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]

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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]

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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.