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]

BILLING CODE 4160–01–P

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