

## PART 50—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for 21 CFR part 50 continues to read as follows:

**Authority:** 21 U.S.C. 321, 343, 346, 346a, 348, 350a, 350b, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 241, 262, 263b–263n.

■ 2. Revise § 50.23(e)(3) to read as follows:

### § 50.23 Exception from general requirements.

\* \* \* \* \*

(e) \* \* \*  
(3) The investigator must submit the written certification of the determinations made by the investigator and an independent physician required in paragraph (e)(1) or (e)(2) of this section to the IRB and FDA within 5 working days after the use of the device.

\* \* \* \* \*

Dated: June 17, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–15816 Filed 6–23–11; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 882

[Docket No. FDA–1997–N–0040] (formerly Docket No. 1997N–0484P)

#### Medical Devices; Neurological Devices; Clarification of Classification for Human Dura Mater; Technical Amendment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the device regulations to clarify the applicability of the device classification for human dura mater. This action is being taken to improve the accuracy of the regulations.

**DATES:** This final rule is effective June 24, 2011.

**FOR FURTHER INFORMATION CONTACT:** Melissa Reisman, 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:** FDA is clarifying the regulatory authority for human dura mater in the Agency's

codified regulations for part 882 (21 CFR part 882). In the **Federal Register** of November 24, 2004 (69 FR 68612), FDA published a final rule regarding current good tissue practice for establishments that manufacture human cell, tissue, and cellular and tissue-based products (HCT/Ps). That rule became effective on May 25, 2005. Prior to the effective date of the final rule, human dura mater was regulated as a medical device under § 882.5975. As stated in the final rule, human dura mater is now defined under 21 CFR 1271.3(d) as a HCT/P. As such, it is regulated under section 361 of the Public Health Service Act (42 U.S.C. 264) and the requirements of 21 CFR part 1271, including requirements related to registration and listing, donor eligibility determinations, and current good tissue practice. Accordingly, the device classification contained in § 882.5975 is only applicable for human dura mater recovered prior to the effective date of the final rule, May 25, 2005. The final rule omitted a corresponding annotation to § 882.5975 to clarify that the device classification is only applicable for human dura mater recovered prior to the effective date of the final rule. This document clarifies the regulatory authority for human dura mater. 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 is nonsubstantive.

#### List of Subjects in 21 CFR Part 882

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

#### PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for 21 CFR part 882 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 882.5975 is amended by adding paragraph (c) to read as follows:

#### § 882.5975 Human dura mater.

\* \* \* \* \*

(c) *Scope.* The classification set forth in this section is only applicable to human dura mater recovered prior to May 25, 2005.

Dated: June 17, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–15817 Filed 6–23–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[TD 9530]

**RIN 1545–BH56**

#### Guidance Under Section 956 for Determining the Basis of Property Acquired in Certain Nonrecognition Transactions

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final and temporary regulations.

**SUMMARY:** This document contains final and temporary regulations under section 956 of the Internal Revenue Code (Code) regarding the determination of basis in certain United States property acquired by a controlled foreign corporation in certain nonrecognition transactions that are intended to repatriate earnings and profits of the controlled foreign corporation without U.S. income taxation. The regulations affect United States shareholders of a controlled foreign corporation that acquires United States property in certain nonrecognition transactions.

**DATES:** *Effective Date:* These regulations are effective on June 24, 2011.

*Applicability Date:* For dates of applicability, see § 1.956–1(e)(6)(vii).

**FOR FURTHER INFORMATION CONTACT:** Kristine A. Crabtree at (202) 622–3840 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

#### Background and Explanation of Provisions

On June 24, 2008, the IRS published final and temporary regulations under section 956 (TD 9402) in the **Federal Register** (73 FR 35580). On the same date, the IRS published a notice of proposed rulemaking (REG–102122–08) (the proposed regulations) in the **Federal Register** (73 FR 35606) cross-referencing the temporary regulations. The temporary and proposed regulations provided guidance regarding the determination of basis in certain United States property (as defined in section 956(c)) acquired by a controlled foreign corporation (as defined in section 957(a)) in certain nonrecognition

transactions that are intended to repatriate earnings and profits of the controlled foreign corporation without an income inclusion by its United States shareholders under section 951(a)(1)(B). The purpose of these regulations is to prevent a United States shareholder of a controlled foreign corporation from avoiding an income inclusion under section 951(a)(1)(B) where the controlled foreign corporation acquires United States property in an exchange to which these regulations apply and claims a basis in the United States property that is less than the amount of earnings and profits repatriated. No comments in response to the proposed regulations were received and no public hearing was requested or held. This Treasury decision adopts the proposed regulations with minor changes, described below, as final regulations and removes the corresponding temporary regulations.

Language was added to § 1.956-1(e)(6)(iii) to clarify the effect of the assumption of a liability by a controlled foreign corporation in connection with an exchange to which § 1.956-1(e)(6) applies. The final regulations also modify § 1.956-1(e)(6)(v) to address the situation in which the controlled foreign corporation exchanges specified United States property the adjusted basis in which has been determined under § 1.956-1(e)(6) for other United States property, by providing that for purposes of applying section 956 the controlled foreign corporation's adjusted basis in the other United States property is no less than its adjusted basis in the specified United States property as determined under § 1.956-1(e)(6)(iii). A cross-reference to the anti-abuse rule of § 1.956-1T(b)(4) was also added to § 1.956-1(e)(6)(vi), *Example 3*.

#### Effective/Applicability Dates

These final regulations apply to property acquired in exchanges occurring on or after June 24, 2011. For transactions that occur prior to June 24, 2011, see § 1.956-1T(e)(6) as contained in 26 CFR Part 1 revised as of April 1, 2011.

#### Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866; therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C.

chapter 6) does not apply. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

#### Drafting Information

The principal author of these regulations is Kristine A. Crabtree, Office of Associate Chief Counsel (International). However, other personnel from the IRS and the Treasury Department participated in their development.

#### List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

#### Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

#### PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order to read in part as follows:

**Authority:** 26 U.S.C. 7805 \* \* \*  
Section 1.956-1(e)(6) also issued under 26 U.S.C. 367(b) and 956(e).

■ **Par. 2.** Section 1.956-1 is amended by revising the last sentence of paragraph (e)(1), revising paragraphs (e)(5) and (e)(6), and removing paragraph (f).

The revisions read as follows:

#### § 1.956-1 Shareholder's pro rata share of a controlled foreign corporation's increase in earnings invested in United States property.

\* \* \* \* \*

(e) \* \* \*

(1) \* \* \* See § 1.956-1(e)(6) for a special rule for determining amounts attributable to United States property acquired as the result of certain nonrecognition transactions.

\* \* \* \* \*

(5) [Reserved]. For further guidance, see § 1.956-1T(e)(5).

(6) *Adjusted basis of property acquired in certain nonrecognition transactions*—(i) *Scope.* This paragraph (e)(6) provides rules for determining, solely for purposes of applying section 956, the adjusted basis of specified United States property acquired by a controlled foreign corporation pursuant to an exchange in which the controlled foreign corporation's basis in such specified United States property is determined under section 362(a). This paragraph (e)(6) also applies if specified United States property, the adjusted basis in which has been determined

under these regulations, is transferred (in one or more subsequent exchanges) to a related person (within the meaning of section 954(d)(3)), pursuant to one or more exchanges in which the related person's adjusted basis in such property is determined, in whole or in part, by reference to the transferor controlled foreign corporation's adjusted basis in such property.

(ii) *Definition of specified United States property.* For purposes of this paragraph (e)(6), *specified United States property* is stock of a domestic corporation described in section 956(c)(1)(B) or an obligation of a domestic corporation described in section 956(c)(1)(C) that is acquired by a controlled foreign corporation from the domestic issuing corporation. Specified United States property does not include property described in section 956(c)(2).

(iii) *Adjusted basis of specified United States property.* Solely for purposes of applying section 956, the adjusted basis of specified United States property acquired by a controlled foreign corporation in connection with an exchange to which this paragraph (e)(6) applies shall be no less than the fair market value of any property transferred by the controlled foreign corporation in exchange for such specified United States property. For purposes of this paragraph (e)(6), the term *property* has the meaning set forth in section 317(a), but also includes any liability that is assumed by the controlled foreign corporation in connection with the exchange notwithstanding the application of section 357(a). The assumption of a liability by the controlled foreign corporation in connection with the exchange will be considered the transfer of property. The fair market value of such property will be the amount of the liability assumed. The fair market value of any property transferred by the controlled foreign corporation in exchange for the specified United States property shall be determined at the time of the exchange.

(iv) *Timing.* For purposes of § 1.956-2(d)(1)(i)(a), a controlled foreign corporation that acquires specified United States property in an exchange to which this paragraph (e)(6) applies acquires an adjusted basis in such property at the time of the controlled foreign corporation's exchange of property for such specified United States property.

(v) *Transfers to related persons.* If a controlled foreign corporation transfers specified United States property, the adjusted basis in which has been determined under this paragraph (e)(6), to a related person (within the meaning

of section 954(d)(3)) (related person transferee) in one or more exchanges pursuant to which the related person transferee's adjusted basis in such specified United States property is determined, in whole or in part, by reference to the controlled foreign corporation's adjusted basis in such specified United States property, then, solely for purposes of applying section 956 following such exchange, the controlled foreign corporation's adjusted basis in any United States property received in the exchange (or exchanges) shall be no less than the aggregate adjusted basis of the specified United States property as determined under paragraph (e)(6)(iii) of this section, and the related person transferee's adjusted basis in such specified United States property shall be no less than the adjusted basis of such specified United States property in the hands of the controlled foreign corporation as determined under paragraph (e)(6)(iii) of this section. This paragraph (e)(6)(v) shall also apply in the case of one or more successive transfers of the specified United States property by a related person transferee to one or more persons related to the controlled foreign corporation (within the meaning of section 954(d)(3)). This paragraph (e)(6)(v) shall apply regardless of whether a subsequent transfer was part of a plan (or series of related transactions) that includes the controlled foreign corporation's acquisition of the specified United States property.

(vi) *Examples.* The rules of this paragraph (e)(6) are illustrated by the following examples:

*Example 1. (i) Facts.* USP, a domestic corporation, is the common parent of an affiliated group that joins in the filing of a consolidated return. USP owns 100 percent of the stock of US1 and US2, both domestic corporations and members of the USP consolidated group. US1 owns 100 percent of the stock of CFC, a controlled foreign corporation. US2 issues \$100x of its stock to CFC in exchange for \$10x of CFC stock and \$90x cash. US2's transfer of its stock to CFC is described in section 351, US2 recognizes no gain in the exchange under section 1032(a), and CFC's basis in the US2 stock acquired in the exchange is determined under section 362(a).

(ii) *Analysis.* The US2 stock acquired by CFC in the exchange constitutes specified United States property under paragraph (e)(6)(ii) of this section because CFC acquires the US2 stock from US2, the issuing corporation. Therefore, because CFC's adjusted basis in the US2 stock is determined under section 362(a), then for purposes of applying section 956, CFC's adjusted basis in the US2 stock shall, under paragraph (e)(6)(iii) of this section, be no less than \$90x, the fair market value of the property

exchanged by CFC for the US2 stock (the \$10x of CFC stock issued in the exchange does not constitute property for purposes of paragraph (e)(6)(iii) of this section). Pursuant to paragraph (e)(6)(iv) of this section, for purposes of § 1.956-2(d)(1)(i)(a) CFC shall be treated as acquiring its adjusted basis of no less than \$90x in the US2 stock at the time of its transfer of property to US2 in exchange for the US2 stock. The result would be the same if, instead of CFC transferring \$90x of cash to US2 in the exchange, CFC assumes a \$90x liability of US2.

*Example 2. (i) Facts.* USP, a domestic corporation, owns 100 percent of the stock of USS, a domestic corporation. USP also owns 100 percent of the stock of CFC, a controlled foreign corporation. USP's adjusted basis in its USS stock equals the fair market value of the USS stock, or \$100x. USP transfers its USS stock to CFC in exchange for \$100x of CFC stock. USP's transfer of its USS stock to CFC is described in section 351, USP recognizes no gain in the exchange under section 351(a), and CFC's adjusted basis in the USS stock acquired in the exchange, determined under section 362(a), equals \$100x.

(ii) *Analysis.* The USS stock acquired by CFC in the exchange does not constitute specified United States property under paragraph (e)(6)(ii) of this section because CFC acquires the USS stock from USP. Therefore, CFC's adjusted basis in the USS stock, for purposes of section 956, is not determined under this paragraph (e)(6). Instead, CFC's adjusted basis in the USS stock is determined under the general rule of section 956(a) and under paragraphs (e)(1) through (4) of this section. As determined under section 362(a), CFC's adjusted basis in the USS stock is \$100x.

*Example 3. (i) Facts.* USP, a domestic corporation, owns 100 percent of the stock of CFC1, a controlled foreign corporation. CFC1 holds specified United States property (within the meaning of paragraph (e)(6)(ii) of this section) with an adjusted basis of \$30x for purposes of applying section 956 that was determined under paragraph (e)(6)(iii) of this section. CFC1 owns 100 percent of the stock of CFC2, a controlled foreign corporation. CFC1 transfers the specified United States property to CFC2 in an exchange described in section 351. CFC2's adjusted basis in the specified United States property is determined under section 362(a).

(ii) *Analysis.* In the section 351 exchange, CFC1 transferred specified United States property to CFC2 with an adjusted basis that was determined under paragraph (e)(6)(iii) of this section. Further, CFC2's adjusted basis in the specified United States property is determined under section 362(a) by reference, in whole or in part, to CFC1's adjusted basis in such property. Therefore, for purposes of applying section 956, pursuant to paragraph (e)(6)(v) of this section CFC2's adjusted basis in the specified United States property shall be no less than \$30x. Paragraph (e)(6)(v) of this section would also apply if CFC2 subsequently transfers the specified United States property to another person related to CFC1 (within the meaning of section 954(d)(3)) if such related person's adjusted basis in the specified United States

property is determined by reference, in whole or in part, to CFC2's adjusted basis in such property. See also § 1.956-1T(b)(4) if one of the principal purposes of CFC1's transfer of property to CFC2 was the avoidance of the application of section 956 with respect to CFC1.

(vii) *Effective/applicability dates.* This paragraph (e)(6) applies to property acquired in exchanges occurring on or after June 24, 2011. For transactions that occur prior to June 24, 2011, see § 1.956-1T(e)(6) as contained in 26 CFR Part 1 revised as of April 1, 2011.

■ **Par. 3.** Section 1.956-1T is amended by removing paragraph (e)(6) and revising paragraph (f) to read as follows:

**§ 1.956-1T Shareholder's pro rata share of a controlled foreign corporation's increase in earnings invested in United States property (temporary).**

\* \* \* \* \*

(f) *Effective/applicability date.* Paragraph (e)(5) of this section applies to investments made on or after June 14, 1988.

**Steven T. Miller,**  
*Deputy Commissioner for Services and Enforcement.*

Approved: June 11, 2011.

**Emily S. Mahon,**  
*Acting Assistant Secretary of the Treasury (Tax Policy).*

[FR Doc. 2011-15741 Filed 6-23-11; 8:45 am]

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**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

[TD 9529]

**RIN 1545-BK01**

**Requirements for Taxpayers Filing Form 5472; Correction**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Correcting amendment.

**SUMMARY:** This document contains correcting amendments to temporary regulations (TD 9529) that were published in the **Federal Register** on Friday, June 10, 2011 (76 FR 33997) removing the duplicate filing requirement for Form 5472, "Information Return of a 25% Foreign-Owned U.S. corporation or a Foreign Corporation Engaged in a U.S. Trade or Business."

**DATES:** This correction is effective on June 24, 2011, and is applicable on June 10, 2011.