Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Federalism

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 Inc.,* v. *Lohr,* 518 U.S. 470 (1996); and *Riegel* v. *Medtronic, Inc.,* 552 U.S. 312 (2008). The special controls established by this final rule create ''requirements'' for specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements. Cf. *Papike* v. *Tambrands, Inc.,* 107 F.3d 737, 740–742 (9th Cir. 1991).

V. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520) is not required. This final rule establishes as special controls a guidance document that refers to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by OMB under the PRA.

VI. References

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 Ulthera, Inc., April 11, 2008.

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 878.4590 is added to subpart E to read as follows:

§ 878.4590 Focused ultrasound stimulator system for aesthetic use.

(a) *Identification.* A Focused Ultrasound Stimulator System for Aesthetic Use is a device using focused ultrasound to produce localized, mechanical motion within tissues and cells for the purpose of producing either localized heating for tissue coagulation or for mechanical cellular membrane disruption intended for noninvasive aesthetic use.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Focused Ultrasound Stimulator System for Aesthetic Use.'' See § 878.1(e) for the availability of this guidance document.

Dated: July 15, 2011.

Nancy K. Stade,

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

[FR Doc. 2011–18278 Filed 7–19–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 41

[TD 9537]

RIN 1545–BK36

Highway Use Tax; Filing and Payment for Taxable Period Beginning July 1, 2011

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations that provide guidance on the filing of Form 2290 (''Heavy Highway Vehicle Use Tax Return'') and payment of the associated highway use tax for the taxable period beginning July 1, 2011. The regulations affect owners and operators of highway motor vehicles with a taxable gross weight of 55,000 pounds or more. The text of the temporary regulations also serves as the text of the proposed regulations on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on July 20, 2011.

Applicability Date: For dates of applicability, see §§ 41.6001–2T(d), 41.6071(a)–1T(c)(3), and 41.6151(a)–1T(b).

FOR FURTHER INFORMATION CONTACT: Natalie Payne, (202) 622–3130 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document amends the Highway Use Tax Regulations (26 CFR Part 41) under section 4481 of the Internal Revenue Code (Code).

Section 4481 imposes a tax on the use in any taxable period of a highway motor vehicle with a taxable gross weight of 55,000 pounds or more. The person in whose name the vehicle is registered at the time of the first use must pay the tax. The rate of tax is based on the weight of the vehicle with a maximum of $550 per vehicle per taxable period (the standard amount).

Generally, a ''taxable period'' is the year that begins on July 1 and ends on the following June 30. For the taxable period beginning on July 1, 2011, however, section 4482(c)(4) of present law provides that the taxable period ends at the close of September 30, 2011. For this three month period, the tax rate is a reduced amount that is 25 percent of the tax rate for a 12-month period.

Section 41.6011(a)–1(a)(1) requires each person that is liable for the tax imposed by section 4481 to file a return for each taxable period and § 41.6011(a)–1(b) provides that the return is Form 2290, ''Heavy Highway Vehicle Use Tax Return.''

The due date for filing Form 2290 is not prescribed by statute and section 6071 provides that when the Code does not set the time for filing a return, the Secretary is to prescribe such time by regulations. Under § 41.6071(a)–1(a), Form 2290 generally must be filed by the last day of the month following the month in which a person becomes liable for tax. For most taxpayers, their first use of a vehicle in a taxable period occurs in July and thus their return is due by August 31.

Section 41.6001–2(b) provides, generally, that a State that receives an application to register a highway motor vehicle must receive from the applicant ''proof of payment'' of the tax imposed by section 4481(a). Section 41.6001–2(c) specifies that this proof of payment generally consists of a receipted

Schedule 1 (Form 2290) that is returned by the IRS to a taxpayer that files Form 2290 and pays the amount of tax due with the return. The taxpayer generally must present proof of payment for the taxable period that includes the date on which the application for registration is filed, but in the case of an application filed in July, August, or September proof of payment for the preceding taxable period may be used.

The tax imposed under section 4481 will expire on September 30, 2011, unless Congress changes the law. Under existing regulations, the person liable for the highway use tax must file a Form 2290 by the last day of the month following the month in which the person becomes liable for the tax. Therefore, under current statutory and regulatory provisions, the person liable for the tax will be required to file a Form 2290 for taxable use during the period of July 1, 2011, through September 30, 2011 (the ''2011 short taxable period''). Further, if Congress extends the tax past September 30, 2011, a person who filed Form 2290 for the 2011 short taxable period would have to file a second Form 2290 covering the period after September 30, 2011, through the earlier of the expiration date of the extension or June 30, 2012.

Explanation of Provisions

For purposes of efficient tax administration and alleviating taxpayers' potential administrative burden, the temporary regulations postpone the due date of Form 2290 for the 2011 short taxable period until November 30, 2011. If Congress does not extend the tax past September 30, 2011, taxpayers will file one Form 2290 and will pay the reduced amount for the 2011 short taxable period by November 30; if Congress does extend the tax past September 30, 2011, and substitutes a longer taxable period for the 2011 short taxable period, taxpayers who become liable for the highway use tax after June 30, 2011, and before November 1, 2011, also will file a Form 2290 for the period July 1, 2011—June 30, 2012 (or the end of the new taxable period, if earlier), by November 30, 2011. In either case, most taxpayers will have to file only one return for the taxable period beginning July 1, 2011. But for the change made by the temporary regulations, most taxpayers would have to file two returns if Congress extends the tax past September 30.

Further, the temporary regulations state that taxpayers should file a Form 2290 no earlier than November 1, 2011, for taxable use during the 2011 short taxable period. The IRS will not provide a receipted Schedule 1 for a return and associated payment for the taxable period beginning July 1, 2011, before November 1, 2011. Because taxpayers will not be able to receive a receipted Schedule 1 for filing a Form 2290 and paying the tax for the taxable period beginning July 1, 2011, until November 1, 2011, the temporary regulations provide that the receipted Schedule 1 for the taxable period ending June 30, 2010, must be accepted by a State as a substitute proof of payment for registration applications filed during the period of July 1, 2011, through November 30, 2011.

Section 41.6001–2(b)(1) provides that a State may register a highway motor vehicle without proof of payment if the person registering the vehicle presents the original or a photocopy of a bill of sale (or other document evidencing transfer) indicating that the vehicle was purchased by the owner either as a new or used vehicle during the preceding 60 days before the date that the State receives the application for registration of such vehicle. Because taxpayers will not be able to obtain proof of payment during the period between July 1, 2011, and November 1, 2011, the temporary regulations provide that between July 1, 2011, and November 30, 2011, a State must register a highway motor vehicle without proof of payment if the person registering the vehicle presents the original or a photocopy of a bill of sale (or other document evidencing the sale) that demonstrates that the owner purchased the vehicle, either as a new or used vehicle, within 150 days of the date that the State receives the application for registration, and the vehicle has not been registered in any State since the purchase date.

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. 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. For applicability of the Regulatory Flexibility Act (5 U.S.C. chapter 6), please refer to the Special Analysis section in the preamble to the cross-referenced notice of proposed rulemaking in the Proposed Rules section in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, this final and temporary regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Natalie Payne, Office of the Associate Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 41

Excise taxes, Motor vehicles, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 41 is amended as follows:

PART 41—EXCISE TAX ON USE OF CERTAIN HIGHWAY MOTOR VEHICLES

■ **Paragraph 1.** The authority citation for part 41 is amended to read in part as follows:

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

Section 41.6001–2T also issued under 26 U.S.C. 6001. * * *

Section 41.6071(a)–1T also issued under 26 U.S.C. 6071(a). * * *

Section 41.6151(a)–1T also issued under 26 U.S.C. 6151(a). * * *

■ **Par. 2.** Section 41.6001–2 is amended by:

■ 1. Redesignating paragraph (b)(1) as paragraph (b)(1)(i) and adding a paragraph heading to newly designated paragraph (b)(1)(i).

■ 2. Adding paragraph (b)(1)(ii).

■ 3. Redesignating paragraph (b)(4) as paragraph (b)(4)(i) and adding a paragraph heading to newly designated paragraph (b)(4)(i).

■ 4. Adding paragraph (b)(4)(ii).

■ 5. Redesignating paragraph (c)(2) as paragraph (c)(2)(i), adding a paragraph heading to newly designated paragraph (c)(2)(i) and adding paragraph (c)(2)(ii).

The additions read as follows:

§ 41.6001–2 Proof of payment for State registration purposes.

* * * * *

(b) * * *

(1) * * *

(i) *Registration generally.* * * *

(ii) [Reserved]. For further guidance, see § 41.6001–2T(b)(1)(ii).

* * * * *

(4) * * *

(i) *General rule.* * * *

(ii) [Reserved]. For further guidance, see § 41.6001–2T(b)(4)(ii).

* * * * *

(c) * * *

(2) * * *

(i) *General rule.* * * *

(ii) [Reserved]. For further guidance, see § 41.6001–2T(c)(2)(ii).

* * * * *

■ **Par. 3.** Section 41.6001–2T is added to read as follows:

§ 41.6001–2T Proof of payment for State registration purposes (temporary).

(a) [Reserved]. For further guidance, see § 41.6001–2(a) .

(b)(1)(i) [Reserved]. For further guidance, see § 41.6001–2(b)(1)(i).

(ii) *Special rule for registration after June 30, 2011, and before December 1, 2011.* Between July 1, 2011, and November 30, 2011, a State must register a highway motor vehicle without proof of payment if the person registering the vehicle presents the original or a photocopy of a bill of sale (or other document evidencing transfer) indicating that the vehicle was purchased by the owner either as a new or used vehicle during the preceding 150 days before the date that the State receives the application for registration of the vehicle, and the vehicle has not been registered in any state subsequent to such date of purchase.

(b)(2) through (b)(4)(i) [Reserved]. For further guidance, see § 41.6001–2(b)(2) through (b)(4)(i).

(ii) *Special rule for registration after June 30, 2011, and before December 1, 2011.* In the case of a highway motor vehicle subject to tax under section 4481(a) for which a State receives an application for registration during the months of July, August, September, October, or November of 2011, a State shall accept proof of payment for the taxable period of July 1, 2010, through June 30, 2011, to verify payment of the tax imposed by section 4481(a).

(c) introductory text through (c)(2)(i) [Reserved]. For further guidance, see § 41.6001–2(c) through (c)(2)(i).

(ii) *Substitute proof of payment for the taxable period beginning July 1, 2011.* For purposes of this section and § 41.6001–2, in the case of a highway motor vehicle for which a State receives an application for registration during the period of July 1, 2011, through November 30, 2011, a State shall accept as a substitute for proof of payment, proof of payment for the taxable period of July 1, 2010, through June 30, 2011.

(iii) *Cross reference.* For provisions relating to the use of proof of payment for the taxable period of July 1, 2010, through June 30, 2011, to verify payment of the tax imposed by section 4481(a), see § 41.6001–2T(b)(4)(ii).

(d) *Effective/applicability date.* Paragraphs (b)(1)(ii), (b)(4)(ii), (c)(2)(ii) and (c)(2)(iii) of this section apply on and after July 20, 2011.

(e) *Expiration date.* The applicability of this section expires on or before July 15, 2014.

■ **Par. 4.** Section 41.6071(a)–1 is amended as follows:

■ 1. In paragraph (a) introductory text, the phrase ''Except as provided in paragraph (b) of this section'' is removed and ''Except as provided in paragraph (b) or paragraph (c) of this section'' is added in its place.

■ 2. Add paragraph (c).

The addition reads as follows:

§ 41.6071(a)–1 Time for filing returns.

* * * * *

(c) [Reserved]. For further guidance, see § 41.6071(a)–1T(c) through (c)(3).

■ **Par. 5.** Section 41.6071(a)–1T is added to read as follows:

§ 41.6071(a)–1T Time for filing returns (temporary).

(a) through (b) [Reserved]. For further guidance, see § 41.6071(a)–1(a) through (b).

(c) *Special rule for highway motor vehicles for which a taxable use occurs during the period July 1, 2011, through September 30, 2011*—(1) *Date for filing returns.* In the case of a highway motor vehicle for which a taxable use occurs during the period July 1, 2011, through September 30, 2011, the person liable for the tax must file a return described in § 41.6011(a)–1 no later than November 30, 2011. The return should be filed no earlier than November 1, 2011. If the return is filed and payment is submitted before November 1, 2011, the IRS will not provide a receipted Schedule 1 (Form 2290, ''Heavy Highway Vehicle Use Tax Return'') as proof of payment until after November 1, 2011, and will provide such receipted Schedule 1 only if the full amount of the tax for the 2011 taxable period (determined under the law in effect as of November 1, 2011) has been paid.

(2) *Cross reference.* For provisions relating to time and place for paying the tax imposed under section 4481, see § 41.6151(a)–1.

(3) *Effective/applicability date.* This paragraph (c) applies on and after July 20, 2011.

(4) *Expiration date.* The applicability of this section expires on or before July 15, 2014.

■ **Par. 6.** Section 41.6151(a)–1 is revised to read as follows:

§ 41.6151(a)–1 Time and place for paying tax.

[Reserved]. For further guidance, see § 41.6071(a)–1T(a) and (b).

■ **Par. 7.** Section 41.6151(a)–1T is added to read as follows:

§ 41.6151(a)–1T Time and place for paying tax (temporary).

(a) *In general.* The tax must be paid at the time prescribed in § 41.6071(a)–1 (or § 41.6071(a)–1T, as appropriate) for filing the return and at the place prescribed in § 41.6091–1 for filing the return.

(b) *Effective/applicability date.* This section applies on and after July 20, 2011.

(c) *Expiration date.* The applicability of this section expires on or before July 15, 2014.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

Approved: July 13, 2011.

Emily S. McMahon,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2011–18244 Filed 7–15–11; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–0597]

Drawbridge Operation Regulations; Cheesequake Creek, Morgan, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Route 35 Bridge, mile 0.0, across Cheesequake Creek at Morgan, New Jersey. The deviation is necessary to facilitate a public event. This deviation allows the bridge to remain in the closed position for an hour and a half to facilitate a public event.

DATES: This deviation is effective between 11:30 a.m. and 1 p.m. on September 18, 2011.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–0597 and are available online at *http://www.regulations.gov,* inserting USCG–2011–0597 in the ''Keyword'' and then clicking ''Search''. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room