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,