designated drug has been conditionally approved or approved. The written notice will inform the sponsor of the requirements for maintaining MUMS-designated drug exclusive marketing rights for the full 7-year term. This notice will generally be contained in the letter conditionally approving or approving the application.

(b) When an application is conditionally approved or approved for a MUMS-designated drug that qualifies for exclusive marketing rights, FDA will publish this information in the **Federal Register** at the time of the conditional approval or approval. This notice will generally be contained in the notice of conditional approval or approval of the application.

§ 516.36 Insufficient quantities of MUMS-designated drugs.

(a) Under section 573 of the act, whenever FDA has reason to believe that sufficient quantities of a conditionally-approved or approved, MUMS-designated drug to meet the needs for which the drug was designated cannot be assured by the sponsor, FDA will so notify the sponsor of this possible insufficiency and will offer the sponsor the following options, one of which must be exercised by a time that FDA specifies:

(1) Provide FDA information and data regarding how the sponsor can assure the availability of sufficient quantities of the MUMS-designated drug within a reasonable time to meet the needs for which the drug was designated; or

(2) Provide FDA in writing the sponsor's consent for the conditional approval or approval of other applications for the same drug before the expiration of the 7-year period of exclusive marketing rights.

(b) If, within the time that FDA specifies, the sponsor fails to consent to the conditional approval or approval of other applications and if FDA finds that the sponsor has not shown that it can assure the availability of sufficient quantities of the MUMS-designated drug to meet the needs for which the drug was designated, FDA will issue a written order terminating designation of the MUMS drug and the associated exclusive marketing rights. This order will state FDA's findings and conclusions and will constitute final agency action. An order terminating designation and associated exclusive marketing rights may issue whether or not there are other sponsors that can assure the availability of alternative sources of supply. Such an order will not withdraw the conditional approval or approval of an application. Once terminated under this section, neither designation, nor exclusive marketing rights may be reinstated.

§ 516.52 Availability for public disclosure of data and information in requests.

(a) FDA will not publicly disclose the existence of a request for MUMS-drug designation under section 573 of the act prior to final FDA action on the request unless the existence of the request has been previously publicly disclosed or acknowledged.

(b) Whether or not the existence of a pending request for designation has been publicly disclosed or acknowledged, no data or information in the request are available for public disclosure prior to final FDA action on the request.

(c) Except as provided in paragraph (d) of this section, upon final FDA action on a request for designation, the public availability of data and information in the request will be determined in accordance with part 20 of this chapter and other applicable statutes and regulations.

(d) In accordance with § 516.28, FDA will make a cumulative list of all MUMS-drug designations available to the public and update such list periodically. In accordance with § 516.29, FDA will give public notice of the termination of all MUMS-drug designations.

Subpart C—[Reserved]

Subpart D—[Reserved]

Dated: March 12, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

Editorial Note: This document was received at the Office of the Federal Register on July 23, 2007.

[FR Doc. E7–14444 Filed 7–25–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9333]

RIN 1545–BG64

Application of Section 6404(g) of the Internal Revenue Code Suspension Provisions; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to temporary regulations.

SUMMARY: This document contains corrections to temporary regulations (TD 9333) that were published in the **Federal Register** on Thursday, June 21, 2007 (72 FR 34176) on the suspension of any interest, penalty, addition to tax, or additional amount with respect to listed transactions or undisclosed reportable transactions. The temporary regulations provide guidance to individual taxpayers who have participated in listed transactions or undisclosed reportable transactions.

DATES: The correction is effective July 26, 2007.

FOR FURTHER INFORMATION CONTACT: Stuart Spielman, (202) 622–7950 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations that are the subject of this correction are under section 6404(g) of the Internal Revenue Code.

Need for Correction

As published, temporary regulations (TD 9333) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the temporary regulations (TD 9333), which was the subject of FR Doc. E7–12081, is corrected as follows:

1. On page 34176, column 2, in the preamble, under the caption ''**SUMMARY:**'', lines 13 and 14, the language ''Opportunity Zone Act of 2005, and the Tax Relief and Health Care Act of 2006.'' is corrected to read ''Opportunity Zone Act of 2005, the Tax Relief and Health Care Act of 2006, and the Small Business and Work Opportunity Tax Act of 2007.''.

2. On page 34176, column 3, in the preamble, under the paragraph heading ''Background'', line 8 from the bottom of the paragraph, the language ''Public Law 110–28 (121 Stat. 112, 200),'' is corrected to read ''Public Law 110–28 (121 Stat. 190, 200),''.

LaNita Van Dyke,

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

[FR Doc. E7–14398 Filed 7–25–07; 8:45 am]

BILLING CODE 4830–01–P