

additional petitions; one requesting an administrative stay of action with an embedded citizen petition and the other requesting an administrative stay of action. Each of the requests for an administrative stay of action concern FDA's use of enforcement discretion related to labeling of dietary supplements, pending the publication of a final rule.² In addition, FDA received numerous comments on the 2010 proposed rule requesting that FDA extend the period of enforcement discretion based on the 2003 letter until publication of a final rule. FDA has received new scientific data and information, through comments to the 2010 proposed rule, or submitted with petitions, relating to several of the factors we set forth in the 2003 letter, e.g., the possible health benefit of free phytosterols in dietary supplements and the minimum daily consumption amount of phytosterols necessary to achieve the claimed effect. We are reviewing the comments and information we received and do not intend to make a determination as to the daily phytosterols consumption amount needed to achieve the claimed effect or the eligibility of dietary supplements containing free phytosterols to bear the authorized health claim until the publication of the final rule.

Based on the new data and information currently under our review that may be important, to our

² FDA received a petition for an administrative stay of action with an embedded citizen petition from Pharmavite LLC ("Pharmavite petition") dated February 24, 2011, and a petition for an administrative stay from Botanical Laboratories, Inc. ("Botanical petition"), dated March 18, 2011 (Docket Nos. FDA-2000-P-0102, FDA-2000-P-0133, and FDA-2006-P-0033). Specifically, Pharmavite LLC requests FDA to stay its February 18, 2011, decision to discontinue enforcement discretion for dietary supplements containing free phytosterols that have been shown, through an adequate and well-controlled clinical trial, to reduce low density lipoprotein (LDL) and total cholesterol, pending publication of a final rule for the health claim. In a citizen petition embedded in the petition for an administrative stay, Pharmavite LLC also asked us to agree that: (1) A dietary supplement produced by Pharmavite LLC has been shown to effectively reduce LDL and total cholesterol; (2) FDA will continue to exercise enforcement discretion to permit this dietary supplement to bear an appropriately worded claim pursuant to the 2010 proposed regulation, pending publication of a final rule addressing the health claim; and (3) the final rule will allow those dietary supplements containing free phytosterols that have been shown through an adequate and well-controlled clinical trial to effectively reduce LDL and total cholesterol to bear the claim. Botanical Laboratories, Inc., requested that FDA stay its February 18, 2011, decision to discontinue enforcement discretion for dietary supplements containing phytosterols in liquid form until the issuance of a final rule for the health claim. We are currently considering these petitions. This document does not represent a decision on these petitions, in whole or in part.

consideration in deciding what requirements to include in the final rule, and the need to focus FDA's resources on other public health priorities, we find it appropriate to continue to extend our consideration of the exercise of enforcement discretion for the labeling of foods, including dietary supplements, bearing a health claim regarding phytosterols and risk of CHD consistent with the 2003 letter, until publication of the final rule.

Therefore, FDA is extending the period during which it intends to exercise enforcement discretion, consistent with the factors set forth in the 2003 letter, until publication of a final rule for the phytosterols and risk of CHD health claim. This document does not change how FDA intends to consider exercising its enforcement discretion when claims are made consistent with the proposed requirements in the proposed rule. Food, including dietary supplements, bearing the health claim would be required to comply with any revised requirements established in the final rule when the final rule becomes effective.

III. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

- Center for Food Safety and Applied Nutrition, Food and Drug Administration, Letter of Enforcement Discretion from FDA to Cargill Health & Food Technologies, Docket No. FDA-2000-P-0102, document ID DRAFT-0059 (formerly 2000P-1275/LET3) and Docket No. FDA-2000-P-0133, document ID DRAFT-0127 (formerly 2000P-1276/LET4), February 14, 2003.

Dated: February 15, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9571]

RIN 1545-BJ84

Allocation and Apportionment of Interest Expense; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to the final regulations (TD 9571), which were published in the **Federal Register** on January 17, 2012 (77 FR 2225) that provide guidance regarding the allocation and apportionment of interest expense.

DATES: This correction is effective on February 21, 2012, and is applicable on January 17, 2012.

FOR FURTHER INFORMATION CONTACT: Jeffrey L. Parry, (202) 622-3850 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations (TD 9571) that are the subject of these corrections are under section 864 of the Internal Revenue Code.

Need for Correction

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

List of Subjects 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 * * *

§ 1.861-9T [Corrected]

■ **Par. 2.** Section 1.861-9T is amended by revising paragraph (l) to read as follows:

§ 1.861-9T Allocation and apportionment of interest expense (temporary).

* * * * *

(l) *Expiration date.* The applicability date of paragraphs (e)(2), (e)(3), and (h)(4) expires on January 13, 2015.

§ 1.861-11T [Corrected]

■ **Par. 3.** Section 1.861-11T is amended by revising paragraph (i) to read as follows:

§ 1.861-11T Special rules for allocating and apportioning interest expense of an affiliated group of corporations (temporary).

* * * * *

(i) *Expiration date.* The applicability date of paragraph (d)(6)(ii) expires on January 13, 2015.

Robin R. Jones,

Federal Register Liaison Officer, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, Procedure and Administration.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9567]

RIN 1545-BK17

Reporting of Specified Foreign Financial Assets; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to final regulations (TD 9567), which were published in the **Federal Register** on Monday, December 19, 2011, relating to the reporting of specified foreign financial assets.

DATES: *Effective date:* This correction is effective February 21, 2012, and is applicable beginning December 19, 2011.

FOR FURTHER INFORMATION CONTACT: Joseph S. Henderson, (202) 622-3880 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections are under section 6038 of the Internal Revenue Code.

Need for Correction

As published on December 19, 2011 (76 FR 78561), final regulation (TD 9567), contains errors which 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.

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 * * *

PART 1—[CORRECTED]

■ **Par. 2.** Section 1.6038D-2T is amended by:

■ 1. Revising the last sentence of paragraph (b)(3).

■ 2. Revising, in paragraph (d), the subject heading and fifth sentence of paragraph (2)(i) in the *Example*.

The revisions read as follows:

§ 1.6038D-2T Requirement to report specified foreign financial assets (temporary).

* * * * *

(b) * * *

(3) * * * See § 1.6038D-5T(f) for rules to determine the maximum value of an interest in a foreign trust or estate.

* * * * *

(d) * * *

Example. * * *

(2) * * *

(i) *Married specified individuals filing separate annual returns.* * * * See § 1.6038D-5T(b) regarding the maximum value of a jointly owned and specified foreign financial asset to be reported by a specified person, including a married specified individual, that is a joint owner of an asset. * * *

* * * * *

■ **Par. 3.** Section 1.6038D-4T is amended by revising paragraph (a)(9) to read as follows:

§ 1.6038D-4T Information required to be reported (temporary).

(a) * * *

(9) The foreign currency exchange rate and, if the source of such rate is other than as described in § 1.6038D-5T(c)(1), the source of the rate used to determine the specified foreign financial asset's U.S. dollar value, including maximum value; and

* * * * *

■ **Par. 4.** Section 1.6038D-5T is amended by revising paragraph (c)(1).

§ 1.6038D-5T Valuation guidelines (temporary).

* * * * *

(c) * * *

(1) *In general.* Except as provided in paragraph (c)(2) of this section, the U.S. Treasury Department's Financial Management Service foreign currency exchange rate is to be used to convert the value of a specified foreign financial asset into U.S. dollars for purposes of determining the aggregate value of specified foreign financial assets in which a specified person has an interest and determining the maximum value of a specified foreign financial asset.

* * * * *

■ **Par. 5.** Section 1.6038D-7T is amended by revising paragraphs (a)(1)(i)(C) and (b) introductory text to read as follows:

§ 1.6038D-7T Exceptions from the reporting of certain assets under section 6038D (temporary).

(a) * * *

(1) * * *

(i) * * *

(C) Form 8621, "Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund";

* * * * *

(b) *Owner of certain trusts.* A specified person that is treated as an owner of any portion of a domestic trust under sections 671 through 678 is not required to file Form 8938 to report any specified foreign financial asset held by the trust if the trust is—

* * * * *

Guy R. Traynor,

Federal Register Liaison, Legal Processing Division, Publication and Regulations Br., Procedure & Administration.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9567]

RIN 1545-BK17

Reporting of Specified Foreign Financial Assets; Correction

AGENCY: Internal Revenue Service (IRS).

ACTION: Final rule; correction.

SUMMARY: This document contains corrections to final regulations (TD 9567), which were published in the **Federal Register** on Monday, December 19, 2011, relating to reporting of specified foreign financial assets.

DATES: *Effective Date:* This correction is effective February 21, 2012, and is applicable beginning December 19, 2011.

FOR FURTHER INFORMATION CONTACT: Joseph S. Henderson, (202) 622-3880 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections are under section 6038 of the Internal Revenue Code.