

(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.

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(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]

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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