Act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Does this final rule have federalism implications?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to "construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Federal law includes an express preemption provision that preempts certain State requirements "different from or in addition to" certain Federal requirements applicable to devices. 21 U.S.C. 360k; *See Medtronic* v. *Lohr* 518 U.S. 470 (1996); *Riegel* v. *Medtronic,* 552 U.S. 312 (2008). The special controls established by this final rule create "requirements" to address each identified risk to health presented by these specific medical devices under 21 U.S.C. 360k, even though product sponsors have flexibility in how they meet those requirements. Cf. *Papike* v. *Tambrands,* Inc., 107 F. 3d 737, 740–42 (9th Cir. 1997).

V. How does this rule comply with the paperwork reduction act of 1995?

This final rule contains no collections of new information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required. Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice announcing availability of the guidance for the final rule. This guidance entitled "Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use" references previously approved collections of information found in FDA regulations.

VI. What references are on display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Zeltiq Aesthetics, October 13, 2009.

List of Subjects in 21 CFR Part 878

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 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

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

■ 2. Section 878.4340 is added to subpart E to read as follows:

§ 878.4340 Contact cooling system for aesthetic use.

(a) *Identification.* A contact cooling system for aesthetic use is a device that is a combination of a cooling pad associated with a vacuum or mechanical massager intended for the disruption of adipocyte cells intended for non-invasive aesthetic use.

(b) *Classification.* Class II (special controls). The special controls for this device is FDA's "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Contact Cooling System for Aesthetic Use." See § 878.1(e) for the availability of this guidance document.

Dated: February 1, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–2552 Filed 2–4–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9514]

RIN 1545–BG34

Time and Manner for Electing Capital Asset Treatment for Certain Self-Created Musical Works

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulation and removal of temporary regulation.

SUMMARY: This document contains a final regulation that provides the time and manner rules for electing to treat the sale or exchange of a musical composition or a copyright in a musical work created by the taxpayer (or received by the taxpayer from the composition or work's creator in a transferred basis transaction) as the sale or exchange of a capital asset. The regulation reflects changes to the law made by the Tax Increase Prevention and Reconciliation Act of 2005 and the Tax Relief and Health Care Act of 2006. The regulation affects taxpayers who elect to treat gain or loss from such a sale or exchange as capital gain or loss.

DATES: *Effective Date:* This regulation is effective on February 7, 2011.

Applicability Date: For date of applicability, see § 1.1221–3(d).

FOR FURTHER INFORMATION CONTACT: Jamie Kim, (202) 622–4950 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains an amendment to the Income Tax Regulations (26 CFR part 1). On February 8, 2008, a temporary regulation (TD 9379) was published in the **Federal Register** (73 FR 7464) that provided the time and manner rules for electing capital asset treatment for certain self-created musical works. A notice of proposed rulemaking (REG–153589–06) cross-referencing the temporary regulation also was published in the **Federal Register** (73 FR 7503) on February 8, 2008. No comments in response to the notice of proposed rulemaking or requests to hold a public hearing were received, and no hearing was held. This Treasury decision adopts the proposed regulation with minor changes and removes the temporary regulation.

Section 1221(a) of the Internal Revenue Code (Code) generally provides that capital assets include all property

held by a taxpayer with certain specified exclusions. Section 1221(a)(1) excludes from the definition of a capital asset inventory property or property held by a taxpayer primarily for sale to customers in the ordinary course of the taxpayer's trade or business. Section 1221(a)(3) excludes from the definition of a capital asset certain property—a copyright; a literary, musical, or artistic composition; a letter or memorandum; or similar property—held by a taxpayer whose personal efforts created the property (or held by a taxpayer whose basis in the property is determined by reference to the basis of such property in the hands of the taxpayer whose personal efforts created the property).

Section 1221(b)(3) of the Code, added by section 204 of the Tax Increase Prevention and Reconciliation Act of 2005, Public Law 109–222 (120 Stat. 345 (2005)), and amended by section 412 of the Tax Relief and Health Care Act of 2006, Public Law 109–432 (120 Stat. 2922 (2006)), provides that, at the election of a taxpayer, the section 1221(a)(1) and (a)(3) exclusions from capital asset status will not apply to a musical composition or a copyright in a musical work sold or exchanged by a taxpayer described in section 1221(a)(3). Thus, if a taxpayer who owns a musical composition or copyright in a musical work created by the taxpayer (or transferred to the taxpayer by the composition or work's creator in a transferred basis transaction) elects the application of this provision, gain or loss from the sale or exchange of the musical composition or copyright is treated as capital gain or loss.

Explanation of Provisions

This final regulation provides rules regarding the time and manner for electing under section 1221(b)(3) to treat gain or loss from the sale or exchange of certain musical compositions or copyrights in musical works as gain or loss from the sale or exchange of a capital asset.

Effective/Applicability Date

This regulation applies to elections under section 1221(b)(3) in taxable years beginning after May 17, 2006.

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 this regulation, and because the regulation does 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, the notice of proposed rulemaking preceding this regulation was 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 this regulation is Jamie Kim of the Office of Associate Chief Counsel (Income Tax & Accounting). However, other personnel from the IRS and the Treasury Department participated in its 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 continues to read in part as follows:

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

■ **Par. 2.** Section 1.1221–3 is added to read as follows:

§ 1.1221–3 Time and manner for electing capital asset treatment for certain self-created musical works.

(a) *Description.* Section 1221(b)(3) allows an electing taxpayer to treat the sale or exchange of a musical composition or a copyright in a musical work created by the taxpayer's personal efforts (or having a basis determined by reference to the basis of such property in the hands of a taxpayer whose personal efforts created such property) as the sale or exchange of a capital asset. As a consequence, gain or loss from the sale or exchange is treated as capital gain or loss.

(b) *Time and manner for making the election.* An election described in this section is made separately for each musical composition (or copyright in a musical work) sold or exchanged during the taxable year. An election must be made on or before the due date (including extensions) of the income tax return for the taxable year of the sale or exchange. The election is made on Schedule D, "Capital Gains and Losses," of the appropriate income tax form (for example, Form 1040, "U.S. Individual Income Tax Return;" Form 1065, "U.S. Return of Partnership Income;" Form 1120, "U.S. Corporation Income Tax Return") by treating the sale or exchange as the sale or exchange of a capital asset, in accordance with the form and its instructions.

(c) *Revocability of election.* The election described in this section is revocable with the consent of the Commissioner. To seek consent to revoke the election, a taxpayer must submit a request for a letter ruling under the applicable administrative procedures. Alternatively, an automatic extension of 6 months from the due date of the taxpayer's income tax return (excluding extensions) is granted to revoke the election, provided the taxpayer timely filed the taxpayer's income tax return and, within this 6-month extension period, the taxpayer files an amended income tax return that treats the sale or exchange as the sale or exchange of property that is not a capital asset.

(d) *Effective/applicability date.* This section applies to elections under section 1221(b)(3) in taxable years beginning after May 17, 2006.

§ 1.1221–3T [Removed]

■ **Par. 3.** Section 1.1221–3T is removed.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

Approved: January 28, 2011.

Michael Mundaca,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2011–2549 Filed 2–4–11; 8:45 am]

BILLING CODE 4830–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Part 1254

[NARA–10–0005]

RIN 3095–AB69

Appeal Authority When Researcher Privileges Are Revoked

AGENCY: National Archives and Records Administration.

ACTION: Direct final rule.

SUMMARY: The National Archives and Records Administration (NARA) is changing the appeal authority for researchers whose privileges have been revoked for specific behaviors, from the Archivist of the United States to the Deputy Archivist of the United States. This change will align the appeal authority for researchers whose research privileges have been revoked with the appeal authority for individuals who have been banned from NARA facilities