

has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required. We invite comments on the federalism implications of this proposed rule.

### VIII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. This comment period runs concurrently with the comment period for the direct final rule; any comments received will be considered as comments regarding the direct final rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### List of Subjects in 21 CFR Part 210

Drugs, Packaging and containers. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs it is proposed that 21 CFR part 210 be amended as follows:

### PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

1. The authority citation for 21 CFR part 210 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

2. Section 210.2 is revised by adding paragraph (c) to read as follows:

#### § 210.2 Applicability of current good manufacturing practice regulations.

\* \* \* \* \*

(c) An investigational drug for use in a Phase 1 study, as defined in § 312.21(a) of this chapter, is subject to the statutory requirements set forth at 21 U.S.C. 351(a)(2)(B). The production of such drug is exempt from compliance with the regulations in part 211 of this chapter. However, this exemption does

not apply to an investigational drug for use in a Phase 1 study once the investigational drug has been made available for use by or for the sponsor in a Phase 2 or Phase 3 study, as defined in § 312.21(b) and (c) of this chapter, or the drug has been lawfully marketed. If the investigational drug has been made available in a Phase 2 or 3 study or the drug has been lawfully marketed, the drug for use in the Phase 1 study must comply with part 211 of this chapter.

Dated: January 9, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 06–350 Filed 1–12–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[REG–158080–04]

RIN–1545–BE79

#### Application of Section 409A to Nonqualified Deferred Compensation Plans; Correction

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Correction to notice of proposed rulemaking.

**SUMMARY:** This document corrects a notice of proposed rulemaking that was published in the **Federal Register** on Tuesday, October 4, 2005 (70 FR 57930), regarding the application of section 409A to nonqualified deferred compensation plans. The regulations affect service providers receiving amounts of deferred compensation, and the service recipients for whom the service providers provide services.

**FOR FURTHER INFORMATION CONTACT:** Stephen Tackney, (202) 927–9639 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Background

The notice of proposed rulemaking (REG–158080–04) that is the subject of this correction is under section 409A of the Internal Revenue Code.

##### Need for Correction

As published, REG–158080–04 contains an error that may prove to be misleading and is in need of clarification.

##### Correction of Publication

Accordingly, the publication of the notice of proposed rulemaking (REG–

158080–04) that was the subject of FR Doc. 05–19379, is corrected as follows:

On page 57930, column 1, in the preamble, under the paragraph heading **FOR FURTHER INFORMATION CONTACT:** lines 4 thru 8, the language “concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Richard A. Hurst at (202) 622–7116 (not toll-free numbers).” is corrected to read “concerning submission of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Richard A. Hurst at (202) 622–7180 (not toll-free numbers).”.

**Guy R. Traynor,**

*Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).*

[FR Doc. 06–395 Filed 1–12–06; 8:45 am]

**BILLING CODE 4830–01–U**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[REG–106418–05]

RIN 1545–BE34

#### Guidance Under Subpart F Relating to Partnerships

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking by cross-reference to temporary regulations.

**SUMMARY:** In the Rule and Regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations that provide rules for determining whether a controlled foreign corporation's (CFC's) distributive share of partnership income is excluded from foreign personal holding company income under the exception contained in section 954(i). The regulations will affect CFCs that are qualified insurance companies, as defined in section 953(e)(3), that have an interest in a partnership and U.S. shareholders of such CFCs. The text of those temporary regulations also serves as the text of these proposed regulations.

**DATES:** Written or electronic comments and requests for a public hearing must be received by April 17, 2006.

**ADDRESSES:** Send submissions to: CC:PA:LPD:PR (REG–106418–05), room 5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington,

DC 20044. Submissions may be hand-delivered between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG-106418-05), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically, via the IRS Internet site at <http://www.irs.gov/reg> or via the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS-REG-106418-05).

**FOR FURTHER INFORMATION CONTACT:**

Concerning the proposed regulations, Kate Y. Hwa, (202) 622-3840; concerning submissions of comments, Treena Garrett, (202) 622-3401 (not toll-free numbers).

**SUPPLEMENTARY INFORMATION:**

**Background**

Temporary regulations in Rules and Regulations section of this issue of the **Federal Register** amend the Income Tax Regulations (26 CFR part 1) relating to the rules under section 954(i) of the Internal Revenue Code (Code) for determining whether a controlled foreign corporation's (CFC's) distributive share of partnership income is excluded from foreign personal holding company income under the exception contained in section 954(i). The text of the temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and these proposed regulations.

**Special Analyses**

It has been determined that this proposed regulation is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedures Act (5 U.S.C. chapter 5) does not apply to these regulations and, because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

**Comments and Requests for Public Hearing**

Before these proposed regulations are adopted as final regulations, consideration will be given to any written (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and the Treasury Department request

comments on the clarity of the proposed rules and how they can be made easier to understand. All comments will be available for public inspection and copying. A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

The IRS and the Treasury Department have become aware of possible uncertainty regarding the application of section 956 in certain transactions involving foreign partnerships. The IRS and the Treasury Department therefore also request comments regarding the proper application of section 956 in the case of a loan by a CFC to a foreign partnership in which one or more partners are domestic corporations that are U.S. shareholders of the CFC. Specifically, comments are requested regarding the circumstances, if any, under which the loan to the foreign partnership should be considered to be the obligation of such partners and, thus, U.S. property for purposes of section 956. The IRS and the Treasury Department are particularly interested in the relevance of (1) the consistent application of section 956 to CFC loans to foreign partnerships, domestic partnerships, foreign branches, and disregarded entities of U.S. shareholders; (2) the foreign partnership's status as a foreign person; (3) the partners' liability for the partnership's debt under local foreign law; (4) the use of the loan proceeds in business activities located inside or outside of the United States; and (5) the fact that the CFC earnings loaned to the partnership would not have been deferred had they been earned by the partnership.

**Drafting Information**

The principal author of these regulations is Kate Y. Hwa of the Office of the Associate Chief Counsel (International), IRS. However, other personnel from the IRS and the Treasury Department participated in their development.

**List of Subjects in 26 CFR Part 1**

Income taxes, Reporting and recordkeeping requirements.

**Proposed Amendments to the Regulations**

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

**PART 1—INCOME TAXES**

**Paragraph 1.** The authority citation for 26 CFR part 1 continues to read, in part, as follows:

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

**Par. 2.** Section 1.954-2 is amended by revising paragraphs (a)(5)(ii)(C) and (a)(5)(iii) *Example 2* to read as follows:

**§ 1.954-2 Foreign personal holding company income.**

- (a) \* \* \*
- (5) \* \* \*
- (ii) \* \* \*

(C) [The text of the proposed amendment to § 1.954-2(a)(5)(ii)(C) is the same as the text for § 1.954-2T(a)(5)(ii)(C) published elsewhere in this issue of the **Federal Register**.]

- (iii) \* \* \*

*Example 2.* [The text of proposed § 1.954-2(a)(5)(iii) *Example 2* is the same as the text of § 1.954-2T(a)(5)(iii) *Example 2* published elsewhere in this issue of the **Federal Register**.]

\* \* \* \* \*

**Mark E. Matthews,**

*Deputy Commissioner for Services and Enforcement.*

[FR Doc. E6-356 Filed 1-13-06; 8:45 am]

**BILLING CODE 4830-01-P**

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 301**

[REG-131739-03]

**RIN 1545-BC45**

**Substitute for Return; Hearing**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of public hearing on proposed rulemaking.

**SUMMARY:** This document provides notice of public hearing on proposed regulations relating to the IRS preparing or executing returns for persons who fail to make required returns.

**DATES:** The public hearing is being held on Wednesday, March 8, 2006, at 10 a.m. The IRS must receive outlines of the topics to be discussed at the hearing by Wednesday, February 15, 2006.

**ADDRESSES:** The public hearing is being held in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building.