Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget and determined that these rules do not meet the criteria for a significant regulatory action under Executive Order 12866.

Regulatory Flexibility Act

We certify that these rules will not have a significant economic impact on a substantial number of small entities since these rules affect only individuals. Therefore, a regulatory flexibility analysis as provided in Public Law 96–354, the Regulatory Flexibility Act, is not required.

Paperwork Reduction Act

These regulations will impose no additional reporting and recordkeeping requirements subject to Office of Management and Budget clearance.

(Catalog of Federal Domestic Assistance: Program No. 96.006–Supplemental Security Income)

List of Subjects in 20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and Recordkeeping Requirements, Supplemental Security Income (SSI).

Approved: September 6, 1996.

Shirley S. Chater,

Commissioner of Social Security.

For the reasons set out in the preamble, part 416, subpart K, of chapter III of title 20 of the Code of Federal Regulations is amended as follows:

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart K—[Amended]

1. The authority citation for subpart K of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1602, 1611, 1612, 1613, 1614(f), 1621, and 1631 of the Social Security Act (42 U.S.C. 902(a)(5), 1381a, 1382, 1382a, 1382b, 1382c(f), 1382j, and 1383); sec. 211, Pub. L. 93–66, 87 Stat. 154 (42 U.S.C. 1382 note).

2. Section 416.1124 is amended by removing the ''and'' at the end of paragraph (c)(17) and the period at the end of paragraph (c)(18), by adding ''; and'' at the end of paragraph (c)(18), by revising paragraphs (c)(7) and (c)(9) and adding new paragraph (c)(19) to read as follows:

§ 416.1124 Unearned income we do not count.

* * * * *

(c) * * *

(7) Alaska Longevity Bonus payments made to an individual who is a resident of Alaska and who, prior to October 1, 1985: met the 25-year residency requirement for receipt of such payments in effect prior to January 1, 1983; and was eligible for SSI;

* * * * *

(9) Any interest earned on excluded burial funds and any appreciation in the value of an excluded burial arrangement which are left to accumulate and become a part of the separate burial fund. (See § 416.1231 for an explanation of the exclusion of burial assets.) This exclusion from income applies to interest earned on burial funds or appreciation in the value of excluded burial arrangements which occur beginning November 1, 1982, or the date you first become eligible for SSI benefits, if later;

* * * * *

(19) Hostile fire pay received from one of the uniformed services pursuant to 37 U.S.C. 310.

3. Section 416.1161 is amended by removing the ''and'' at the end of paragraph (a)(21), and removing the period at the end of paragraph (a)(22) and adding a semi-colon in its place, and by revising paragraph (a)(12) and adding new paragraphs (a)(23), (a)(24) and (a)(25) to read as follows:

§ 416.1161 Income of an ineligible spouse, ineligible parent, and essential person for deeming purposes.

* * * * *

(a) * * *

(12) Alaska Longevity Bonus payments made to an individual who is a resident of Alaska and who, prior to October 1, 1985: met the 25-year residency requirement for receipt of such payments in effect prior to January 1, 1983; and was eligible for SSI;

* * * * *

(23) Hostile fire pay received from one of the uniformed services pursuant to 37 U.S.C. 310;

(24) Impairment-related work expenses, as described in 20 CFR 404.1576, incurred and paid by an ineligible spouse or parent, if the ineligible spouse or parent receives disability benefits under title II of the Act; and

(25) Interest earned on excluded burial funds and appreciation in the value of excluded burial arrangements which are left to accumulate and become part of separate burial funds, and interest accrued on and left to accumulate as part of the value of agreements representing the purchase of excluded burial spaces (see § 416.1124(c) (9) and (15)).

[FR Doc. 96–24277 Filed 9–23–96; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 93N–0481]

RIN 0910–AA23

Food Labeling: Health Claims and Label Statements; Folate and Neural Tube Defects; Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking the regulation authorizing a health claim on the relationship between folic acid and neural tube defects on the labels and in the labeling of dietary supplements that became final by operation of law. The agency has replaced this revoked regulation with one that it adopted in a final rule that published in the Federal Register of March 5, 1996 (61 FR 8752).

EFFECTIVE DATE: October 8, 1996.

FOR FURTHER INFORMATION CONTACT: Jeanne I. Rader, Center for Food Safety and Applied Nutrition (HFS–175), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5375.

SUPPLEMENTARY INFORMATION:

I. Background

The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535) amended the Federal Food, Drug, and Cosmetic Act (the act) to give the Secretary of the Department of Health and Human Services (the Secretary), and by delegation FDA, the authority to issue regulations authorizing health claims on the labels and in the labeling of foods. Section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B)) provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with procedures and standards established under section 403(r)(3) and (r)(5)(D) of the act.

The 1990 amendments also directed the Secretary to determine through rulemaking whether claims regarding 10 nutrient-disease relationships met the

requirements of the act. The relationship of folic acid and neural tube defects was among those 10 topics (section 3(b)(1)(A)(x) of the 1990 amendments).

A. The 1991 Proposed Rule

In the Federal Register of November 27, 1991 (56 FR 60537), FDA proposed to not authorize a health claim on folic acid and neural tube defects. The agency tentatively concluded that there was not significant scientific agreement, based on the totality of publicly available scientific evidence, that such a claim would be valid. Thus, the standard that the act established for health claims for conventional foods, which FDA had proposed, under section 403(r)(5)(D), as the standard for health claims for dietary supplements, had not been met.

B. The Public Health Service Recommendation

In September 1992, following the availability of significant new data, the Public Health Service (PHS) issued a recommendation that all women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 milligram (mg) of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other neural tube defects. The recommendation was based on data suggesting that folic acid, when given at a high dose (4 mg), can reduce the risk of recurrence of neural tube defects and on studies that used multivitamins containing folic acid at dose levels from 0 to 1,000 micrograms per day. The PHS recommendation identified approaches and identified outstanding issues, including the recommended intake of folate, the potential role of other nutrients in reducing the risk of neural tube defects, safety concerns, and the ''folate-preventable'' fraction of neural tube defects.

C. The Dietary Supplement Act of 1992

In October 1992, the Dietary Supplement Act of 1992 (the DS act) was enacted. This statute imposed a moratorium on FDA's implementation of the 1990 amendments with respect to dietary supplements until December 15, 1993. The DS act directed FDA to issue proposed rules to implement the 1990 amendments with respect to dietary supplements by June 15, 1993, and to issue final rules based on these proposals by December 31, 1993. The DS act also amended the so-called ''hammer'' provision of the 1990 amendments, section 3(b)(2) of the 1990 amendments, to provide that if the agency did not meet the established December 31, 1993, timeframe for issuance of final rules, the proposed regulations would be considered final regulations.

D. The 1993 Final Rules for Health Claims for Food in Conventional Food Form

In the Federal Register of January 6, 1993 (58 FR 2606), FDA published a final rule in which it decided not to authorize a health claim for folic acid and neural tube defects. However, the agency reaffirmed its support of the PHS recommendation that all women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid daily to reduce their risk of having a pregnancy affected with spina bifida or other neural tube defects. The agency noted, however, that unresolved questions about the safe use of folate remained. The agency concluded that it could not authorize a health claim until these questions were resolved. Because of the DS act, FDA took no final action with respect to the use of a health claim on folic acid and neural tube defects on dietary supplements.

E. The 1993 Proposal to Authorize a Health Claim on Folic Acid and Neural Tube Defects

In the Federal Register of October 14, 1993 (58 FR 53254), FDA published a proposed rule to authorize the use of a health claim about the relationship of folate and neural tube defects on the labels of foods in conventional food form and dietary supplements. FDA tentatively concluded, based on its discussions with an advisory committee, that it could ensure the safe use of folate. FDA provided 60 days for comment on this proposed action. The comment period closed on December 13, 1993.

F. The 1994 Final Rule

Section 3(b)(2) of the 1990 amendments, as amended by section 202(a)(2)(B)(ii) of the DS act, provides that if the Secretary does not issue final regulations on any of the health claims applicable to dietary supplements in a timely manner, the proposed regulations shall be considered final regulations but not until December 31, 1993. Because FDA was unable to publish a final rule by December 31, 1993, in the proceeding instituted in October of 1993, FDA published a document in the Federal Register of January 4, 1994 (59 FR 433), announcing that the regulation that it had proposed in October 1993 on folate and neural tube defects was considered to be a final regulation for dietary supplements by operation of law, effective July 1, 1994.

This document did not conclude the rulemaking begun in October of 1993, however. Rather, the January 4, 1994, document was part of a separate proceeding that is compelled under section 3(b)(2) of the 1990 amendments (see H. Rept. 101–538, 101st Cong., 2d Sess. 18 and 136 Congressional Record 5842 on the effect of this ''hammer'' provision).

In the January 4, 1994, document FDA stated that the rulemaking that it instituted in October of 1993 was ongoing, and that it intended to issue a final rule that would resolve the issues in that ongoing proceeding. FDA issued that final rule on March 5, 1996 (61 FR 8752).

In the Federal Register of March 5, 1996 (61 FR 8750), FDA proposed to withdraw the regulation that became final by operation of law on January 4, 1994 (the January 4, 1994, regulation). FDA tentatively found that this action is in the best interests of consumers, manufacturers, and regulatory officials for several reasons.

The agency stated that the January 4, 1994, regulation did not have the benefit of public comment, and that it reflects FDA's initial views on the folic acid/neural tube defects health claim and what it should say. FDA tentatively found from the comments received in response to the folic acid/neural tube defects health claim proposal that the January 4, 1994, regulation did not adequately address several issues related to this health claim. Because the regulation included in the final rule published in the March 5, 1996, issue of the Federal Register addressed the comments that the agency received and included changes that the agency made in response to those comments, FDA tentatively found that the March 5, 1996, regulation is better able to implement the act than the January 4, 1994, regulation, and that it provides for a more useable and scientifically valid health claim.

FDA tentatively found that replacing the January 4, 1994, regulation with the regulation included in the final rule would not result in any hardship to manufacturers who have relied on the January 4, 1994, regulation. The regulation in the March 5, 1996, final rule in most respects was consistent with the January 4, 1994, regulation. The only differences were those modifications that the agency made to shorten the claim and to provide more flexibility to those who decide to use it on their labels or in their labeling.

FDA gave interested persons 30 days to comment on its proposal to withdraw

the January 4, 1994, regulation. It also proposed to make any final rule that issued in this proceeding effective on the date of its publication. FDA received one comment that addressed this proposed action. This comment fully supported the agency's proposal.

II. Environmental Impact

In the March 5, 1996 (61 FR 8750 at 8751), proposal FDA stated that it had determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. FDA received no comments on this conclusion. Therefore, FDA restates it in this document.

III. Analysis of Other Impacts

In the March 5, 1996 (61 FR 8750 at 8751), proposal FDA announced that it had fully assessed the effects of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354) and found that it was fully consistent with the Executive Order, and that it will not have a significant impact on a substantial number of small entities. The agency received no comments on these conclusions and consequently is restating them in this document.

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, § 101.79 *Health claims; folate and neural tube defects* (as published in the Federal Register of January 4, 1994 (59 FR 434), which became final by operation of law, is removed. FDA has replaced the January 4, 1994, regulation with a regulation that appeared in the Federal Register of March 5, 1996 (61 FR 8779), and is currently codified in the 1996 edition of Title 21 of the Code of Federal Regulations (pp. 131–134).

This document is issued under sections 4, 5, and 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, and 1455); and sections 201, 301, 402, 403, 409, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C, 321, 331, 342, 343, 348, and 371).

Dated: September 17, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–24223 Filed 9–23–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

22 CFR Part 33

[Public Notice 2425]

Fishermen's Protective Act Guaranty Fund Procedures

AGENCY: Department of State.

ACTION: Direct final rule.

SUMMARY: The Department of State issues this direct final rule to revise the administration of the Fishermen's Guaranty Fund under section 7 of the Fishermen's Protective Act of 1967, as amended (the Act). These revisions are made in partial fulfillment of the Department's commitment that certain regulations would be modified or eliminated as part of the President's Regulatory Reinvention Initiative. The revisions are also need to reflect the recent reauthorization of the Fishermen's Guaranty Fund, as well as amendments related to fees charged for participation the Guaranty Fund, and to reflect changes in the criteria for claims to be eligible for compensation under the Act.

This revision provides a single set of guidelines for compensation.

EFFECTIVE DATE: This action is effective January 23, 1997, unless notice is received on or before November 25, 1996 that adverse or critical comments will be submitted. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Send comments to Bureau of Oceans and International Environmental and Scientific Affairs, Office of Marine Conservation, Room 7820, U.S. Department of State, Washington, DC 20520–7818.

FOR FURTHER INFORMATION CONTACT: Stetson Tinkham, Office of Marine Conservation, (202) 647–3941.

SUPPLEMENTARY INFORMATION: Section 7 of the Act established the Guaranty Fund, and Section 408 of Public Law 99–659, November 14, 1986, transferred the administration of the Fund from the Department of Commerce to the Department of State, effective October 1, 1986. The Fishermen's Guaranty Fund regulations formerly appeared as Department of Commerce regulations at 50 CFR Part 258.

The Guaranty Fund compensates U.S. fishing vessel owners who have entered into guaranty agreements for certain losses caused by the seizure and detention of their vessels by foreign countries. Losses covered by the Guaranty Fund include: confiscation, spoilage, damage, lost fishing time, and other incidental costs. Fees for these agreements historically have paid about 60 percent of claims; about 40 percent of claims have been paid from direct appropriations. To implement this rule, the Department of State does not intend to seek annual direct appropriations, but will operate the Fund based on fees collected from participants and on funds which remain available from prior year balances. A separate fee notice will be published for each fiscal year. This direct final rule clarifies the procedure for submission of claims, the processing of guaranty agreement applications, and the computations involved in adjudicating those claims.

The Secretary of State also administers a separate program, the Fishermen's Protective Fund, under Section 3 of the Act. Under the Fishermen's Protective Fund, vessel owners may apply for reimbursement of fines, license fees, registration fees, or any other direct charge imposed by a foreign country to secure the release of a seized vessel. Claims under the Protective Fund are paid from direct appropriations.

The publication of this Department of State direct final rule was delayed pending reauthorization of the Fishermen's Guaranty Fund program. Title IV of Public Law 104–43 amended and reauthorized the program on November 3, 1995. Other legislative changes, such as the change in the U.S. position on the international law respecting highly migratory species, effective upon the President's signing of Public Law 101–627, and other measures in Public Law 104–43 dealing with high seas fishing have been taken into account in this direct final rule.

The method of computing compensation of lost fishing time is standardized. Depreciated replacement cost is made the standard compensation basis for capital equipment other than vessels. The standard compensation basis for vessels remains market value.

This rule will be open for public comment for a period of sixty (60) days following publication. Unless adverse comment is received within that period, the rule will become final thirty days after the publication of a separate ''confirmation notice'' at the close of the comment period. That confirmation notice will be accompanied by a notice establishing the fee for participation in the Fishermen's Guaranty Fund for FY 1997.

This action is not subject to Executive Order 12866 but has been reviewed to ensure consistency with the overall policies and purposes of that order. The action creates no unfunded mandates on State, local, and tribal governments, or on the private sector, nor does it require