

mutation detection system 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 Economic 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 (Public Law 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 and so it not subject to review under 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 classification of this device into class II will relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the 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 \$115 million using the most current (2003) 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. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. How Does This Rule Comply with the Paperwork Reduction Act of 1995?

FDA concludes that this rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also concludes that the special controls guidance document identified by this rule contains information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the draft guidance entitled “Class II Special Controls Guidance Document: CFTR Gene Mutation Detection Systems.”

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 Tm Bioscience Corp., dated April 4, 2005.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, 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 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

- 1. The authority citation for 21 CFR part 866 continues to read as follows:

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

■ 2. Add § 866.5900 to subpart F to read as follows:

§ 866.5900 Cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection system.

(a) *Identification.* The CFTR gene mutation detection system is a device used to simultaneously detect and identify a panel of mutations and variants in the CFTR gene. It is intended as an aid in confirmatory diagnostic testing of individuals with suspected cystic fibrosis (CF), carrier identification, and newborn screening. This device is not intended for stand-alone diagnostic purposes, prenatal diagnostic, pre-implantation, or population screening.

(b) *Classification.* Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: CFTR Gene Mutation Detection System.” See § 866.1(e) for the availability of this guidance document.

Dated: October 17, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–21348 Filed 10–25–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD05–05–124]

RIN 1625–AA–09

Drawbridge Operation Regulations; Knapps Narrows, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the Route 33/Knapps Narrows Bridge, at mile 0.4, across Knapps Narrows, at Tilghman, Maryland. This deviation allows the drawbridge to remain closed-to-navigation each day from 9 p.m. to 5 a.m., beginning on Monday, October 24 until Friday, October 28, 2005, to facilitate mechanical repairs.

DATES: The deviation is effective from 9 p.m. to 5 a.m. from October 24 until October 28, 2005.

ADDRESSES: Materials referred to in this document are available for inspection or copying at Commander (obr), Fifth Coast Guard District, Federal Building, 1st Floor, 431 Crawford Street, Portsmouth, VA 23704-5004 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays. The telephone number is (757) 398-6422. Commander (obr), Fifth Coast Guard District maintains the public docket for this temporary deviation.

FOR FURTHER INFORMATION CONTACT: Bill H. Brazier, Bridge Management Specialist, Fifth Coast Guard District, at (757) 398-6422.

SUPPLEMENTARY INFORMATION: The Route 33/Knapps Narrows Bridge, a bascule-type drawbridge, has a vertical clearance in the closed position to vessels of 7 feet, at mean high water.

Covington Machine and Welding, Inc. (CMW), is the contractor engaged to perform these repairs for the Maryland State Highway Administration (SHA), the bridge owner. CMW, on behalf of SHA, requested a temporary deviation from the operating regulations for the Route 33/Knapps Narrows Bridge, set out in 33 CFR 117.5, that requires to bridge to open promptly and fully for the passage of vessels when a request to open is given.

CMW requested the temporary deviation to close the Route 33/Knapps Narrow Bridge to navigation to facilitate replacing leaking oil seals in the main drive gear reducer and the hydraulic braking system of the draw span. The lift span will be locked in the closed-to-navigation position each day from 9 p.m. to 5 a.m. beginning on Monday, October 24, 2005 until and including Friday, October 28, 2005. At all other times, the bridge will operate in accordance with 33 CFR 117.5.

The Coast Guard has informed the known users of the waterway of the closure periods for the bridge so that these vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: October 18, 2005.

Waverly W. Gregory, Jr.,

Chief, Bridge Administration Branch, Fifth Coast Guard District.

[FR Doc. 05-21322 Filed 10-25-05; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP St. Petersburg 05-120]

RIN 1625-AA00

Safety Zone Regulation; Tampa Bay, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of Tampa Bay, Florida, in the vicinity of the Clearwater Memorial bascule bridge. This safety zone is being established to protect mariners from the hazards associated with the blasting demolition of the concrete portions of the Clearwater Memorial bascule bridge. This rule is necessary to provide for the safety of life on the navigable waters of the United States.

DATES: This rule is effective from 9:30 a.m. on October 4, 2005 through 2 p.m. on November 8, 2005.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket [COTP St. Petersburg 05-120] and are available for inspection or copying at Coast Guard Sector St. Petersburg, Prevention Department, 155 Columbia Drive, Tampa, Florida 33606-3598 between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Junior Grade Jennifer Andrew at Coast Guard Sector St. Petersburg, Prevention Department, (813) 228-2191 Ext 8203.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The necessary details for the blasting demolition of the Clearwater Memorial bascule bridge were not provided with sufficient time remaining to publish an NPRM. Publishing a NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to minimize potential danger to the public during the blasting demolition of the Clearwater Memorial bascule bridge. The Coast Guard will issue a broadcast notice to mariners to advise mariners of the restriction along with Coast Guard

assets on scene who will also provide notice of the safety zone to mariners.

For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Background and Purpose

PCL construction was contracted to build a fixed bridge to replace the Clearwater Memorial Causeway Bridge and remove the existing bridge. The fixed bridge was completed early September and the removal of the bascule bridge was commenced on September 12, 2005. On September 13, 2005 PCL contacted Coast Guard Sector St. Petersburg Prevention Department to discuss blasting the large concrete portions of the bascule bridge directly adjacent to the navigation channel along with the concrete counterweights for the metal bridge leafs. PCL will conduct two separate blasts on two different days to break up the concrete into smaller sections for removal. The first blast will be conducted tentatively on October 5, 2005, at approximately 7:30 a.m. This first blast will fracture the main concrete vertical portions adjacent to the channel from the top to three feet above the waterline. The second blast will be conducted tentatively on October 26, 2005, at approximately 7:30 a.m. This second and final blast will fracture the remaining three feet and the 16 feet of bridge below the waterline. The use of explosives and the proximity of the concrete bridge structure to the navigable channel present a hazard to mariners transiting the area. This safety zone is being established to ensure the safety of life on the navigable waters of the United States.

Discussion of Rule

The safety zone will extend out from the Clearwater Memorial Causeway bascule Bridge in a 1,000 foot radius. Vessels and persons not under contract or employees of PCL are prohibited from entering, anchoring or transiting within this zone unless authorized by the Captain of the Port St. Petersburg or his designated representative. This safety zone is effective from 7:30 a.m. on October 4, 2005, through 2 p.m. on November 8, 2005. The Coast Guard does not know the exact dates that this safety zone will be enforced at this time. Coast Guard Sector St. Petersburg will give notice of the enforcement of the safety zone by issuing a Broadcast Notice to Mariners beginning 24 to 48 hours before the blasting is scheduled to begin. On-scene notice will be provided by local Coast Guard and Pinellas