of health claims based on authoritative statements on all foods. The agency expects that those implementing regulations would maintain the equal treatment intended by this proposal. Therefore, the agency expects to withdraw this regulation, if finalized, when that implementing regulation is issued because this regulation would then no longer be necessary.

III. Analysis of Economic Impacts

A. Benefit-Cost Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. The administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB) has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), requiring cost-benefit and other analyses, in section 1531(a) defines a significant rule as ''a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any 1 year.'' FDA has determined that this rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this proposed rule is not a major rule for the purpose of congressional review.

In this rule, FDA is proposing to permit the use on dietary supplements of health claims based on authoritative statements under the notification procedures in FDAMA. The proposed rule potentially affects the entire dietary supplement industry.

There are several types of products that may be considered to be dietary supplements. These products include, but are not limited to, vitamin and mineral supplements, herbal products, and products that contain other similar nutritional substances. Estimates of the number of dietary supplements are approximate because no one source collects information on all types of dietary supplements. Some sources include only dietary supplements of vitamins and minerals, others include herbals or botanicals, and still others include types of products that may or may not be dietary supplements, such as sports nutrition products and ''functional foods,'' a term for which there is no definition. FDA tentatively estimates the number of dietary supplement products to be 29,000. FDA estimates the number of stockkeeping units, a count of the number of labels, to be approximately 75,000.

In its analysis of the proposed rule to establish regulations on statements made for dietary supplements concerning the effect of the product on the structure or function of the body (63 FR 23624 at 23628 and 23629, April 29, 1998), FDA estimated that approximately 850 firms manufacture dietary supplements. For purposes of determining the benefits and costs of this regulation, FDA will use 850 as an estimate of the number of dietary supplement firms.

Because the notification procedure established by FDAMA is voluntary, the only dietary supplement firms likely to take advantage of this procedure will be those firms who anticipate that private benefits will exceed private costs. Consequently, FDA will not attempt to estimate the internal benefits and costs for individual dietary supplement firms. Those firms who anticipate that the benefits will exceed the costs will make health claims based on authoritative statements. The number of health claim notifications submitted can, therefore, measure the effects of the proposed rule. Since the notification procedures for statements on dietary supplements were established in October 1997, FDA has received more than 3,000 notifications of nutritional support statements (structure-function claims). FDA believes that dietary supplement firms will continue to rely mainly on structure-function rather than health claims. FDA expects the number of health claim notifications to be a small fraction of the number of nutritional support statement notifications. Based on FDA's experience with health claims and with other similar notification procedures that fall under its jurisdiction, FDA has estimated that 12 firms per year may submit an average of 5 health claim notifications each, for a total of 60 notifications. The agency specifically invites comments on this estimate.

In addition to the benefits and costs internal to dietary supplement firms, FDA expects this proposed rule to generate benefits and costs to society. Most of the benefits from this proposed rule will come from the increased availability of the information provided by health claims. FDA cannot quantify those benefits. To the extent that the

lack of these claims has caused consumers to seek out the information from other sources, this rule will benefit consumers by reducing the cost of searching for information and by ensuring that the information provided to consumers is appropriate. The proposed rule will also impose additional costs on FDA and on the scientific bodies of the U.S. Government whose authoritative statements form the basis for the claims. FDA is unable to quantify those costs at this time, however.

B. Small Entity Analysis

FDA has examined the economic implications of this proposed 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 finds that this proposed rule would have a significant economic impact on a substantial number of small businesses.

According to the Regulatory Flexibility Act, the definition of a small entity is a business independently owned and operated and not dominant in its field. The Small Business Administration (SBA) has set size standards for most business categories through use of four-digit Standard Industrial Classification (SIC) codes. Dietary supplements fall into several codes, including Food Preparations Not Elsewhere Classified (SIC 2099), Industrial Inorganic Chemicals Not Elsewhere Classified (SIC 2819), Medicinal Chemicals and Botanical Products (SIC 2833), Pharmaceutical Preparations (SIC 2834), and Industrial Organic Chemicals Not Elsewhere Classified (SIC 2869). According to SBA size standards, dietary supplement firms are small entities if they have fewer than 500 employees in SIC codes 2099 and 2899, fewer than 750 employees in SIC codes 2833 and 2834, and fewer than 1,000 employees in SIC codes 2819 and 2969. Based on these standards, FDA has previously estimated that approximately 95 percent of dietary supplement manufacturers could be considered small under SBA size standards (63 FR 23624 at 23631).

As discussed earlier, FDA estimates that about 12 firms per year will submit health claims notifications based on authoritative statements. Because most businesses in the dietary supplement industry would be classified as small under SBA standards, FDA assumes that many businesses potentially affected by this proposed rule will be small. FDA, therefore, concludes that the proposed rule will affect a substantial number of small entities. The proposed rule would, however, impose no involuntary costs and would benefit small businesses wishing to make health claims based on authoritative statements.

The Regulatory Flexibility Act requires agencies to examine regulatory alternatives that would minimize the impact on small entities. FDA believes that the proposed rule will impose no involuntary burdens on small entities. Other regulatory options were nevertheless considered, including taking no new regulatory action and waiting until the implementing regulation for section 303 of FDAMA to propose that health claims based on authoritative statements be permitted for dietary supplements. FDA rejected the option of taking no new regulatory action because it would make conventional foods and dietary supplements subject to different standards for health claims. As stated previously in this document, the agency expects to withdraw this rule, if finalized, when the implementing regulation for section 303 of FDAMA is issued.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

V. Effective Date

FDA is proposing that any final rule that may be issued based upon this proposal become effective upon publication in the **Federal Register**. Under section 553(e) of the Administrative Procedure Act (5 U.S.C. 553(e)) and FDA's procedural regulations at 21 CFR 10.40(c)(4)(i), the agency may make a final substantive rule effective immediately upon publication if the rule ''grants or recognizes an exemption or relieves a restriction.'' If it becomes final, this rule would not place an affirmative requirement on anyone but rather would relieve a restriction on the dietary supplement industry. As more fully discussed previously, FDAMA makes the streamlined notification procedures for health claims available only to the conventional food industry. The agency is proposing to relieve this restriction in FDAMA to make health claims based on authoritative statements also available for use by the dietary supplement industry.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Notification Procedures for Dietary Supplement Health Claims Based on Authoritative Statements.

Description: This proposed rule would permit producers of dietary supplements to market a product whose label or labeling bears a health claim based on authoritative statements of certain scientific bodies of the Federal Government or the National Academy of Sciences, or any of its subdivisions, using the same process and standard established for conventional foods by the provisions of section 403(r)(3)(C) of the act. Under this proposed rule, a dietary supplement producer may use such a health claim in the labeling of an appropriate product 120 days after a complete notification of the claim is submitted to FDA, unless: (1) The agency has issued an effective regulation that prohibits or modifies the claim, (2) the agency has issued a regulation finding that the requirements of proposed § 101.90(a) have not been met, or (3) a Federal District Court in an enforcement proceeding under chapter III of the act (21 U.S.C. 301–310) has determined that the requirements of proposed § 101.90(a) have not been met. This proposed rule would prescribe the type of information that a dietary supplement producer must include in a notification that it would submit to the agency.

As noted previously, FDA recently announced the availability of a guidance on the submission of a notification of a nutrient content claim or health claim based on an authoritative statement of a scientific body under the provisions of section 403(r)(2)(G) or (r)(3)(C) of the act. In estimating the annual reporting burden under this proposed rule, FDA has assumed that submitters of notifications will follow that guidance.

Description of Respondents: Persons and businesses, including small businesses.

TABLE 1.—Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Annual Hours
101.90	12	5	60	40	2,400

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

These estimates are based on FDA's experience with health claims and with other similar notification procedures that fall under its jurisdiction. Because the claims are based on authoritative statements of certain scientific bodies of the Federal Government or the National Academy of Sciences, or any of its subdivisions, FDA believes that the information submitted with a notification will be either provided as part of the authoritative statement or readily available to anyone wishing to submit a notification.

In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send written comments regarding information collection by February 22, 1999, to the Office of Information and Regulatory Affairs, OMB (address above), Attn: Desk Officer for FDA.

VII. Comments

Interested persons may, on or before April 6, 1999, 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.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Commission on Dietary Supplement Labels, ''Report of the Commission on Dietary Supplement Labels,'' p. vii, November 1997.

2. ''Guidance for Industry—Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body,'' FDA, DHHS, June 11, 1998.

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: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.90 is added to subpart F to read as follows:

§ 101.90 Notifications for health claims based on authoritative statements.

(a) A claim of the type described in § 101.14(a)(1) which is not authorized by the Food and Drug Administration (FDA) in a regulation found in this part shall be authorized and may be made with respect to a dietary supplement if:

(1) A scientific body of the U.S. Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(2) A person has submitted to FDA, at least 120 days (during which FDA may notify any person who is making a claim as authorized by paragraph (a) of this section that such person has not submitted all the information required by this paragraph) before the first introduction into interstate commerce of the dietary supplement with a label containing the claim:

(i) A notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of paragraph (a)(1) of this section have been satisfied;

(ii) A copy of the statement referred to in paragraph (a)(1) of this section upon which such person relied in making the claim; and

(iii) A balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

(3) The claim and the dietary supplement for which the claim is made are in compliance with § 101.14(a)(5) and (e)(3) and are otherwise in compliance with sections 403(a) and 201(n) of the act (21 U.S.C. 343(a) and 21 U.S.C. 321(n)); and

(4) The claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in paragraph (a)(1) of this section and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet. For purposes of this paragraph, a statement shall be regarded as an authoritative statement of a scientific body described in paragraph (a)(1) of this section only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(b) A claim submitted under the requirements of paragraph (a) of this section may be made until:

(1) Such time as FDA issues a regulation under the standard in § 101.14(c):

(i) Prohibiting or modifying the claim and the regulation has become effective; or

(ii) Finding that the requirements of paragraph (a) of this section have not

been met, including finding that the petitioner has not submitted all the information required by such clause; or

(2) A District Court of the United States in an enforcement proceeding under chapter III of the act (21 U.S.C. 301–310) has determined that the requirements of paragraph (a) of this section have not been met.

Dated: October 7, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 99–1365 Filed 1–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 98N–0970]

Medical Devices; Labeling for Menstrual Tampons; Ranges of Absorbency

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its menstrual tampon labeling regulation to provide an absorbency term for tampons that absorb 15 to 18 grams (g) of fluid. The purpose of this proposed rule is to enable consumers to compare the absorbency of one brand and style of tampons with the absorbency of other brands and styles. FDA is issuing this proposed rule under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Written comments on the proposed rule should be submitted by April 21, 1999. See section II of this document for the proposed effective date of a final rule based on this document. Written comments on the information collection requirements should be submitted by February 22, 1999.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document. Submit written comments regarding the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 26, 1989 (54 FR 43766), FDA published a final rule which, among other things, amended its menstrual tampon labeling regulation to standardize the existing absorbency terms (junior, regular, super, and super plus) corresponding to the following four absorbency ranges: Less than 6, 6 to 9, 9 to 12, and 12 to 15 g of fluid. The final rule did not include corresponding terms of absorbency for 15 to 18 g nor the range above 18 g of fluid. Tampon manufacturers have asserted that many women with heavy menstrual flow need higher absorbency tampons to manage their heavy menstrual flow (see 54 FR 43766 at 43769).

FDA has consulted with the Center for Disease Control on this proposed rule. Tampons with absorbency up to 18 g have been marketed in other countries with very low Toxic Shock Syndrome (TSS) rates. FDA believes that the proposed rule will not materially increase the risk of TSS for women using tampons in accordance with the labeling.

Tampons are currently classified into class II (special controls) (see 21 CFR 884.5460 and 884.5470). Any person who is required to register under section 510 of the act (21 U.S.C. 360) and part 807 (21 CFR part 807) and who intends to begin the introduction or delivery for introduction into interstate commerce of a tampon for commercial distribution is required to submit a premarket notification to FDA at least 90 days before making such introduction or delivery in accordance with section 510(k) of the act and subpart E of part 807. Under § 807.87(e), a premarket notification for a device is to contain, among other things, labeling for the device. Because there is no uniform labeling term for tampons that absorb 15 to 18 g of fluid, the agency is now proposing that tampons that absorb 15 to 18 g of fluid be labeled as'' ultra absorbency''. The agency is specifically seeking comment on the term ''ultra'' for this absorbency range, and it invites suggestions of any alternative terms. At this time, FDA is not proposing a term describing tampons with absorbency above 18 g of fluid, and does not anticipate that tampons in the above 18 g absorbency range will be considered for premarket clearance based on this proposed rule.

II. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after the date of publication of the final rule in the **Federal Register**.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) and (k) 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 impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because manufacturers already are required to identify the absorbency ranges of their tampons, establishing a standardized term for tampons that absorb 15 to 18 g of fluid will impose no significant economic impact on any small entities. The agency therefore certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities. The rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any 1 year.