

(2) No. 058005 for use of 5 mg/mL solution in swine as in paragraph (d)(4) of this section.

(3) No. 000010 for use of 50 mg/mL solution in dogs as in paragraph (d)(5) of this section.

(4) No. 059130 for use of 100 mg/mL solution in turkeys as in paragraph (d)(2) and in chickens as in paragraph (d)(3) of this section.

* * * * *

Dated: December 13, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E6-21951 Filed 12-21-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 812

[Docket No. 2006N-0494]

Medical Device Regulations; Disqualification of a Clinical Investigator; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending a medical device regulation to include references to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). This regulation pertains to the disqualification of a clinical investigator. Currently, only a reference to the Center for Devices and Radiological Health is listed in this regulation. This action is being taken to ensure the accuracy of FDA's regulations.

DATES: This rule is effective December 22, 2006.

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, 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 amending 21 CFR 812.119(a) to include references to CBER and CDER. This regulation pertains to the disqualification of a clinical investigator. Currently, only a reference to the Center for Devices and Radiological Health is listed in this regulation. The appropriate Center that

has regulatory responsibility for the medical device subject to this regulation is responsible for corresponding with the investigator of the study concerning any possible violations of the applicable requirements. Therefore, FDA is updating this regulation to include the references to CBER and CDER.

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only a technical change to update references in the Code of Federal Regulations, and is nonsubstantive.

List of Subjects in 21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 812 is amended as follows:

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

■ 1. The authority citation for 21 CFR part 812 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c-360f, 360h-360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b-263n.

■ 2. Section 812.119 is amended by revising paragraph (a) to read as follows:

§ 812.119 Disqualification of a clinical investigator.

(a) If FDA has information indicating that an investigator has repeatedly or deliberately failed to comply with the requirements of this part, part 50, or part 56 of this chapter, or has repeatedly or deliberately submitted false information either to the sponsor of the investigation or in any required report, the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, or the Center for Drug Evaluation and Research will furnish the investigator written notice of the matter under complaint and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference. If an explanation is offered and accepted by the applicable Center, the disqualification process will be terminated. If an explanation is offered but not accepted by the Center, the investigator will be given an opportunity for a regulatory hearing under part 16 of this chapter on the

question of whether the investigator is entitled to receive investigational devices.

* * * * *

Dated: December 12, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6-21952 Filed 12-21-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9278]

RIN 1545-BB31, 1545-AY38, 1545-BC52

Treatment of Services Under Section 482; Allocation of Income and Deductions From Intangibles; Stewardship Expense; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to final and temporary regulations (TD 9278) that was published in the **Federal Register** on Friday, August 4, 2006 (71 FR 44466) regarding the treatment of controlled services transactions under section 482 and the allocation of income from intangibles, in particular with respect to contributions by a controlled party to the value of an intangible owned by another controlled party. This document also contains corrections to final and temporary regulations that modify the regulations under section 861 concerning stewardship expenses to be consistent with the changes made to the regulations under section 482.

DATES: *Effective Date:* The amendments are effective on January 1, 2007.

FOR FURTHER INFORMATION CONTACT: Thomas A. Vidano, (202) 435-5265, or Carol B. Tan (202) 435-5159, for matters relating to section 482, and David F. Bergkuist, (202) 622-3850, for matters relating to stewardship expenses (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations that are the subject of these corrections are under sections 482 and 861 of the Internal Revenue Code.

Need for Correction

As published, the final and temporary regulations (TD 9278) contains 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 1.482-0T is amended by removing the entries for paragraphs (i)(1) through (i)(10), (j)(1), (j)(2) and (j)(3) from § 1.482-1T.

■ **Par. 3.** Section 1.482-1 is amended by revising paragraph (i) introductory text to read as follows:

§ 1.482-1 Allocation of income and deductions among taxpayers.

* * * * *

(i) [Reserved]. For further guidance, see § 1.482-1T(i) introductory text.

* * * * *

■ **Par. 4.** Section 1.482-1T is amended as follows:

■ 1. Paragraphs (i)(1) through (i)(10) are added and reserved.

■ 2. Paragraphs (j)(1) through (j)(5) are amended by adding “§” before the language “1.482-1(j)(1)”.

The addition reads as follows:

§ 1.482-1T Allocation of income and deductions among taxpayers (temporary).

* * * * *

(i)(1) through (i)(10) [Reserved]. For further guidance, see § 1.482-1(i)(1) through (i)(10).

* * * * *

■ **Par. 5.** Section 1.482-8T is amended by revising paragraph (b) *Example 12*. (iv), second sentence to read as follows:

§ 1.482-8T Example of the best method rule (temporary).

* * * * *

(b) * * *

Example 12. (i) * * *

(iv) * * * USP contributed the long-term endorsement contracts with professional athletes. * * *

* * * * *

■ **Par. 6.** Section 1.482-9T is amended as follows:

■ 1. Paragraph (b)(6), *Example 22*. (vi), introductory text is revised.

■ 2. Paragraph (g)(2), *Example 2*. (iv), fifth sentence is revised.

■ 3. Paragraph (i)(2) is revised.

■ 4. Paragraph (i)(5), *Example 1*. (iii), first sentence is revised.

■ 5. Paragraph (i)(5), *Example 3*. (ii), first sentence is revised.

■ 6. Paragraph (l)(5), *Example 20*. (i), second sentence is revised.

■ 7. Paragraph (m)(5), *Example 1*. (ii), fourth sentence is revised.

The revisions read as follows:

§ 1.482-9T Methods to determine taxable income in connection with a controlled services transaction (temporary).

* * * * *

(b) * * *

(6) * * *

Example 22. (i) * * *

(vi) In contrast, if aggregated services AB were allocated by reference to the total U.S. dollar value of sales to uncontrolled parties (trade sales) by each company, the following results would obtain:

* * * * *

(g) * * *

(2) * * *

Example 2. * * *

(iv) * * * In the bid on the Country 2 contract for Level 1 waste remediation, Company B proposes to use a multidisciplinary team of specialists from Company A and Company B. * * *

* * * * *

(i) * * *

(2) * * * For purposes of this paragraph (i), an arrangement will be treated as a contingent-payment arrangement if it meets all of the requirements in paragraph (i)(2)(i) of this section and is consistent with the economic substance and conduct requirement in paragraph (i)(2)(ii) of this section.

* * * * *

(5) * * *

Example 1. (i) * * *

(iii) The years under examination are years 6 through 9. * * *

* * * * *

Example 3. (i) * * *

(ii) The years under examination are years 6 through 9. * * *

* * * * *

(l) * * *

(5) * * *

Example 20. (i) * * * Y, a Country B corporation, is a distribution and marketing company that also performs clinical trials for X in Country B. * * *

* * * * *

(m) * * *

(5) * * *

Example 1. (i) * * *

(ii) * * * The comparable profits method may provide the most reliable measure of an arm's length result if uncontrolled parties are identified that perform similar, combined functions of maintaining and providing spare parts for similar equipment. * * *

* * * * *

■ **Par. 7.** Section 1.861-8T is amended as follows:

■ 1. Paragraph (b)(3) is revised.

■ 2. Paragraph (g), paragraph (i) following *Example 30*. (i)(C) is

redesignated as paragraph (ii) and the paragraph designation for *Example 30*. (i)(C) is removed.

■ 3. Paragraph (h)(1), first three sentences are revised.

■ 4. Paragraph (h)(3) is revised.

The revisions read as follows:

§ 1.861-8T Computation of taxable income from sources within the United States and from other sources and activities (temporary).

* * * * *

(b) * * *

(3) *Supportive functions.* Deductions which are supportive in nature (such as overhead, general and administrative, and supervisory expenses) may relate to other deductions which can more readily be allocated to gross income. In such instance, such supportive deductions may be allocated and apportioned along with the deductions to which they relate. On the other hand, it would be equally acceptable to attribute supportive deductions on some reasonable basis directly to activities or property which generate, have generated or could reasonably be expected to generate gross income. This would ordinarily be accomplished by allocating the supportive expenses to all gross income or to another broad class of gross income and apportioning the expenses in accordance with paragraph (c)(1) of this section. For this purpose, reasonable departmental overhead rates may be utilized. For examples of the application of the principles of this paragraph (b)(3) to expenses other than expenses attributable to stewardship activities, see *Examples 19* through *21* of paragraph (g) of this section. See paragraph (e)(4)(ii) of this section for the allocation and apportionment of deductions attributable to stewardship expenses. However, supportive deductions that are described in § 1.861-14T(e)(3) shall be allocated and apportioned in accordance with the rules of § 1.861-14T and shall not be allocated and apportioned by reference only to the gross income of a single member of an affiliated group of corporations as defined in § 1.861-14T(d).

* * * * *

(h) * * * (1) * * * In general, the rules of this section, as well as the rules of §§ 1.861-9T, 1.861-10T, 1.861-11T, 1.861-12T, and 1.861-14T apply for taxable years beginning after December 31, 1986, except for paragraphs (a)(5)(ii), (b)(3), (e)(4), (f)(4)(i), and paragraph (g) *Example 17*, *Example 18*, and *Example 30* of this section, which are generally applicable for taxable years beginning after December 31, 2006. Also, see §§ 1.861-8(e)(12)(iv) and 1.861-14(e)(6)

for rules concerning the allocation and apportionment of deductions for charitable contributions. In the case of corporate taxpayers, transition rules set forth in § 1.861-13T provide for the gradual phase-in of certain provisions of this and the foregoing sections. * * *

(3) *Expiration date.* The applicability of the paragraphs (a)(5)(ii), (b)(3), (e)(4), (f)(4)(i), and paragraph (g) *Example 17, Example 18, and Example 30* of this section, expires on or before July 31, 2009.

■ **Par. 8.** Section 1.6662-6T is amended by revising paragraph (d)(2)(ii)(B), first sentence to read as follows:

§ 1.6662-6T Transactions between parties described in section 482 and net section 482 transfer price adjustments (temporary).

* * * * *

(d)(2)(ii)(B) A taxpayer's selection of the services cost method for certain services, described in § 1.482-9T(b), and its application of that method to a controlled services transaction will be considered reasonable for purposes of the specified method requirement only if the taxpayer reasonably allocated and apportioned costs in accordance with § 1.482-9T(k), reasonably concluded that the controlled services transaction meets the conditions of § 1.482-9T(b)(3), and reasonably concluded that the controlled services transaction is not described in § 1.482-9T(b)(2). * * *

* * * * *

Cynthia Grigsby,

Senior Federal Register Liaison Officer, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. E6-21908 Filed 12-21-06; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 5

[TD 9304]

RIN 1545-BF26

Guidance Necessary To Facilitate Business Electronic Filing Under Section 1561

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains temporary regulations that affect component members of controlled groups of corporations and consolidated groups filing life-nonlife Federal income tax returns. They provide guidance

regarding the apportionment of tax benefit items and the amount and type of information these members are required to submit with their returns. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on December 22, 2006.

Applicability Date: For dates of applicability, see §§ 1.1502-43T(e)(1), 1.1502-47T(t)(1), 1.1561-1T(d)(1), 1.1561-2T(f)(1), 1.1561-3T(d)(1) and 1.1563-1T(e)(1). The applicability of these regulations will expire on December 21, 2009.

FOR FURTHER INFORMATION CONTACT: Grid Glycer, (202) 622-7930 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 1561(a) provides that the *component members of a controlled group of corporations* (as those terms are defined in section 1563) are limited to using the amounts of certain tax benefit items described therein in the same manner as if they were one corporation. Although section 1561(a) provides that these amounts shall generally be divided equally among those members, it also provides that if those members consent to adopt an apportionment plan, then, except as provided below, they will be permitted to allocate these amounts among themselves unequally. Section 1.1561-3(b) provides the procedural format by which those members may adopt an apportionment plan.

On May 26, 2006, the IRS and Treasury Department released temporary regulations (TD 9264), which, among other things, eliminated regulatory impediments to the electronic filing (e-filing) of many statements that corporate taxpayers were previously required to include on or with their Federal income tax returns. As noted in section 2.C. of the preamble to those regulations, § 1.1561-3(b) presents an impediment to the e-filing of that information which each member of a controlled group is required to provide with its Federal income tax return when it makes the consent provided therein. These temporary regulations remove that impediment and also clarify the amount and type of information that each member of such group is required to submit with its return, whether or not the group chooses to apportion unequally the specified tax benefit items among its

members. Thus, these regulations require each member of such group to provide the requisite information, whether or not it consents to adopt an apportionment plan, on a form (*i.e.*, Schedule O or any successor to that form) to be filed with each member's Federal income tax return for each taxable year for which it is a component member of a controlled group.

Explanation of Provisions

1. Revision of the Regulations Under Section 1561

The IRS and Treasury Department are publishing temporary regulations under section 1561 for several reasons. First, the current regulations are outdated in that they refer to tax benefit items that are no longer listed in section 1561(a). Except as provided below, to minimize this issue in the future, the temporary regulations refer generically to the tax benefit items listed in section 1561(a) rather than refer specifically to those items by listing and describing each one.

Second, the current regulations do not provide guidance to taxpayers regarding how to allocate the amounts of the section 1561(a) tax benefit items among the component members of a controlled group of corporations which have an apportionment plan in effect. As a result, the IRS often can not determine whether taxpayers have correctly allocated these items. Thus, the temporary regulations refer to a new form (*i.e.*, Schedule O or any successor to that form) on which such members will provide information about these items.

Except as provided below, each component member of a controlled group must file this form every year with its Federal income tax return whether or not: (1) An apportionment plan is in effect, or (2) any change is made to the group's apportionment of its section 1561(a) tax benefit items from the previous year. However, whenever one or more of the component members of a controlled group of corporations are also members of a consolidated group, the parent of such consolidated group shall file one form on behalf of all of its members. That form shall contain all the information required for each such member.

Finally, § 1.1561-3(b) presents an impediment to e-filing where such members have consented to the adoption of an apportionment plan. That section requires each member of a controlled group to attach to its return, for each year following the adoption of the plan, a copy of its signed consent to such plan. As explained in TD 9264,