proposing to require the application of the black box warning to labeling and advertising through notice and comment rulemaking. For the purposes of this analysis, we assume that this final rule will establish special controls with a reference to a black box warning regarding off-label use, but the analysis of the impact of the addition of the warning to the product label will be included in a separate rulemaking.

B. Costs of the Final Rule

This final rule is deregulatory. Device manufacturers currently subject to class III requirements will be subject to the less burdensome requirements for makers of class II devices. Through this classification, manufacturers of ovarian adnexal mass assessment test system devices will be relieved of the obligation to submit a PMA prior to marketing. The cost of submitting a PMA can reach $1,000,000, plus user fees of an additional $217,787 in FY 2010, increasing to $256,384 in 2012. This device classification will substantially reduce an existing burden on manufacturers of ovarian adnexal mass assessment test system devices. Considering the cost of submitting a PMA plus the relevant user fees, the reduction could be $1,000,000 per device.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Classification of the affected device into class II after it had automatically been placed in class III will relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the FD&C Act. Because of the reduced burden, the Agency does not believe that this final rule will have a significant economic impact on a substantial number of small entities.

VII. 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 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, Inc.,* 552 U.S. 312 (2008). The special controls established by this rulemaking 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 may have flexibility in how they meet those requirements. Cf. *Papike* v. *Tambrands, Inc.,* 107 F.3d 737, 740–42 (9th Cir. 1997).

VIII. Paperwork Reduction Act of 1995

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 the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the guidance document entitled "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Ovarian Adnexal Mass Assessment Score Test System." The notice contains an analysis of the paperwork burden for the guidance.

IX. 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 Vermillion, Inc., for reclassification of the OVA1™ Test submitted July 22, 2009.

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. Section 866.6050 is added to subpart G to read as follows:

§ 866.6050 Ovarian adnexal mass assessment score test system.

(a) *Identification.* An ovarian/adnexal mass assessment test system is a device that measures one or more proteins in serum or plasma. It yields a single result for the likelihood that an adnexal pelvic mass in a woman, for whom surgery is planned, is malignant. The test is for adjunctive use, in the context of a negative primary clinical and radiological evaluation, to augment the identification of patients whose gynecologic surgery requires oncology expertise and resources.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled "Class II Special Controls Guidance Document: Ovarian Adnexal Mass Assessment Score Test System." For the availability of this guidance document, *see* § 866.1(e).

Dated: March 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–6620 Filed 3–22–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–0100]

RIN 1625–AA09

Drawbridge Operation Regulation; Buffalo Bayou, Mile 4.3, Houston, Harris County, TX

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is removing the existing drawbridge operation regulation for the drawbridge across Buffalo Bayou, mile 4.3, Houston, Harris County, Texas. The bridge was replaced with a fixed bridge in 1991 and the operating regulation is no longer applicable or necessary.

DATES: This rule is effective March 23, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket USCG–2011–0100 and are available by going to *http://www.regulations.gov,* inserting USCG–2011–0100 in the "Keyword" box, and then clicking "Search." This material is 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 Mr. Jim Wetherington, Bridge Specialist, Coast Guard; telephone 504–671–2128, e-mail *james.r.wetherington@uscg.mil*. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the drawbridge requiring draw operations in 33 CFR 117.955(b), was removed and replaced with a fixed span bridge in 1991. The bridge operator and those transiting in the vicinity of this bridge have not been governed by the draw operations since the bridge was removed and replaced. Therefore, the regulation is no longer applicable and should be removed from publication.

Under 5 U.S.C. 553(d)(1), a rule that relieves a restriction is not required to provide the 30 day notice period before its effective date. This rule removes the draw operations requirements under 33 CFR 117.955(b), thus removing a regulatory restriction on the public. Additionally, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**. The bridge has been a fixed bridge for 20 years and this rule only requires an administrative change to the **Federal Register**, omitting a regulatory requirement that is no longer applicable or necessary.

Basis and Purpose

The drawbridge across Buffalo Bayou, mile 4.3, was removed and replaced with a fixed bridge in 1991. The elimination of this drawbridge necessitates the removal of the drawbridge operation regulation pertaining to this drawbridge.

The regulation governing the operation of the bridge is found in 33 CFR 117.955(b). The purpose of this rule is to remove the section of 33 CFR 117.955 (b) that refers to the bridge at mile 4.3, from the Code of Federal Regulations since it governs a bridge that is no longer able to be opened.

Discussion of Rule

The Coast Guard is changing the regulation in 33 CFR 117 by removing restrictions and the regulatory burden related to the draw operations for this bridge that is no longer in existence without publishing an NPRM. The change removes the section of the regulation governing the bridge since the bridge has been replaced with a fixed bridge. This change does not affect vessel operators using the waterway. Thus, it is not necessary to publish an NPRM.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

The Coast Guard does not consider this rule to be "significant" under that Order because it is an administrative change and does not affect the way vessels operate on the waterway.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considers whether this final rule will have a significant economic impact on a substantial number of small entities. "Small entities" include (1) small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and (2) governmental jurisdictions with populations of less than 50,000.

Since the drawbridge across the Buffalo Bayou, mile 4.3 at Houston, Texas, has been removed and replaced with a fixed bridge, the regulation governing draw operations for this bridge is no longer needed. There is no new restriction or regulation being imposed by this rule; therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this final rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial

direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.955 (b) to read as follows:

§ 117.955 Buffalo Bayou.

* * * * *

(b) The draw of the Union Pacific Rail Road Bridge, mile 3.1, need not be opened to the passage of vessels.

Dated: March 10, 2011.

Mary E. Landry,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 2011–6876 Filed 3–22–11; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–0113]

Drawbridge Operation Regulation; Pocomoke River, Snow Hill, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has issued a temporary deviation from the regulations governing the operation of the S12 Bridge across Pocomoke River, mile 29.9, at Snow Hill, MD. The deviation restricts the operation of the draw span to facilitate the cleaning and painting of the bridge.

DATES: This deviation is effective from 7 a.m. on March 15, 2011 through 11:59 p.m. on May 30, 2011.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–0113 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–0113 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 Mr. Waverly W. Gregory, Jr., Bridge Administrator, Fifth Coast Guard District; telephone 757–398–6222, e-mail *Waverly.W.Gregory@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 Maryland State Highway Administration (SHA), who owns and operates this single leaf bascule drawbridge, has requested a temporary deviation from the current operating schedule to facilitate the cleaning and painting of the structure. Under the regular operating schedule, the bridge opens on signal as required by 33 CFR 117.569(c) if at least five hours advance notice is given.

The S12 Bridge across Pocomoke River, mile 29.9 at Snow Hill MD, has a vertical clearance in the closed position of two feet above mean high water and five feet above mean low water. Under this temporary deviation, the contractor has requested to maintain the bridge in the closed position to vessels from 7 a.m. on March 15, 2011 through 11:59 p.m. on May 30, 2011, to allow for the potential delays caused by anticipated seasonal weather patterns that will interfere with environmental conditions required for sandblasting and painting of the bridge.

Bridge opening data supplied by SHA and reviewed by the Coast Guard revealed vessel openings of the draw span from March 2010 through May 2010. Specifically, the drawbridge opened for vessels a total of 23, 13, and 25 times during the months of March 2010 through May 2010, respectively. We also contacted a nearby canoe shop owner who indicated that he can work around the restrictions.

The Coast Guard has coordinated the restrictions with the local users of the waterway and will inform other users through our Local and Broadcast Notices to Mariners of the closure periods for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation. There are no alternate routes for vessels transiting this section of the Pocomoke River and the drawbridge will be able to open in the event of an emergency.