

agencies for Restricted Areas R-6412A and R-6412B, Camp Williams, UT. This is an administrative change initiated by the Northwest Mountain Region. There are no changes to the boundaries, altitudes, times of designation, or activities conducted within the restricted areas.

Since this action simply changes the published controlling agency of the affected restricted areas, and does not involve a change in the dimensions or operating requirements of the restricted areas, the FAA finds that notice and public procedure under 5 U.S.C. 553(b) are unnecessary. Section 73.64 of part 73 of the Federal Aviation Regulations was republished in FAA Order 7400.8E, dated November 7, 1997.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, it (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal.

#### Environmental Review

In accordance with FAA Order 1050.1D, "Policies and Procedures for Considering Environmental Impacts," this action is not subject to environmental assessments and procedures.

#### List of Subjects in 14 CFR Part 73

Airspace, Navigation (air).

#### Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73, as follows:

#### PART 73—SPECIAL USE AIRSPACE

1. The authority citation for part 73 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389

#### § 73.64 [Amended]

2. § 73.64 is amended as follows:

\* \* \* \* \*

#### R-6412A Camp Williams UT [Amended]

By removing "Controlling agency. FAA, Salt Lake City Tower" and substituting the following:

"Controlling agency. FAA, Salt Lake City TRACON."

#### R-6412B Camp Williams UT [Amended]

By removing "Controlling agency. FAA, Salt Lake City Tower" and substituting the following:

"Controlling agency. FAA, Salt Lake City TRACON."

\* \* \* \* \*

Issued in Washington, DC, on December 2, 1997.

**Reginald C. Matthews,**

*Acting Program Director for Air Traffic Airspace Management.*

[FR Doc. 97-32571 Filed 12-16-97; 8:45 am]

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 15 CFR Part 922

[Docket No. 960712192-6192-01]

RIN 0648-AD85

#### Florida Keys National Marine Sanctuary Final Regulations

**AGENCY:** Sanctuaries and Reserves Division (SRD), Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

**ACTION:** Correction to final regulations.

**SUMMARY:** This document contains a correction to the final regulations which were published Thursday, January 30, 1997 (62 FR 4578). The regulations pertain to the Florida Keys National Marine Sanctuary and made revisions to the national marine sanctuary program regulations at 15 CFR Part 922.

**EFFECTIVE DATE:** December 17, 1997.

**FOR FURTHER INFORMATION CONTACT:** Michael Weiss (301) 713-2969, ext. 216.

**SUPPLEMENTARY INFORMATION:** Final regulations for the Florida Keys National Marine Sanctuary were published on Thursday, January 30, 1997 (62 FR 4578). These regulations were subsequently amended on June 12, 1997 (62 FR 32154). The January 30, 1997 **Federal Register** document made revisions to the national marine sanctuary program regulations at 15 CFR Part 922. The January 30, 1997 **Federal Register** document that is the subject of this correction contains amendatory language for § 922.48(b) of the national marine sanctuary program regulations, which pertains to national marine sanctuary permits. The amendatory instruction for paragraph (b) of section 922.48 was incorrect by failing to state

that only the introductory language to paragraph (b) was amended, thus leaving the remaining subparagraphs to paragraph (b) unchanged. Left uncorrected, the amendatory language would erroneously result in subparagraphs (1) through (5) of paragraph 922.48(b) being deleted from the Code of Federal Regulations.

#### Correction of Publication

Accordingly, the **Federal Register** document published on January 30, 1997 (62 FR 4578) is corrected by revising amendatory instruction 14 on page 4607, third column, to read as follows:

"14. Section 922.48 is amended by revising paragraph (a) and the introductory text of paragraph (b) as follows:"

**Nancy Foster,**

*Assistant Administrator for Ocean Services and Coastal Zone Management.*

[FR Doc. 97-32857 Filed 12-16-97; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 866

[Docket No. 95P-0136]

#### Medical Devices; Reclassification of Tumor-Associated Antigen Immunological Test Systems

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that it is codifying the reclassification of tumor-associated antigen immunological test systems intended as an aid in monitoring patients for disease progression or response to therapy or for the detection of recurrent or residual disease from class III (premarket approval) to class II (special controls). FDA is also announcing that it has issued an order in the form of a letter to Centocor, Inc., reclassifying serum tumor markers into class II. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990.

**EFFECTIVE DATES:** The reclassification was effective September 19, 1996. The codification becomes effective December 17, 1997.

**FOR FURTHER INFORMATION CONTACT:** Joseph M. Sheehan, Center for Devices

and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-2974.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On April 18, 1995, FDA filed a petition submitted by Centocor, Inc., requesting reclassification from class III to class II of tumor-associated antigen immunological test systems, commonly called serum tumor markers, indicated for use in the monitoring of tumor-associated antigen levels in patient serum samples. The tumor-associated antigen immunological test system was a class III "transitional" device under section 520(l) of the act (21 U.S.C. 360j(l)). The petition, was seeking reclassification under the procedures set forth in section 520(l)(2) of the act and 21 CFR 860.136 of the agency's regulations.

FDA consulted with the Immunology Devices Panel (the Panel). During the open public meeting on December 1, 1995, the Panel recommended that FDA reclassify the tumor-associated antigen immunoassay systems for use in monitoring from class III to class II. It further recommended that those tumor markers used for screening indications remain in class III.

Based on its consultation with the Panel, review of the data and information contained in the petition and presented before the Panel, published studies and professional standards, FDA concurred with the Panel's recommendation that tumor-associated antigen immunoassay systems should be reclassified from class III into class II with implementing special controls. FDA further concurred that markers used for screening indications will remain in class III.

On September 19, 1996, FDA issued an order (Ref. 1) in the form of a letter to Centocor, Inc., reclassifying the generic type of device, tumor-associated antigen immunological test systems intended as an aid in monitoring patients for disease progression or response to therapy or for the detection of recurrent or residual disease, from class III to class II. The order identified the generic type of tumor-associated antigen immunological test system as a device that consists of the reagents used to qualitatively or quantitatively measure, by immunochemical techniques, tumor-associated antigens in serum, plasma, urine, or other body fluids. This generic type of device does not include tissue receptor assays, immunohistochemical stains, or direct tests for oncogenes or other genetic markers associated with a

predisposition to development of certain cancers.

Measurement of tumor-associated antigen levels aid in the monitoring of certain cancers. Monitoring is defined here as assessing disease progression, recurrence, or response to therapy. This includes the serial measurement of antigens in patients with histologically confirmed diagnoses who are undergoing therapy for residual or advanced disease. Increasing tumor marker concentrations are indicative of progressive disease, decreasing concentrations are indicative of response to therapy, and constant serial tumor marker concentrations are associated with a stable disease state. Monitoring is further defined as single or serial measurements used as an aid in the detection of recurrent or residual disease in patients following primary curative treatment. Sustained elevations in marker concentrations are suggestive of residual disease, whereas increasing concentrations are indicative of recurring disease.

The order also identified FDA's designated special controls as a premarket notification, section 510(k) (21 U.S.C. 360(k)), guidance document for tumor-associated antigens (Ref. 2), and existing voluntary standards for assay performance by the National Committee for Clinical Laboratory Standards (the NCCLS) (Ref. 3). The guidance document provides the review criteria and data requirements for a 510(k) submission. The guidance document also provides suggestions for non-clinical laboratory studies and the design, conduct, and analysis of appropriate clinical studies to support the performance of these devices. The NCCLS assay performance standards provide evaluative techniques to assure the accurate performance of the antigen tests. FDA believes that these special controls provide the necessary control to reasonably assure the safety and effectiveness of these devices.

FDA notes that the risks associated with the use of tumor markers are relatively low in comparison to the benefits that result from their use for patient monitoring. Furthermore, the risks and benefits associated with the use of tumor markers in the practice of medical oncology are well understood by clinicians. The use and performance characteristics of these devices have been addressed in thousands of peer-review scientific reports and the evaluative techniques used to establish acceptable performance are well described and referenced in the special controls. Additionally, FDA has 20 years of scientific review experience to draw upon in the evaluation of new

tumor markers, and believes that tumor antigen immunoassay systems are well characterized.

Consistent with the act and the regulations, FDA is announcing that on September 19, 1996, an order in the form of a letter was sent to Centocor, Inc., reclassifying the generic type tumor-associated antigen immunoassay system that is intended as an aid in monitoring patients for disease progression or response to therapy or for the detection of recurrent or residual disease from class III to class II. Additionally, FDA is codifying the reclassification of this device, by amending 21 CFR 866.6010.

##### II. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) 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. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104-121)), 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 consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is 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. 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 act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs. The Commissioner of Food and Drugs, certifies that this final rule will not have a significant economic impact on a

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 or 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.*

[FR Doc. 97-32876 Filed 12-16-97; 8:45 am]

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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.