(17) Indianapolis-Anderson-Columbus, IN—consisting of the Indianapolis-Anderson-Columbus, IN CSA, plus Grant County, IN;

(18) Los Angeles-Long Beach-Riverside, CA—consisting of the Los Angeles-Long Beach-Riverside, CA CSA, plus the Santa Barbara-Santa Maria-Goleta, CA MSA and all of Edwards Air Force Base, CA;

(19) Miami-Fort Lauderdale-Pompano Beach, FL—consisting of the Miami-Fort Lauderdale-Pompano Beach, FL MSA, plus Monroe County, FL;

(20) Milwaukee-Racine-Waukesha, WI—consisting of the Milwaukee-Racine-Waukesha, WI CSA;

(21) Minneapolis-St. Paul-St. Cloud, MN-WI—consisting of the Minneapolis-St. Paul-St. Cloud, MN-WI CSA;

(22) New York-Newark-Bridgeport, NY-NJ-CT-PA—consisting of the New York-Newark-Bridgeport, NY-NJ-CT-PA CSA, plus Monroe County, PA, Warren County, NJ, and all of Joint Base McGuire-Dix-Lakehurst;

(23) Philadelphia-Camden-Vineland, PA-NJ-DE-MD—consisting of the Philadelphia-Camden-Vineland, PA-NJ-DE-MD CSA excluding Joint Base McGuire-Dix-Lakehurst, plus Kent County, DE, Atlantic County, NJ, and Cape May County, NJ;

(24) Phoenix-Mesa-Scottsdale, AZ—consisting of the Phoenix-Mesa-Scottsdale, AZ MSA;

(25) Pittsburgh-New Castle, PA—consisting of the Pittsburgh-New Castle, PA CSA;

(26) Portland-Vancouver-Hillsboro, OR-WA—consisting of the Portland-Vancouver-Hillsboro, OR-WA MSA, plus Marion County, OR, and Polk County, OR;

(27) Raleigh-Durham-Cary, NC—consisting of the Raleigh-Durham-Cary, NC CSA, plus the Fayetteville, NC MSA, the Goldsboro, NC MSA, and the Federal Correctional Complex Butner, NC;

(28) Richmond, VA—consisting of the Richmond, VA MSA;

(29) Sacramento—Arden-Arcade—Yuba City, CA-NV—consisting of the Sacramento—Arden-Arcade—Yuba City, CA-NV CSA, plus Carson City, NV;

(30) San Diego-Carlsbad-San Marcos, CA—consisting of the San Diego-Carlsbad-San Marcos, CA MSA;

(31) San Jose-San Francisco-Oakland, CA—consisting of the San Jose-San Francisco-Oakland, CA CSA, plus the Salinas, CA MSA and San Joaquin County, CA;

(32) Seattle-Tacoma-Olympia, WA—consisting of the Seattle-Tacoma-Olympia, WA CSA, plus Whatcom County, WA;

(33) Washington-Baltimore-Northern Virginia, DC-MD-VA-WV-PA—consisting of the Washington-Baltimore-Northern Virginia, DC-MD-VA-WV CSA, plus the Hagerstown-Martinsburg, MD-WV MSA, the York-Hanover-Gettysburg, PA CSA, and King George County, VA; and

(34) Rest of U.S.—consisting of those portions of the United States and its territories and possessions as listed in 5 CFR 591.205 not located within another locality pay area.

■ 4. In § 531.606—

■ a. Revise paragraph (b)(1);

■ b. Redesignate paragraph (b)(2) and (b)(3) as (b)(3) and (b)(4), respectively;

■ c. Add a new paragraph (b)(2); and

■ d. Revise newly designated paragraph (b)(4).

The revisions and addition read as follows:

531.606 Maximum limits on locality rates.

(a) * * *

(b)(1) A locality rate for an employee in a category of positions described in 5 U.S.C. 5304(h)(1)(A) and 5304(h)(1)(B) may not exceed the rate for level III of the Executive Schedule.

(2) A locality rate for an employee in a category of positions described in 5 U.S.C. 5304(h)(1)(C) may not exceed—

(i) The rate for level III of the Executive Schedule, when the positions are not covered by an appraisal system certified under 5 U.S.C. 5307(d); or

(ii) The rate for level II of the Executive Schedule, when the positions are covered by an appraisal system certified under 5 U.S.C. 5307(d).

* * * * *

(4) If initial application of paragraph (b)(3) of this section otherwise would reduce an employee's existing locality rate, the employee's locality rate is capped at the higher of—

(i) The amount of the employee's locality rate on the day before paragraph (b)(3) of this section was initially applied; or

(ii) The rate for level IV of the Executive Schedule.

* * * * *

[FR Doc. 2011–13993 Filed 6–6–11; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312 and 320

[Docket No. FDA–2010–D–0482]

Guidance for Industry and Investigators on Enforcement of Safety Reporting Requirements for Investigational New Drug Applications and Bioavailability/Bioequivalence Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of guidance.

SUMMARY: The Food and Drug Administration (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 intended to inform sponsors and investigators of FDA's intent to exercise enforcement discretion regarding the reporting requirements in the 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, September 29, 2010), until September 28, 2011. This action is being taken in response to requests from sponsors to extend the March 28, 2011, effective date of the final rule. FDA expects all sponsors and investigators to be in compliance with the new regulations no later than September 28, 2011.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–

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