

shortage. This biological product shortages list will include the following information:

- (i) The names and National Drug Codes for such biological products, or the alternative standards for identification and labeling that have been recognized as acceptable by the Center Director;
- (ii) The name of each applicant for such biological products;
- (iii) The reason for the shortage, as determined by FDA, selecting from the following categories: Requirements related to complying with good manufacturing practices; regulatory delay; shortage of an active ingredient; shortage of an inactive ingredient component; discontinuation of the manufacture of the biological product; delay in shipping of the biological product; demand increase for the biological product; or other reason; and
- (iv) The estimated duration of the shortage.

(2) *Confidentiality*. FDA may choose not to make information collected to implement this paragraph available on the biological product shortages list or available under section 506C(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356c(c)) if FDA determines that disclosure of such information would adversely affect the public health (such as by increasing the possibility of hoarding or other disruption of the availability of the biological product to patients). FDA will also not provide information on the public shortages list or under section 506C(c) of the Federal Food, Drug, and Cosmetic Act that is protected by 18 U.S.C. 1905 or 5 U.S.C. 552(b)(4), including trade secrets and commercial or financial information that is considered confidential or privileged under § 20.61 of this chapter.

(e) *Noncompliance letters*. If an applicant fails to submit a notification as required under paragraph (a) of this section and in accordance with paragraph (b) of this section, FDA will issue a letter to the applicant informing it of such failure.

(1) Not later than 30 calendar days after the issuance of such a letter, the applicant must submit to FDA a written response setting forth the basis for noncompliance and providing the required notification under paragraph (a) of this section and including the information required under paragraph (c) of this section; and

(2) Not later than 45 calendar days after the issuance of a letter under this paragraph, FDA will make the letter and the applicant's response to the letter public, unless, after review of the applicant's response, FDA determines that the applicant had a reasonable basis

for not notifying FDA as required under paragraph (a) of this section.

(f) *Definitions*. The following definitions of terms apply to this section:

Biological product shortage or shortage means a period of time when the demand or projected demand for the biological product within the United States exceeds the supply of the biological product.

Intended for use in the prevention or treatment of a debilitating disease or condition means a biological product intended for use in the prevention or treatment of a disease or condition associated with mortality or morbidity that has a substantial impact on day-to-day functioning.

Life supporting or life sustaining means a biological product that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

Meaningful disruption means a change in production that is reasonably likely to lead to a reduction in the supply of a biological product by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product, and does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

Significant disruption means a change in production that is reasonably likely to lead to a reduction in the supply of blood or blood components by a manufacturer that substantially affects the ability of the manufacturer to fill orders or meet expected demand for its product, and does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

Dated: July 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9722]

RIN 1545-BM35

Partnership Transactions Involving Equity Interests of a Partner; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to final and temporary regulations (TD 9722) that were published in the **Federal Register** on June 12, 2015 (80 FR 33402). The final and temporary regulations prevent a corporate partner from avoiding corporate-level gain through transactions with a partnership involving equity interests of the partner.

DATES: This correction is effective on July 2, 2015 and applicable beginning June 12, 2015.

FOR FURTHER INFORMATION CONTACT: Kevin I. Babitz at (202) 317-6852 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations (TD 9722) that are the subject of this correction are under sections 311(b), 336(a), and 337(d) of the Internal Revenue Code.

Need for Correction

As published, the final and temporary regulations (TD 9722) contain errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

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

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

■ **Par. 2.** Section 1.337(d)-3T is amended by revising paragraphs (c)(2)(i) and (f)(2)(ii) to read as follows:

§ 1.337(d)-3T Gain recognition upon certain partnership transactions involving a partner's stock (temporary).

* * * *

(c) * * *
 (2) * * * (i) *In general.* With respect to a Corporate Partner, Stock of the Corporate Partner includes the Corporate Partner's stock, or other equity interests, including options, warrants, and similar interests, in the Corporate Partner or a corporation that controls the Corporate Partner within the meaning of section 304(c), except that section 318(a)(1) and (3) shall not apply. Stock of the Corporate Partner also includes interests in any entity to the extent that the value of the interest is attributable to Stock of the Corporate Partner.

(f) * * *

(2) * * *

(ii) Is not distributed to the Corporate Partner or a corporation that controls the Corporate Partner within the meaning of section 304(c), except that section 318(a)(1) and (3) shall not apply.
 * * * *

§ 1.732-1T [Amended]

■ **Par 3.** Section 1.732-1T paragraph (c)(5)(ii) is amended by removing the word "Nothwithstanding" and adding in its place the word "Notwithstanding".

Martin V. Franks,

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

[FR Doc. 2015-16674 Filed 7-2-15; 4:15 pm]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9722]

RIN 1545-BM35

Partnership Transactions Involving Equity Interests of a Partner; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations; correction.

SUMMARY: This document contains corrections to final and temporary regulations (TD 9722) that were published in the *Federal Register* on June 12, 2015 (80 FR 33402). The final and temporary regulations prevent a corporate partner from avoiding corporate-level gain through transactions with a partnership involving equity interests of the partner.

DATES: This correction is effective on July 2, 2015 and applicable beginning June 12, 2015.

FOR FURTHER INFORMATION CONTACT:
 Kevin I. Babitz at (202) 317-6852 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations (TD 9722) that are the subject of this correction are under sections 311(b), 336(a), and 337(d) of the Internal Revenue Code.

Need for Correction

As published, the final and temporary regulations (TD 9722) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the final regulations (TD 9722), that are the subject of FR Doc. 2015-14405, are corrected as follows:

1. On page 33404, in the preamble, the first column, the tenth and eleventh lines from the top of the column, the language "that controls (within the meaning of section 304(c)) the Corporate Partner." is corrected to read "that controls the Corporate Partner within the meaning of section 304(c), except that section 318(a)(1) and (3) shall not apply (section 304(c) control.)".

2. On page 33404, in the preamble, the first column, the eighteenth through the twentieth line from the top of the first full paragraph, the language "that controls the Corporate Partner within the meaning of section 304(c) (section 304(c) control), whereas the" is corrected to read "that possesses section 304(c) control of the Corporate Partner, whereas the".

Martin V. Franks,

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

[FR Doc. 2015-16673 Filed 7-2-15; 4:15 pm]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2015-0527]

Safety Zones; Recurring Events in Captain of the Port Boston Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the safety zones in the Captain of the Port Boston Zone on the specified dates and times listed below. This action is necessary to ensure the protection of the maritime public and event participants from the hazards associated with these annual recurring events. Under the provisions of our regulations, no person or vessel, except for the safety vessels assisting with the event may enter the safety zones unless given permission from the COTP or the designated on-scene representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

DATES: The regulation for the safety zones described in 33 CFR 165.118 will be enforced on July 3, 2015 between 7:00 p.m. to 11:00 p.m., on July 4, 2015 from 9:00 p.m. to 11:00 p.m., on July 10, 2015 from 6:00 a.m. to 4:00 p.m., and on July 11, 2015 from 8:30 a.m. to 10:30 a.m., as listed in the table located in the Supplementary Information.

FOR FURTHER INFORMATION CONTACT: If you have questions on this document, call or email Mr. Mark Cutter, Coast Guard Sector Boston Waterways Management Division, telephone 617-223-4000, email Mark.E.Cutter@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zones listed in 33 CFR 165.118 on the specified dates and times as indicated in Table 1 below.

TABLE 1

7.1 City of Lynn 4th of July Celebration Fireworks

- Event Type: Firework Display.
- Sponsor: City of Lynn.
- Date: July 3, 2015.
- Time: 7:00 p.m. to 11:00 p.m.