device, which contains information about the tissue adhesive with adjunct wound closure intended for topical approximation of skin that they intend to market.

II. What is the environmental impact of this rule?

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. What is the analysis impact of this rule?

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs 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 as defined by the Executive order.

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 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 $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 preempt 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 some 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 new collections of 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 the availability of a guidance for the final rule. The guidance, "Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin," references previously approved collections of information found in FDA's 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 Closure Medical Corp., March 23, 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, 3601, 371.

■ 2. Section 878.4011 is added to subpart E to read as follows:

§ 878.4011 Tissue adhesive with adjunct wound closure device for topical approximation of skin.

(a) *Identification.* A tissue adhesive with adjunct wound closure device intended for the topical approximation of skin is a device indicated for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. It may be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of wound during application of the liquid adhesive.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin." See § 878.1(e) for the availability of this guidance document.

Dated: November 4, 2010.

Nancy K. Stade,

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

[FR Doc. 2010–28356 Filed 11–9–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2010–0998]

Drawbridge Operation Regulation; Upper Mississippi River, Rock Island, IL

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Rock Island Railroad and Highway Drawbridge across the Upper Mississippi River, mile 482.9, at Rock Island, Illinois. The deviation is necessary to allow the bridge owner time to perform preventive maintenance and critical repairs that are essential to the continued safe operation of the drawbridge. This deviation allows the bridge to be maintained in the closed to navigation position for fifty-six days.

DATES: This deviation is effective from 7:30 a.m., January 4, 2011 to 7:30 a.m. February 28, 2011.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2010–0998 and are available online by going to *http://www.regulations.gov,* inserting USCG–2010–0998 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 e-mail Eric A. Washburn, Bridge Administrator, Coast Guard; telephone 314–269–2378, e-mail *Eric.Washburn@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The U.S. Army Rock Island Arsenal requested a temporary deviation for the Rock Island Railroad and Highway Drawbridge, across the Upper Mississippi River, mile 482.9, at Rock Island, Illinois to remain in the closed to navigation position for 56 days from 7:30 a.m., January 4, 2011 to 7:30 a.m., February 28, 2011 to allow the bridge owner time for critical repairs and preventive maintenance. In order to perform extensive repairs and required annual maintenance, the bridge must be kept inoperative and in the closed to navigation position. The Rock Island Railroad and Highway Drawbridge currently operates in accordance with 33 CFR 117.5, which states the general requirement that drawbridges shall open promptly and fully for the passage of vessels when a request to open is given in accordance with the subpart.

There are no alternate routes for vessels transiting this section of the Upper Mississippi River.

The Rock Island Railroad and Highway Drawbridge, in the closed-to-navigation position, provides a vertical clearance of 23.8 feet above normal pool. Navigation on the waterway consists primarily of commercial tows and recreational watercraft. The drawbridge will not be able to open for emergencies during the repair period. This temporary deviation has been coordinated with waterway users. No objections were received.

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: October 28, 2010.

Eric A. Washburn,

Bridge Administrator.

[FR Doc. 2010–28326 Filed 11–9–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 62

RIN 2900–AN53

Supportive Services for Veteran Families Program

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its regulations to establish the Supportive Services for Veteran Families Program (SSVF Program). These amendments implement the provisions of section 604 of the Veterans' Mental Health and Other Care Improvements Act of 2008 (Act). The purpose of the SSVF Program is to provide supportive services grants to private non-profit organizations and consumer cooperatives who will coordinate or provide supportive services to very low-income veteran families who are residing in permanent housing, are homeless and scheduled to become residents of permanent housing within a specified time period, or after exiting permanent housing, are seeking other housing that is responsive to such very low-income veteran family's needs and preferences. The new SSVF Program is within the continuum of VA's homeless services programs.

DATES: This final rule is effective December 10, 2010.

FOR FURTHER INFORMATION CONTACT: John Kuhn, National Center for Homelessness Among Veterans, Supportive Services for Veteran Families Program Office, 4100 Chester Avenue, Suite 200, Philadelphia, PA 19104, (877) 737–0111 (this is a toll-free number).

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** (75 FR 24514) on May 5, 2010, VA proposed to establish a new 38 CFR part 62 consisting of regulations captioned "SUPPORTIVE SERVICES FOR VETERAN FAMILIES PROGRAM" (referred to below as the proposed rule). This document adopts as a final rule, with changes discussed below, the proposed rule. This final rule establishes regulations concerning the SSVF Program and is necessary to implement section 604 of the Act, which is codified at 38 U.S.C. 2044.

VA provided a 30-day comment period that ended on June 4, 2010. VA received four submissions during this comment period on the proposed rule. One submission consisted of an inquiry about the timing for the award of supportive services grants, but did not contain any substantive comments on the proposed rule. The subject matter of the other submissions can be grouped into several categories, and we have organized our discussion of the comments accordingly.

Selecting Applicants To Receive Supportive Services Grants

Two commenters provided recommendations regarding the scoring criteria used to rate applicants fulfilling the threshold requirements. Proposed § 62.22 described the scoring criteria VA would use to score applicants fulfilling the threshold requirements.

One commenter recommended that proposed § 62.22(b)(2), the scoring criterion regarding the applicant's outreach and screening plan, include an examination of the thoroughness of coverage by using available data to estimate the total number of veterans who could be eligible for participation over the course of a year, and then to determine the percentage of veterans in the applicant's area or community that will be contacted through outreach and screening.

We agree that the estimated number of participants and percentage of very low-income veterans served in an area or community should be considered when scoring the supportive services grant application; however, we think this can be better addressed through the scoring criterion relating to the need for program (§ 62.22(b)(1)) rather than the scoring criterion relating to the outreach and screening plan (§ 62.22(b)(2)). Section 62.20(a)(3) of the proposed rule stated that a complete supportive services grant application would include "an estimate with supporting documentation of the number of very