

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of this device from class III to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the FD&C 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 \$136 million, using the most current (2010) 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. 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” under 21 U.S.C. 360(k).

V. Paperwork Reduction Act of 1995

This final rule establishes special controls that refer to currently approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801 regarding labeling have been approved under OMB control number 0910–0485.

VI. Reference

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 InfraScan, Inc., April 8, 2010.

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 882.1935 is added to subpart B to read as follows:

§ 882.1935 Near Infrared (NIR) Brain Hematoma Detector.

(a) *Identification.* A Near Infrared (NIR) Brain Hematoma Detector is a noninvasive device that employs near-infrared spectroscopy that is intended to be used to evaluate suspected brain hematomas.

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

(1) The sale, distribution, and use of this device are restricted to prescription use in accordance with § 801.109 of this chapter;

(2) The labeling must include specific instructions and the clinical training needed for the safe use of this device;

(3) Appropriate analysis/testing should validate electromagnetic compatibility (EMC), electrical safety, and battery characteristics;

(4) Performance data should validate accuracy and precision and safety features;

(5) Any elements of the device that may contact the patient should be demonstrated to be biocompatible; and,

(6) Appropriate software verification, validation, and hazard analysis should be performed.

Dated: March 16, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2012–0132]

Drawbridge Operation Regulation; Willamette River, Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Thirteenth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Broadway Bridge across the Willamette River, mile 11.7, at Portland, OR. This deviation is necessary to accommodate the Race for the Roses event scheduled for April 1, 2012. This deviation allows the bridge to remain in the closed position to allow safe movement of event participants.

DATES: This deviation is effective from 6:30 a.m. on April 1, 2012 through 7:30 a.m. April 1, 2012.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2012–0132 and are available online by going to <http://www.regulations.gov>, inserting USCG–2012–0132 in the “Keyword” box 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 W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email the Bridge Administrator, Coast Guard Thirteenth District; telephone 206-220-7282 email randall.d.overton@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Multnomah County has requested that the Broadway Bascule Bridge remain closed to vessel traffic to facilitate safe, uninterrupted roadway passage of participants of the Race for the Roses event. The Broadway Bridge crosses the Willamette River at mile 11.7 and provides 90 feet of vertical clearance above Columbia River Datum 0.0 while in the closed position. Vessels which do not require a bridge opening may continue to transit beneath the bridge during this closure period. Under normal conditions this bridge operates in accordance with 33 CFR 117.897(c) which allows for the bridge to remain closed between 7 a.m. and 9 a.m. and 4 p.m. and 6 p.m. Monday through Friday and also requires advance notification when a bridge opening is needed. This deviation period is from 6:30 a.m. on April 1, 2012 through 7:30 a.m. April 1, 2012. The deviation allows the bascule span of the Broadway Bridge across the Willamette River, mile 11.7, to remain in the closed position and need not open for maritime traffic for one hour from 6:30 a.m. through 7:30 a.m. on April 1, 2012. The bridge shall operate in accordance to 33 CFR 117.897 at all other times. Waterway usage on this stretch of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft. Mariners will be notified and kept informed of the bridge's operational status via the Coast Guard Notice to Mariners publication and Broadcast Notice to Mariners as appropriate. The draw span will be required to open, if needed, for vessels engaged in emergency response operations during this closure period.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: February 22, 2012.

Randall D. Overton,

Bridge Administrator.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2012-0078]

Drawbridge Operation Regulation; Miami River, Miami, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulation; request for comments.

SUMMARY: The Commander, Seventh Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the N.W. 12th Avenue Bridge across the Miami River, mile 2.1, in Miami, Florida. This deviation will test a change to the drawbridge operation schedule to determine whether a permanent change to the schedule is needed. The test deviation is necessary to determine whether possible vehicle traffic congestion during Miami Marlins home baseball games poses a safety concern. This 90 day test deviation will allow the N.W. 12th Avenue Bridge to remain closed to navigation for a short period prior to the start of Miami Marlins home baseball games. Tugs and tugs with tows, public vessels of the United States, and vessels in distress shall be passed at any time.

DATES: This deviation is effective from 6:46 p.m. on April 4, 2012 through 7:30 p.m. on July 3, 2012.

Comments and related material must be received by the Coast Guard on or before August 1, 2012. Requests for public meetings must be received by the Coast Guard on or before May 15, 2012.

ADDRESSES: You may submit comments identified by docket number USCG-2012-0078 using any one of the following methods:

(1) *Federal eRulemaking Portal:*

<http://www.regulations.gov>.

(2) *Fax:* (202) 493-2251.

(3) *Mail:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except

Federal holidays. The telephone number is (202) 366-9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Michael Lieberum, Seventh District Bridge Branch, Coast Guard; telephone (305) 415-6744, email Michael.B.Lieberum@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG-2012-0078), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (<http://www.regulations.gov>), or by fax, mail or hand delivery, but please use only one of these means. If you submit a comment online via <http://www.regulations.gov>, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, click on the "submit a comment" box, which will then become highlighted in blue. In the "Keyword" box insert "USCG-2012-0078," click "Search," and then click on the balloon shape in the "Actions" column. If you submit your comments