305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Stephanie Shapley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6323, Silver Spring, MD 20993–0002, 301–796–4836; or Laura Rich, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and investigators entitled "Enforcement of Safety Reporting Requirements for INDs and BA/BE Studies." This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (§ 10.115 (21 CFR 10.115)). The guidance provides that the Agency intends to grant a 6-month period of enforcement discretion relating to the new reporting requirements (described in this document) that became effective on March 28, 2011. Accordingly, this guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). The Agency made this determination because the guidance deals with a short-term and highly time-sensitive issue. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's GGPs regulation.

On September 29, 2010, FDA published a final rule "Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans" (75 FR 59935) and issued related draft guidance "Safety Reporting Requirements for INDs and BA/BE Studies" (75 FR 60129, Docket No. FDA–2010–D–0482). The final rule amended the investigational new drug safety reporting requirements under part 312 (21 CFR part 312) and added safety reporting requirements for persons conducting bioavailability and bioequivalence studies under part 320 (21 CFR part 320). The effective date for the final rule was March 28, 2011. In comments to the docket, and in other communications to the Agency placed in the docket, stakeholders have requested an extension to the effective date of the final rule because of the need for significant internal process changes in order to meet the new requirements. Specifically, the comments indicated that sponsors needed additional time to implement changes to their internal procedures to comply with the new reporting requirements. The Agency acknowledges these concerns and intends to exercise enforcement discretion regarding the reporting requirements in the final rule until September 28, 2011. During this period of time, FDA does not intend to take enforcement action if sponsors and investigators report in compliance with the reporting requirements under §§ 312.32, 312.64, and 320.31 that were in effect prior to March 28, 2011.

The guidance represents the Agency's current thinking on enforcement of safety reporting requirements for investigational new drug applications and bioavailability/bioequivalence studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/default.htm,* or *http://www.regulations.gov.* Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

Dated: June 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–13950 Filed 6–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[TD 9524]

RIN 1545–BG45

Extension of Withholding to Certain Payments Made by Government Entities; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document describes corrections to final regulations (TD 9524) that were published in the **Federal Register** on Monday, May 9, 2011 (76 FR 26583) relating to withholding by government entities. These regulations reflect changes in the law made by the Tax Increase Prevention and Reconciliation act of 2005 that require Federal, State, and local government entities to withhold income tax when making payments to persons providing property or services. These regulations affect Federal, State, and local government entities that will be required to withhold and report tax from payments to persons providing property or services and also affect the person receiving payments for property or services from the government entities.

DATES: This correction is effective on June 7, 2011, and is applicable on May 9, 2011.

FOR FURTHER INFORMATION CONTACT: A. G. Kelley, (202) 622–6040 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of this correction are under sections 3402(t), 3406(g), 6011(a), 6051, 6071(a), and 6302 of the Internal Revenue Code.

Need for Correction

As published, final regulations (TD 9524) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the final regulations (TD 9524) which were the subject of FR Doc. 2011–10760 is corrected as follows:

1. On page 26584, column 1, in the preamble, under the paragraph heading "Summary of Comments and Explanation of Provisions", the second paragraph of the column, line 1, the

language "As discussed in section IX of the" is corrected to read "As discussed in section VIII of the".

2. On page 26854, column 1, in the preamble, under the paragraph heading "Summary of Comments and Explanation of Provisions", the second paragraph of the column, line 13, the language "materially modified (but see section IX" is corrected to read "materially modified (but see section VIII".

3. On page 26586, column 2, in the preamble, under the paragraph heading "D. Advance and Interim Payments", first paragraph, last line, the language "IV.E.1 of this preamble)." is corrected to read "III.E.1 of this preamble).".

4. On page 26587, column 2, in the preamble, the language of the paragraph heading "*IV. Payments Excepted From the Section 3402(t) Withholding Requirements*" is corrected to read "*III. Payments Excepted From the Section 3402(t) Withholding Requirements*".

5. On page 26591, column 1, in the preamble, the language of the paragraph heading "*V. Application of Section 3402(t) to Passthrough Entities*" is corrected to read "*IV. Application of Section 3402(t) to Passthrough Entities*".

6. On page 26591, column 2, in the preamble, the language of the paragraph heading "*VI. Deposits and Reporting of Amounts Withheld Under Section 3402(t)*" is corrected to read "*V. Deposits and Reporting of Amounts Withheld Under Section 3402(t)*".

7. On page 26591, column 3, in the preamble, the language of the paragraph heading "*VII. Crediting of Amounts Withheld*" is corrected to read "*VI. Crediting of Amounts Withheld*".

8. On page 26592, column 2, in the preamble, the language of the paragraph heading "*VIII. Correction of Errors and Liability of Government Entity*" is corrected to read "*VII. Correction of Errors and Liability of Government Entity*".

9. On page 26593, column 2, in the preamble, the language of the paragraph heading "*IX. Extension of Applicability Date and Transition Relief for Existing Contracts*" is corrected to read "*VIII. Extension of Applicability Date and Transition Relief for Existing Contracts*".

10. On page 26594, column 1, in the preamble, the language of the paragraph heading "*X. Transition Rule for Interest and Penalties on Underpayments*" is corrected to read " *IX. Transition Rule for Interest and Penalties on Underpayments*".

LaNita Van Dyke,

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

[FR Doc. 2011–13932 Filed 6–6–11; 8:45 am]

BILLING CODE 4830–01–P

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 (DoN) 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 (DAJAG) (Admiralty and Maritime Law) has determined that USS SAN DIEGO (LPD 22) 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 ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

DATES: This rule is effective June 7, 2011 and is applicable beginning May 18, 2011.

FOR FURTHER INFORMATION CONTACT: Lieutenant Jaewon Choi, JAGC, U.S. Navy, Admiralty Attorney, (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave., SE., Suite 3000, Washington Navy Yard, DC 20374–5066, telephone 202–685–5040.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the DoN amends 32 CFR part 706.

This amendment provides notice that the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS SAN DIEGO (LPD 22) 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 without interfering with its special function as a naval ship: Rule 27 (a)(i) and (b)(i), pertaining to the placement of all-round task lights in a vertical line; Annex I, paragraph 3(a), pertaining to the horizontal distance between the forward and after masthead lights; and Annex I, paragraph 2(k), pertaining to the vertical separation between anchor lights. The DAJAG (Admiralty and Maritime Law) 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.

For the reasons set forth in the preamble, amend part 706 of title 32 of the CFR as follows:

PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

■ 1. The authority citation for part 706 continues to read:

Authority: 33 U.S.C. 1605.

■ 2. Section 706.2 is amended as follows:

■ A. In Table Three by adding, in alpha numerical order, by vessel number, an entry for USS SAN DIEGO (LPD 22); and

■ B. In Table Four, under paragraph 20, add, in alpha numerical order, by vessel number, and entry for USS SAN DIEGO (LPD 22); and

■ C. In Table Five by adding, in alpha numerical order, by vessel number, and entry for USS SAN DIEGO (LPD 22).

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

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