

and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910-0485.

## VII. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) of the FD&C Act as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this final order, we are revoking the requirements in 21 CFR 872.3640 related to the classification of blade-form endosseous implants as class III devices and codifying the reclassification of blade-form endosseous into class II.

### List of Subjects in 21 CFR Part 872

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 872 is amended as follows:

### PART 872—DENTAL DEVICES

■ 1. The authority citation for 21 CFR part 872 continues to read as follows:

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

■ 2. Section 872.3640 is amended by revising paragraph (a) and (b)(2) to read as follows:

#### § 872.3640 Endosseous dental implant.

(a) *Identification.* An endosseous dental implant is a prescription device made of a material such as titanium or titanium alloy that is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.

(b) \* \* \*

(2) *Classification.* Class II (special controls). The device is classified as class II if it is a blade-form endosseous dental implant. The special controls for this device are:

(i) The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use;

(ii) Mechanical performance (fatigue) testing under simulated physiological conditions to demonstrate maximum load (endurance limit) when the device is subjected to compressive and shear loads;

(iii) Corrosion testing under simulated physiological conditions to demonstrate corrosion potential of each metal or alloy, couple potential for an assembled dissimilar metal implant system, and corrosion rate for an assembled dissimilar metal implant system;

(iv) The device must be demonstrated to be biocompatible;

(v) Sterility testing must demonstrate the sterility of the device;

(vi) Performance testing to evaluate the compatibility of the device in a magnetic resonance (MR) environment;

(vii) Labeling must include a clear description of the technological features, how the device should be used in patients, detailed surgical protocol and restoration procedures, relevant precautions and warnings based on the clinical use of the device, and qualifications and training requirements for device users including technicians and clinicians;

(viii) Patient labeling must contain a description of how the device works, how the device is placed, how the patient needs to care for the implant, possible adverse events and how to report any complications; and

(ix) Documented clinical experience must demonstrate safe and effective use and capture any adverse events observed during clinical use.

Dated: June 12, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 301

[TD 9669]

RIN 1545-BM25

#### Participation of a Person Described in Section 6103(n) in a Summons Interview Under Section 7602(a)(2) of the Internal Revenue Code

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

**ACTION:** Temporary regulations.

**SUMMARY:** This document contains temporary regulations modifying regulations promulgated under section

7602(a) of the Internal Revenue Code relating to administrative summonses. Specifically, these temporary regulations clarify that persons with whom the IRS or the Office of Chief Counsel (Chief Counsel) contracts for services described in section 6103(n) and its implementing regulations may be included as persons designated to receive summoned books, papers, records, or other data and to take summoned testimony under oath. These temporary regulations may affect taxpayers, a taxpayer's officers or employees, and any third party who is served with a summons, as well as any other person entitled to notice of a summons. The text of these temporary regulations serves as the text of the proposed regulations (REG-121542-14) 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 June 18, 2014.

*Applicability Date:* For date of applicability, see paragraph (d) of this temporary regulation.

**FOR FURTHER INFORMATION CONTACT:** A M Gulas at (202) 317-6834 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

#### Background and Explanation of Provisions

These temporary regulations amend Procedure and Administration Regulations (26 CFR part 301) promulgated under section 7602 of the Internal Revenue Code. These temporary regulations make clear that persons described in section 6103(n) and Treas. Reg. § 301.6103(n)-1(a) with whom the IRS or Chief Counsel contracts for services may receive books, papers, records, or other data summoned by the IRS and take testimony of a person who the IRS has summoned as a witness to provide testimony under oath. While IRS officers and employees remain responsible for issuing summonses and developing and conducting examinations, the temporary regulations clarify that contractors are permitted to participate fully in a summons interview. Full participation includes, but is not limited to, receipt, review, and use of summoned books, papers, records, or other data, being present during summons interviews, questioning the person providing testimony under oath, and asking a summoned person's representative to clarify an objection or an assertion of privilege.

The assistance of persons from outside the IRS or Chief Counsel promotes efficient administration and enforcement of laws administered by the IRS, by providing specialized knowledge, skills, or abilities that the IRS officers or employees assigned to the case may not possess. For example, outside persons often assist the IRS in matters involving transfer pricing. To clarify the role of these outside persons, these temporary regulations expressly provide that when an IRS officer or employee summons a taxpayer or other witness to produce books, papers, records, or other data and/or to give testimony, an outside person hired by the IRS or Chief Counsel authorized to receive returns or return information pursuant to section 6103(n) may receive the summoned books, papers, records, or other data and take the testimony of the witness under oath.

When the IRS hires an outside person to assist an IRS officer or employee to review books and papers, analyze data, or take testimony from a summoned witness, the IRS will ensure that the inherently governmental functions associated with section 7602, for example, deciding whether to issue a summons, deciding whom to summon, what information must be produced or who will be required to testify, and issuing the summons, will still be performed by an IRS officer or employee. The contractors' role will be limited to functions that are not inherently governmental, such as taking testimony by asking questions, reviewing books or papers, or analyzing other data. As a further safeguard, the temporary regulations expressly provide that any contractor that the IRS authorizes to ask questions of a summoned witness testifying under oath must do so in the presence and under the guidance of an IRS officer or employee.

The conclusion that contractors may receive summoned books and papers, analyze data, and question summoned witnesses is consistent with Treas. Reg. § 301.7602-2(c)(1)(i)(B) and (c)(1)(ii) *Example 2*. Under those rules, which implement the provision requiring notice to the taxpayer of contacts by IRS officers or employees with third parties, contractors (in this case appraisers) are treated in the same manner as IRS officers or employees when they contact industry experts to discuss a taxpayer's business.

The temporary regulations are effective for summons interviews conducted on or after June 18, 2014. The applicability of the temporary regulations will expire on June 16, 2017.

### Special Analyses

It has been determined that this Treasury Decision is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. The IRS has determined that sections 553(b) and (d) of the Administrative Procedure Act (5 U.S.C. chapter 5) do 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 Internal Revenue Code, the IRS will submit these temporary regulations to the Chief Counsel for Advocacy of the Small Business Administration for comments about the regulations' impact on small business.

### Drafting Information

The principal author of these regulations is A M Gulas of the Office of Associate Chief Counsel (Procedure and Administration).

### List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

### Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 301 is amended as follows:

### PART 301—PROCEDURE AND ADMINISTRATION

#### ■ Paragraph 1.

The authority citation for part 301 continues to read in part as follows:

**Authority:** 26 U.S.C. 7805 \* \* \*

■ **Par. 2.** Section 301.7602-1T is added to read as follows:

#### § 301.7602-1T Examination of books and witnesses (temporary).

(a) [Reserved]. For further guidance, see § 301.7602-1(a).

(b) through (b)(2) [Reserved]. For further guidance, see § 301.7602-1(b) through (b)(2).

(b)(3) *Participation of a person described in section 6103(n)*. For purposes of this paragraph (b), a person authorized to receive returns or return information under section 6103(n) and § 301.6103(n)-1(a) of the regulations may receive and examine books, papers, records, or other data produced in compliance with the summons and, in the presence and under the guidance of

an IRS officer or employee, participate fully in the interview of the witness summoned by the IRS to provide testimony under oath. Fully participating in an interview includes, but is not limited to, receipt, review, and use of summoned books, papers, records, or other data; being present during summons interviews; questioning the person providing testimony under oath; and asking a summoned person's representative to clarify an objection or assertion of privilege.

(c) [Reserved]. For further guidance, see § 301.7602-1(c).

(d) *Effective/applicability date*. This section applies to summons interviews conducted on or after June 18, 2014.

(e) *Expiration date*. The applicability of this section expires on or before June 16, 2017.

**Heather C. Maloy,**

*Acting Deputy Commissioner for Services and Enforcement.*

Approved: June 9, 2014

**Mark J. Mazur,**

*Assistant Secretary of the Treasury (Tax Policy).*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG-2013-0214]

#### Safety Zones; Recurring Events in Captain of the Port Duluth Zone—Point to LaPointe Swim

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce the safety zone in 33 CFR 165.943 for the Point to LaPointe Swim in LaPointe, WI from 7:20 a.m. through 10 a.m. on August 2, 2014. This action is necessary to protect participants and spectators during the Point to LaPointe swim. During the enforcement period, entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Duluth or his designated on-scene representative.

**DATES:** The regulations in 33 CFR 165.943(b) will be enforced from 7:20 a.m. through 10 a.m. on August 2, 2014, for the Point to LaPointe Swim safety zone, § 165.943(a)(7).