between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 886

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

§ 886.5200 Eyelid thermal pulsation system.

(a) Identification. An eyelid thermal pulsation system is an electrically-powered device intended for use in the application of localized heat and pressure therapy to the eyelids. The device is used in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye. The system consists of a component that is inserted around the eyelids and a component to control the application of heat and pressure to the eyelids.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing should validate electromagnetic compatibility (EMC) and safety of exposure to non-ionizing radiation;

(2) Design, description, and performance data should validate safeguards related to the temperature and pressure aspects of the device, including during fault conditions;

(3) Performance data should demonstrate the sterility of patient-contacting components and the shelf-life of these components;

(4) The device should be demonstrated to be biocompatible; and

(5) Performance data should demonstrate that any technological changes do not adversely effect safety and effectiveness.

Dated: August 12, 2011.

Nancy K. Stade,
Deputy Director for Policy, Center for Devices and Radiological Health.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9538]

RIN 1545–BK14

Modifications of Certain Derivative Contracts; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final and temporary regulations.

SUMMARY: This document describes corrections to final and temporary regulations (TD 9538) that address when a transfer or assignment of certain derivative contracts does not result in an exchange to the nonassigning counterpart for purposes of § 1.1001–1(a). These regulations were published in the Federal Register on Friday, July 22, 2011.

DATES: This correction is effective on August 19, 2011, and is applicable on July 22, 2011.

FOR FURTHER INFORMATION CONTACT: Andrea M. Hoffenson, (202) 622–3920 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations that are the subject of this correction are under section 1001 of the Internal Revenue Code.

Need for Correction

As published July 22, 2011 (76 FR 43892), final and temporary regulations (TD 9538) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the final and temporary regulations (TD 9538) which were the subject of FR Doc. 2011–18529 is corrected as follows:

1. On page 43892, column 3, in the preamble, under the paragraph heading “Explanation of Provisions”, first paragraph of the column, lines 5, 6, and 7, the language “in securities or a clearinghouse transfers or assigns a derivative contract to another dealer in securities or” is corrected to read “or a clearinghouse transfers or assigns a derivative contract to another dealer or”.

2. On page 43892, column 3, in the preamble, under the paragraph heading “Explanation of Provisions”, first paragraph of the column, lines 12 and 13, the language “those described in section 475(c)(2)(D), 475(c)(2)(E), or 475(c)(2)(F). In addition,” is corrected to read “those described in sections 475(c)(2)(D), 475(c)(2)(E), and 475(c)(2)(F), or 475(e)(2)(B), 475(e)(2)(C), or 475(e)(2)(D), or § 1.446–3(c)(1). In addition.”.

3. On page 43892, column 3, in the preamble, under the paragraph heading “Special Analyses”, the last line of the paragraph, the language “on their impact on small businesses.” is corrected to read “on their impact on small businesses.”.

LaNita Van Dyke,
Chief, Publications and Regulations Branch.

[FR Doc. 2011–21179 Filed 8–18–11; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9538]

RIN 1545–BK14

Modifications of Certain Derivative Contracts; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document describes correcting amendments to final and temporary regulations (TD 9538) that address when a transfer or assignment of certain derivative contracts does not result in an exchange to the nonassigning counterpart for purposes.

These regulations were published in the Federal Register on Friday, July 22, 2011.

DATES: This correction is effective on August 19, 2011, and is applicable beginning July 22, 2011.

FOR FURTHER INFORMATION CONTACT: Andrea M. Hoffenson, (202) 622–3920 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations that are the subject of this correction are under section 1001 of the Internal Revenue Code.

Need for Correction

As published July 22, 2011 (76 FR 43892), the final and temporary regulations (TD 9538) contain errors that may prove to be misleading and are in need of clarification.
PART 1—INCOME TAXES

§ 1.1001–4T Modifications of certain derivative contracts (temporary).

(a) * * * *

(1) Both the party transferring or assigning its rights and obligations under the derivative contract and the party to which the rights and obligations are transferred or assigned are either a dealer or a clearinghouse; * * * *

(b) * * * *

(1) Dealer. For purposes of this section, a dealer is a taxpayer who meets the definition of a dealer in securities in section 475(c)(1) or is a dealer in commodities derivative contracts.

* * * *

(3) Derivative contract. For purposes of this section, a derivative contract is a contract described in—

(i) Section 475(c)(2)(D), 475(c)(2)(E), or 475(c)(2)(F) without regard to the last sentence of section 475(c)(2) referencing section 1256;

(ii) Section 475(e)(2)(B), 475(e)(2)(C), or 475(e)(2)(D); or

(iii) Section 1.446–3(c)(1).

* * * *

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

[FR Doc. 2011–21180 Filed 8–18–11; 8:45 am]
BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 17
[TD 9546]
RIN 1545–BD04

Definition of Solid Waste Disposal Facilities for Tax-Exempt Bond Purposes

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations on the definition of solid waste disposal facilities for purposes of the rules applicable to tax-exempt bonds issued by State and local governments. These regulations provide guidance to State and local governments that issue tax-exempt bonds to finance solid waste disposal facilities and to taxpayers that use those facilities.

DATES: Effective Date: These regulations are effective August 19, 2011.

Applicability Date: For dates of applicability, see § 1.142(a)(6)–1(i).

FOR FURTHER INFORMATION CONTACT: Timothy Jones, (202) 622–3980 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document amends the Income Tax Regulations (26 CFR part 1) under section 142 of the Internal Revenue Code (Code) to provide final rules for determining whether a facility is a solid waste disposal facility under section 142(a)(6). This document also removes certain existing regulations on this subject. On September 16, 2009, the IRS published a Notice of Proposed Rulemaking (REG–140492–02) in the Federal Register (74 FR 47500) (the Proposed Regulations). The Proposed Regulations under proposed § 1.142(a)(6)–1 would modify existing regulations under § 1.103–8(f)(2) of the Income Tax Regulations and § 17.1 of the temporary Income Tax Regulations (together, the Existing Regulations) on this subject. Public comments on the Proposed Regulations were received and a public hearing was held on January 5, 2010.

After consideration of the public comments, the IRS and the Treasury Department adopt the Proposed Regulations, with revisions, as final regulations by this Treasury decision (the Final Regulations). Significant aspects of the public comments and the revisions made in the Final Regulations are discussed in this preamble.

Explanation of Provisions

1. Introduction

In general, interest on State or local bonds is excludable from gross income under section 103(a). Under section 103(b), however, interest on private activity bonds is excludable from gross income under section 103 only if the bond meets the requirements for a qualified bond under section 141(e) and other applicable requirements under section 103. Section 141(e) defines a qualified bond to include an exempt facility bond that meets certain requirements. Section 142(a) defines an exempt facility bond to mean any bond that is issued as part of an issue 95 percent or more of the net proceeds of which are to be used to provide an exempt facility specified in section 142(a). Section 142(a)(6) includes a solid waste disposal facility as one specified type of qualified exempt facility.

In general, the Proposed Regulations addressed the requirements for solid waste disposal facilities under section 142(a)(6) for purposes of eligibility for tax-exempt private activity bond financing. The Proposed Regulations provided that a facility qualifies as a solid waste disposal facility if it processes solid waste in a qualified solid waste disposal process, performs preliminary functions, or is a functionally related or subordinate facility. The Proposed Regulations also provided a more developed definition of solid waste which focused on used materials and residual materials, with certain specific exclusions. The Proposed Regulations eliminated a “no-value” test from the solid waste definition under § 1.103–8(f)(2)(ii)(b) of the Existing Regulations, which provides that material does not qualify as solid waste unless, on the issue date of the tax-exempt bonds used to provide the solid waste disposal facility, the property is useless, unused, unwanted, or discarded solid material “that has no market or other value at the place where the property is located” (No-Value Test). The Proposed Regulations also proposed various allocation and accounting rules based on existing principles for mixed-input facilities and mixed-use facilities. Overall, the Proposed Regulations implement a policy in favor of recycling through the use of solid waste disposal facilities.

Commentators generally supported the approach taken towards solid waste disposal facilities.