

(d) * * *

(2) The claim may indicate that development of cancer depends on many factors and identify one or more of the following as risk factors for the disease: Family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(3) The claim may characterize fruits and vegetables that meet the requirements described in paragraph (c)(2)(ii) of this section as foods that are low in fat and that contain (or are a good source of) one or more of vitamin A, vitamin C, or dietary fiber.

* * * * *

(e) * * *

(1) Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A and vitamin C), may reduce the risk of some types of cancer.

(2) A diet low in fat and high in certain fruits and vegetables, foods that are low in fat and that may contain vitamin A and vitamin C, may reduce your risk of some cancer.

Dated: December 13, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-31008 Filed 12-20-95; 8:45 am]

BILLING CODE 4160-01-F

Food and Drug Administration

21 CFR Part 888

[Docket No. 95N-0176]

Orthopedic Devices: Classification, Reclassification, and Codification of Pedicle Screw Spinal Systems; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting certain statements in the preamble to a proposed rule that appeared in the Federal Register of October 4, 1995 (60 FR 51946). The document proposed to classify certain unclassified preamendments pedicle screw spinal systems into class II (special controls), and to reclassify certain postamendments pedicle screw spinal systems from class III (premarket approval) to class II. The document states further that FDA is issuing for public comment the recommendations of the Orthopedic and Rehabilitation Devices Panel (the Panel) concerning

the classification/reclassification of pedicle screw spinal systems, and the agency's tentative findings on the Panel's recommendations. The document is being corrected to reflect an accurate description of the formation, membership, and activities of the Spinal Implant Manufacturers Group (SIMG), and the Scientific Committee, two separate entities established by the spinal implant manufacturers and medical professional societies to collect and submit to FDA all available valid scientific data on the performance of pedicle screw spinal devices.

FOR FURTHER INFORMATION CONTACT: Mark N. Melkerson, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2036.

In the FR Doc. 95-24686, appearing on page 51946 in the Federal Register of Wednesday, October 4, 1995, the following corrections are made:

1. On page 51947, in the second column, in the fourth paragraph, beginning in line 7, the second, third, and fourth sentences are removed and the following text is added in their place to read as follows:

In response, two groups were founded: The Spinal Implant Manufacturers Group (SIMG), and the Scientific Committee. SIMG, founded by 16 medical device manufacturers, agreed to provide the funding that would be required to conduct a nationwide study of pedicle screw devices. The Scientific Committee was formed by five professional medical societies, including the North American Spine Society, the American Academy of Orthopedic Surgeons, the Scoliosis Research Society, the Congress of Neurosurgeons, and the American Association of Neurological Surgeons. The Scientific Committee was formed to develop and implement a uniform research protocol to gather clinical experience from the use of the device. The Scientific Committee consisted of four surgeons and two nonvoting SIMG representatives, a biostatistician, and a clinical/regulatory affairs professional.

2. On page 51947, in the third column, in the first paragraph, beginning in the fifteenth line, the fourth and fifth sentences are removed and the following text is added in their place to read as follows:

At this meeting, the Scientific Committee presented clinical data from its nationwide "Historical Cohort Study of Pedicle Screw Fixation in Thoracic, Lumbar, and Sacral Spinal Fusions" (Cohort Study). FDA presented a comprehensive review of the medical

literature, an analysis of the medical literature, an analysis of the Cohort study conducted by the Scientific Committee, and a summary of the clinical data that had been released by IDE sponsors.

3. On page 51950, in the first column, in the fourth paragraph, in the first line, the abbreviation "SIMG" is corrected to read "Scientific Committee".

Dated: December 8, 1995.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 95-31047 Filed 12-20-95; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[INTL-52-86]

RIN 1545-AL99

Statements to Recipients of Dividends and Patronage Dividends

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Partial withdrawal of a notice of proposed rulemaking.

SUMMARY: This document withdraws a portion of the notice of proposed rulemaking under sections 6042 and 6044 of the Internal Revenue Code that was published in the Federal Register on February 29, 1988, as proposed to be amended on September 27, 1990. The proposed regulations prescribed rules for official statements to recipients of dividends and patronage dividends paid after December 31, 1983.

DATES: This withdrawal is effective on December 21, 1995.

FOR FURTHER INFORMATION CONTACT: Renay France, (202)622-4910 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On February 29, 1988, the IRS issued proposed regulations on backup withholding (INTL-52-86, 53 FR 5991). The proposed regulations related, in part, to official statements to recipients of dividends and patronage dividends under sections 6042 and 6044, respectively (proposed §§ 1.6042-5 and 1.6044-6). On September 27, 1990, the IRS issued additional proposed regulations on backup withholding (IA-224-82, 55 FR 39427). Those proposed

regulations contained amendments to the regulations previously proposed under sections 6042 and 6044.

In the Rules and Regulations section of this issue of the Federal Register, the IRS is issuing final regulations relating to backup withholding that were proposed in INTL-52-86 and IA- 224-82. Those final regulations do not include proposed §§ 1.6042-5 and 1.6044-6. Further, when the IRS issues additional final regulations that were proposed under INTL-52-86, those additional final regulations will not include proposed §§ 1.6042- 5 and 1.6044-6. Accordingly, this document withdraws those proposed regulations sections. See §§ 1.6042-4 and 1.6044-5 of the final regulations for substantive rules proposed under the withdrawn sections.

List of Subjects 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Withdrawal of Portion of Notice of Proposed Rulemaking

Accordingly, under the authority of 26 U.S.C. 7805, proposed §§ 1.6042-5 and 1.6044-6 that were published in the Federal Register on February 29, 1988 (53 FR 5991) and amended in the Federal Register on September 27, 1990 (55 FR 39427) are withdrawn.

Margaret Milner Richardson,
Commissioner of Internal Revenue
[FR Doc. 95-30735 Filed 12-20-95; 8:45 am]
BILLING CODE 4830-01-U

26 CFR Part 1

[EE-53-95]

RIN 1545-AT95

Requirements for Tax Exempt Section 501(c)(5) Organizations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: This document contains proposed regulations clarifying certain requirements of section 501(c)(5). The requirements are being clarified to provide needed guidance to organizations as to the requirements an organization must meet in order to be exempt from tax as an organization described in section 501(c)(5).

DATES: Written comments and requests for a public hearing must be received by March 20, 1996.

ADDRESSES: Send submissions to: CC:DOM:CORP:T:R (EE-53-95), room 5228, Internal Revenue Service, POB

7604, Ben Franklin Station, Washington, DC 20044. In the alternative, submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:T:R (EE-53-95), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Robin Ehrenberg, (202) 622-6080 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This notice of proposed rulemaking clarifies the scope of the exemption provided in section 501(c)(5) of the Internal Revenue Code for labor, agricultural and horticultural organizations.

An income tax exemption for labor organizations was first provided in the Corporation Excise Tax Act of 1909, Public Law No. 61-5, 36 Stat. 11, 112-118, and has been in effect continuously since that time. A labor organization is an entity that is organized "to protect and promote the interests of labor." *Portland Cooperative Labor Temple Association v. Commissioner*, 39 B.T.A. 450 (1939), acq., 1939-1 C.B. 28. The principal purpose of the organization must be to better the working conditions of people engaged in a common pursuit. See, Treas. Reg. § 1.501(c)(5)-1. Organizations meeting this requirement have traditionally engaged in collective action directed toward the workers' common objective of improving working conditions. They include labor unions that negotiate with employers on behalf of workers for improved wages, fringe benefits, hours and similar working conditions, and certain union-controlled organizations, like strike funds, that provide benefits to workers that enhance the union's ability to bargain effectively. See Rev. Rul. 67-7 (1967-1 C.B. 137). They do not include strike funds that provide income to union members but are not controlled by unions. See Rev. Rul. 76-420 (1976-2 C.B. 153). Such an organization will not pay the strike benefits "with the objective of bettering conditions of employment, but by reason of its contractual agreements with the workers."

Labor organizations may also meet the requirements of section 501(c)(5) by providing benefits that directly improve working conditions or compensate for unpredictable hazards that interrupt work. Examples of such benefits include operating a dispatch hall to match union members with work assignments and providing industry stewards who represent employees with grievances

against management. See Rev. Rul. 75-473 (1975-2 C.B. 213); Rev. Rul. 77-5 (1977-1 C.B. 148). On the other hand, managing saving and investment plans for workers, including retirement plans, does not bear directly on working conditions. See Rev. Rul. 77-46 (1977-1 C.B. 147). Accordingly, section 501(c)(5) has not been applied to organizations that manage retirement savings plans as their principal activity.

Nevertheless, in *Morganbesser v. United States*, 984 F.2d 560 (2d Cir. 1993), the court held that a trust managing a pension benefit plan pursuant to a collective bargaining agreement qualified as a labor organization described in section 501(c)(5). The IRS and the Treasury Department believe that this decision is contrary to existing law, and the IRS is issuing an action on decision reflecting its view that the *Morganbesser* court erred in its holding. These proposed regulations are a clarification of the existing legal standard.

Like labor organizations, agricultural and horticultural organizations must also better the conditions of those engaged in a common pursuit in order to be described in section 501(c)(5). See § 1.501(c)(5)-1. There is no authority indicating that the law is to be interpreted differently for agricultural and horticultural organizations than for labor organizations. Accordingly, the proposed regulations clarify the law as it applies to all section 501(c)(5) organizations.

Certain organizations have taken the position in refund actions that they are labor organizations described in section 501(c)(5) even though their principal activity was to manage retirement savings plans for workers. In addition, some such foreign organizations have claimed exemption from withholding on dividend, interest and similar income that they have earned. The IRS will continue to oppose these claims for refund and exemption from withholding.

A health plan is not a retirement savings plan. Thus, the IRS will continue to follow Rev. Rul. 62-17 (1962-1 C.B. 87) (regarding a labor organization providing health benefits) even in circumstances where a majority of the organization's members are retired. Furthermore, the IRS will continue to recognize that negotiating the terms of a retirement plan and other postretirement benefits and designating one or more representatives to the board of a multiemployer pension trust are proper activities for a labor organization. The proposed regulations are not intended to apply to or affect