

of such tissue), the recipient of the written order or prior possessor of such tissue shall request a hearing on the matter in accordance with part 16 of this chapter. The order for destruction will be held in abeyance pending resolution of the hearing request.

Dated: July 7, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 97-19819 Filed 7-28-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 211

[Docket No. 88N-0320]

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls; Partial Extension of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial extension of compliance date.

SUMMARY: The Food and Drug Administration (FDA) is announcing a continuation of the partial extension of the compliance date for a provision of the final rule, published in the **Federal Register** of August 3, 1993 (58 FR 41348), revising the packaging and labeling control provisions of the current good manufacturing practice (CGMP) regulations for the use of cut labeling. FDA is extending the date for compliance with a specific provision, as it applies to labeling other than immediate container labels, until the effective date of the regulation finalizing the proposed rule on this subject published elsewhere in this issue of the **Federal Register**.

DATES: The date for compliance with the cut labeling provision at § 211.122(g) (21 CFR 211.122(g)), as it applies to labeling other than immediate container labels, is extended until the effective date of the regulation finalizing the proposed rule on this subject published elsewhere in this issue of the **Federal Register**. The date for compliance with all other provisions of the August 3, 1993, final rule remains August 3, 1994.

FOR FURTHER INFORMATION CONTACT:

Thomas C. Kuchenberg, Center for Drug Evaluation and Research

(HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5621 (Internet electronic mail: kuchenbergt@cder.fda.gov), or Paul J. Motise, Center for Drug Evaluation and Research (HFD-325), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1089 (Internet electronic mail: motise@cder.fda.gov).

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 3, 1993 (58 FR 41348), FDA published a final rule amending the current good manufacturing practice (CGMP) regulations to require that special control procedures be instituted if cut labeling is used in packaging and labeling operations. One of these procedures requires the use of "appropriate electronic or electromechanical equipment to conduct a 100-percent examination for correct labeling during or after completion of finishing operations" (§ 211.122(g)(2)). The rule applied to all types of labeling, including product inserts, multiunit containers packaged in individual containers, and shipping containers.

In May 1994, FDA received two citizen petitions from several trade associations requesting that the agency extend the effective date of the rule and reopen the administrative record to receive additional comments on the application of § 211.122(g) to items of labeling other than the immediate container label. The petitions stated that additional time was needed to obtain, install, or validate equipment necessary to comply with the rule. The citizen petitions also asserted that the final rule inappropriately expanded the scope of § 211.122(g) from immediate container labels to all drug product labeling.

In the **Federal Register** of August 2, 1994 (59 FR 39255), FDA extended the compliance date for § 211.122(g) as it applies to labeling other than immediate container labels, and opened the administrative record through October 4, 1994, for comments on the scope of § 211.122(g). All other provisions of the final rule became effective on August 3, 1994. FDA further extended the compliance date to August 2, 1996, in the **Federal Register** of April 28, 1995 (60 FR 20897), and to August 1, 1997, in the **Federal Register** of July 19, 1996 (61 FR 37679).

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule that would limit the scope of § 211.122(g) to immediate container labels, individual unit cartons, or

multiunit cartons when immediate containers are not packaged in individual cartons. The proposed rule would also permit the use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment.

In this final rule, FDA is extending the date for compliance with § 211.122(g), as it applies to labeling other than immediate container labels, until the effective date of the regulation finalizing the proposed rule on this subject published elsewhere in this issue of the **Federal Register**. The date for compliance with all other provisions of the August 3, 1993, final rule remains August 3, 1994.

Dated: July 22, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-19818 Filed 7-28-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8726]

RIN 1545-AT95

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

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

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

DATES: These regulations are effective on December 21, 1995.

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

SUPPLEMENTARY INFORMATION:

Background

On December 21, 1995, the IRS published in the **Federal Register** (60 FR 66228) a notice of proposed rulemaking under section 501(c)(5). The proposed regulations clarified that organizations whose principal activity is administering retirement plans are not section 501(c)(5) organizations.

A public hearing was held on June 5, 1996. Written comments were received. After consideration of all of the comments, the proposed regulations under section 501(c)(5) are adopted as revised by this Treasury Decision. The comments and revisions are discussed below.

Explanation of Revisions and Summary of Comments

Section 501(c)(5) describes certain labor, agricultural and horticultural organizations. Section 401(a) sets forth the requirements for exemption for qualified employee benefit pension trusts. Section 501(a) exempts from federal income taxes organizations described in section 401(a) or section 501(c). Thus, section 401(a) and section 501(c)(5) should be read as enactments of Congress *in pari materia*, taken together as one consistent body of law. *Pacific Co. v. Johnson*, 285 U.S. 480, 495 (1932).

The Treasury and IRS believe that section 501(c)(5) should be interpreted in a manner consistent with the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (1974) (ERISA), as amended. ERISA was enacted as a "comprehensive and reticulated statute" to regulate retirement plans and trusts, "the product of a decade of Congressional study of the Nation's private employee benefit system." *Mertens versus Hewitt Assoc.*, 508 U.S. 248, 251 (1993), citing *Nachman versus PBGC*, 46 U.S. 359, 361 (1980). Congress intended that pension trusts satisfy the comprehensive requirements of section 401(a), as amended by ERISA, in order to be tax exempt. See S. Rep. No. 383, 93d Cong., 1st Sess. at 33, reprinted in 1974-3 C.B. (Supp.) 112; H. Rep. No. 807, 93d Cong., 1st Sess. at 33, reprinted in 1974-3 C.B. (Supp.) 236, 266.

Accordingly, Treasury and the IRS continue to believe that an organization whose principal purpose is managing employer-sponsored retirement plans is not an exempt labor organization described in section 501(c)(5). (However, an employer-sponsored pension trust may nevertheless qualify for exemption under section 501(a) if it meets the requirements of section 401(a).) *Morganbesser versus United States*, 984 F.2d 560 (2d Cir. 1993), nonacq. 1995-2 C.B. 2.; In re *Morganbesser*, AOD CC-1995-016 (Dec. 26, 1995).

Consistent with ERISA and interpreting section 401(a) and section 501(c)(5) as part of a consistent whole, these regulations provide a general rule that an organization is not described in section 501(c)(5) if its principal activity

is to receive, hold, invest, disburse or otherwise manage funds associated with savings or investment plans or programs, including pension or other retirement savings plans or programs. However, to the extent that ERISA provides special rules for certain types of retirement savings plans, it is appropriate to take those rules into account in interpreting provisions of the Code relating to such plans, including section 501(c)(5).

As noted by one commentator, ERISA excepts certain dues-financed plans from Parts 2 and 3 of Title I of ERISA (vesting, funding and certain other qualification requirements). Those pension trusts sponsored by labor organizations for their members, which accept no employer contributions, do not qualify for exemption under section 401(a) because they are not maintained by an employer. Section 401(a), Rev. Rul. 80-306, 1980-2 C.B. 131. Accordingly, the regulations provide that an organization (including a pension trust) may qualify as an organization described in section 501(c)(5) if it meets all of the following requirements:

(1) The organization is established and maintained by another labor organization described in section 501(c)(5) (determined without reference to the tests in Treas. Reg. § 1.501(c)(5)-1(b)(2));

(2) The organization is not directly or indirectly established or maintained in whole or in part by any employer or by any government (or any agency, instrumentality or controlled entity thereof);

(3) The organization is funded by membership dues paid to the labor organization establishing and maintaining the organization and earnings thereon; and

(4) After September 2, 1974 (the date of enactment of ERISA, 88 Stat. 829), the organization's governing documents have not permitted or provided for nor did the organization accept, any contribution from any employer or from any government (or any agency, instrumentality or controlled entity thereof). Treas. Reg. § 1.501(c)(5)-1(b)(2).

Treas. Reg. § 1.892-2T(c) governs the tax status of a pension trust that is wholly owned and controlled by a foreign sovereign.

Scope

These regulations solely address the tax exempt status of organizations under section 501(c)(5) whose principal activity is to receive, hold, invest, disburse, or otherwise manage funds associated with savings or investment

plans or programs. Other Code sections and tax principles apply to the tax exempt status of these organizations and the tax consequences of these arrangements to employers and participants in these arrangements.

One commentator requested that the IRS clarify that the regulations do not apply to health and welfare benefits not specifically mentioned in the regulations, such as retiree health benefits, death benefits, and group legal services. The regulations address only savings or investment plans or programs, (including pension or other retirement savings plans or programs) and do not address other types of benefits. *Cf.* Rev. Rul. 62-17, 962-1 C.B. 87.

Special Analyses

It has been determined that this Treasury Decision is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the notice of proposed rulemaking preceding the regulations was issued prior to March 29, 1996, the Regulatory Flexibility Act, (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Robin Ehrenberg, Office of Associate Chief Counsel (Employee Benefits and Exempt Organizations). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.501(c)(5)-1 is amended by:

1. Redesignating paragraph (b) as paragraph (c).

2. Adding a new paragraph (b).
The addition reads as follows:

§ 1.501(c)(5)-1 Labor, agricultural, and horticultural organizations.

* * * * *

(b)(1) *General rule.* An organization is not an organization described in section 501(c)(5) if the principal activity of the organization is to receive, hold, invest, disburse or otherwise manage funds associated with savings or investment plans or programs, including pension or other retirement savings plans or programs.

(2) *Exception.* Paragraph (b)(1) of this section shall not apply to an organization which—

(i) Is established and maintained by another labor organization described in section 501(c)(5) (determined without regard to this paragraph (b)(2));

(ii) Is not directly or indirectly established or maintained in whole or in part by one or more—

(A) Employers;

(B) Governments or agencies or instrumentalities thereof; or

(C) Government controlled entities;

(iii) Is funded by membership dues from members of the labor organization described in this paragraph (b)(2) and earnings thereon; and

(iv) Has not at any time after September 2, 1974 (the date of enactment of the Employee Retirement Income Security Act of 1974, Pub. L. 93-406, 88 Stat. 829) provided for, permitted or accepted employer contributions.

(3) *Example.* The principles of this paragraph (b) are illustrated by the following example:

Example. Trust A is organized in accordance with a collective bargaining agreement between labor union K and multiple employers. Trust A forms part of a plan that is established and maintained pursuant to the agreement and which covers employees of the signatory employers who are members of K. Representatives of both the employers and K serve as trustees. A receives contributions from the employers who are subject to the agreement. Retirement benefits paid to K's members as specified in the agreement are funded exclusively by the employers' contributions and accumulated earnings. A also provides information to

union members about their retirement benefits and assists them with administrative tasks associated with the benefits. Most of A's activities are devoted to these functions. From time to time, A also participates in the renegotiation of the collective bargaining agreement. A's principal activity is to receive, hold, invest, disburse, or otherwise manage funds associated with a retirement savings plan. In addition, A does not satisfy all the requirements of the exception described in paragraph (b)(2) of this section. (For example, A accepts contributions from employers.) Therefore, A is not a labor organization described in section 501(c)(5).

* * * * *

Michael P. Dolan,

Acting Commissioner of Internal Revenue.

Approved: July 8, 1997.

Donald C. Lubick,

Acting Assistant Secretary of the Treasury.

[FR Doc. 97-19814 Filed 7-28-97; 8:45 am]

BILLING CODE 4830-01-U

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (Admiralty) of the Navy has determined that USS PEARL HARBOR (LSD 52) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval vessel. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: June 26, 1997.

FOR FURTHER INFORMATION CONTACT:

Captain R. R. Pixa, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, Virginia,

22332-2400, Telephone Number: (703) 325-9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR part 706. This amendment provides notice that the Deputy Assistant Judge Advocate General (Admiralty) of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS PEARL HARBOR (LSD 52) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS: Annex I, section 3(a), pertaining to the horizontal distance between the forward and after masthead lights, without interfering with its special function as a naval vessel. The Deputy Assistant Judge Advocate General (Admiralty) of the Navy has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), and Vessels.

Accordingly, 32 CFR Part 706 is amended as follows:

PART 706—[AMENDED]

1. The authority citation for 32 CFR Part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

2. Table Five of § 706.2 is amended by adding, in numerical order, the following entry for the USS PEARL HARBOR:

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

* * * * *