

substantial number of small entities. This final rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of \$100 million of more by State, local, or tribal governments in the aggregate, or by the private sector, in any 1 year.

IV. References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA letter (order) to Centocor, Inc., dated September 19, 1996.
2. Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications (510(k)) to FDA, September 19, 1996.
3. The National Committee for Clinical Laboratory Standards: Document EP5-T2, Evaluation of Precision Performance of Clinical Chemistry Devices; Document EP9-A, Method Comparison and Bias Estimation Using Patient Samples; Document EP7-P, Interference Testing in Clinical Chemistry.

List of Subjects in 21 CFR Part 866

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 866.6010 is revised to read as follows:

§ 866.6010 Tumor-associated antigen immunological test system.

(a) *Identification.* A tumor-associated antigen immunological test system is a device that consists of reagents used to qualitatively or quantitatively measure, by immunochemical techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This device is intended as an aid in monitoring patients for disease progress or response to therapy or for the detection of recurrent or residual disease.

(b) *Classification.* Class II (special controls). Tumor markers must comply with the following special controls: (1) A guidance document entitled "Guidance Document for the Submission of Tumor Associated

Antigen Premarket Notifications (510(k)s) to FDA," and (2) voluntary assay performance standards issued by the National Committee on Clinical Laboratory Standards.

Dated: November 6, 1997.

Joseph A. Levitt,

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

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD05-97-009]

RIN 2115-AE47

Drawbridge Operation Regulations; Pasquotank River, Elizabeth City, North Carolina

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the regulations that govern the operation of the Highway 158 drawbridge across the Pasquotank River, mile 50.7, at Elizabeth City, North Carolina, by eliminating bridge openings for pleasure vessels from Monday through Friday between 7 a.m. and 9 a.m., and 4 p.m. and 6 p.m., except that, openings will be scheduled at 7:30 and 8:30 a.m., and 4:30 and 5:30 p.m. for any waiting pleasure vessels. This rule is intended to help relieve automobile traffic congestion during the morning and afternoon rush hours, while still providing for the reasonable needs of navigation.

DATES: This final rule is effective January 16, 1998.

ADDRESSES: Documents as indicated in this preamble are available for inspection or copying at the office of the Commander (Aowb), Fifth Coast Guard District, Federal Building, 4th Floor, 431 Crawford Street, Portsmouth, Virginia 23704-5004, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The telephone number is (757) 398-6222.

FOR FURTHER INFORMATION CONTACT: Ann B. Deaton, Bridge Administrator, Fifth Coast Guard District, at (757) 398-6222.

SUPPLEMENTARY INFORMATION:

Regulatory History

On July 1, 1997, the Coast Guard published a Notice of Proposed Rulemaking (NPRM) entitled

"Drawbridge Operation Regulations; Pasquotank River, Elizabeth City, North Carolina" in the Federal Register (62 FR 35453). The Coast Guard did not receive any comments on the proposed rulemaking. No public hearing was requested and none was held.

Background and Purpose

The Highway 158 drawbridge across the Pasquotank River, mile 50.7, at Elizabeth City, North Carolina is currently required to open on signal year round. The City of Elizabeth City, through the North Carolina Department of Transportation (NCDOT), requested permission to restrict drawbridge openings for pleasure vessels only to reduce highway traffic congestion during the morning and evening rush hours. In support of its request, the NCDOT contends that 10 years of records during the period from 1985 through 1995 show that highway traffic increases have caused excessive highway congestion.

Prior to publishing the Notice of Proposed Rulemaking the Coast Guard reviewed the NCDOT highway traffic data during the 10 year period from 1985 through 1995, and the drawbridge opening logs from January 1995 to December 1995, copies of which are included in the docket for this rulemaking. This data supports NCDOT's request. According to the 1995 drawbridge logs, 234 openings occurred between 7 a.m. and 9 a.m. and 235 openings occurred between 4 p.m. and 6 p.m. Thus, the daily average for the year was 0.6 openings for each of the proposed restricted periods. Only during the month of May 1995 were there more than 2.0 openings during the time periods in question. During May 1995, an average of 2.6 openings occurred between 7 a.m. and 9 a.m. Even though 2.6 openings is not excessive, NCDOT states that the random timing of the openings caused highway traffic to backup four to six blocks. In support of this contention, the NCDOT provided highway traffic data which shows that highway traffic volumes increased by an average of between 200 and 300 vehicles during the morning and evening restricted periods as compared to other daylight hours. Based upon this data, the Coast Guard believes that 2.0 scheduled openings for pleasure vessels for each time period is adequate for marine traffic and should help to reduce highway traffic congestion.

Discussion of Comment and Changes

The Coast Guard received no comments on the proposed rulemaking.

Therefore, the proposed rule is being implemented without change.

Regulatory Evaluation

This final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this final rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this final rule will have significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632). Because it expects the impact of this rule to be minimal, 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 final rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this final rule under the principles and criteria contained in Executive Order 12612, and has determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this final rule and concluded that under section 2.B.2.e.(32)(e) of Commandant Instruction M16475.1B (as amended, 59 FR 38654, 29 July 1994), this final rule is categorically excluded from further environmental documentation. A Categorical Exclusion Determination statement has been prepared and placed in the rulemaking docket.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

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; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. The text of § 117.833 is redesignated as paragraph (a) and a new paragraph (b) is added to read as follows:

§ 117.833 Pasquotank River.

(a) * * *

(b) The draw of the US 158 Highway Bridge, mile 50.7, at Elizabeth City, shall open on signal; except that between 7 a.m. and 9 a.m., and 4 p.m. and 6 p.m., Monday through Friday, the draw need open only at 7:30 a.m., 8:30 a.m., 4:30 p.m., and 5:30 p.m. for any pleasure vessels waiting to pass.

Dated: December 8, 1997.

Roger Rufe, Jr.,

Vice Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 97–32885 Filed 12–16–97; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD05–97–086]

RIN 2115–AE47

Drawbridge Operation Regulations; Elizabeth River, Eastern Branch

AGENCY: Coast Guard, DOT.

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 US 460 (Berkley Bridge) drawbridge across the Eastern Branch of the Elizabeth River, mile 0.4, at Norfolk, Virginia. Beginning December 15, 1997 through January 9, 1998, this deviation restricts bridge openings between the hours of 9 a.m. to 3:30 p.m., seven days a week. During these times, vessels requiring bridge lifts

will be required to provide the Berkley Bridge bridge tender with a two-hour advance notice. This closure is necessary to allow the Virginia Department of Transportation to conduct an oil change on the major lift equipment while still providing for the reasonable needs of navigation.

DATES: This deviation is effective from December 15, 1997 through January 9, 1998.

FOR FURTHER INFORMATION CONTACT:

Ann B. Deaton, Bridge Administrator, Fifth Coast Guard District, at (757) 398–6222.

SUPPLEMENTARY INFORMATION: The Berkley Bridge is owned and operated by the Virginia Department of Transportation (VDOT) and maintained by the Elizabeth River Tunnels Department of Maintenance. On December 1, 1997, VDOT sent a letter to the Coast Guard requesting a temporary deviation from the normal operation of the bridge in order to accommodate the maintenance work. Presently, the draw is required to open on signal at any time except from 5:30 a.m. to 9 a.m. and from 3:30 p.m. to 6:30 p.m., Monday through Friday, except Federal holidays. Between the hours of 5:30 a.m. and 9 a.m. and 3:30 p.m. and 6:30 p.m., vessels with a draft of 22 feet or more may request a bridge lift provided at least 12 hours advance notice is given.

The maintenance work involves draining and subsequent refilling of oil in the gear boxes in the major lift equipment of the US 460 (Berkley Bridge) drawbridge. Vessels presently transiting through the Berkley Bridge during the hours of deviation will not be negatively impacted since bridge lifts will be provided with a two-hour advance notice.

From December 15, 1997 to January 9, 1998, this deviation restricts bridge lifts of the Berkley Bridge between the hours of 9 a.m. and 3:30 p.m. seven days a week. Vessels requiring a bridge lift during these times will be required to provide a two-hour advance notice to the Berkley Bridge bridge tender. All other provisions of § 117.1007 remain in effect during the period of the deviation.

Dated: December 8, 1997.

Roger Rufe, Jr.,

Vice Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

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