

these devices already comply with the proposed special controls. Because reclassification will reduce regulatory costs with respect to ADCCs, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. Federalism

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.

VII. Paperwork Reduction Act of 1995

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

List of Subjects in 21 CFR Part 864

Biologics, Blood, Laboratories, Medical devices, Packaging and containers.

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR part 864 continues to read as follows:

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

2. Section 864.5220 is revised to read as follows:

§ 864.5220 Automated differential cell counter.

(a) *Identification.* An automated differential cell counter is a device used to identify one or more of the formed elements of the blood. The device may

also have the capability to flag, count, or classify immature or abnormal hematopoietic cells of the blood, bone marrow, or other body fluids. These devices may combine an electronic particle counting method, optical method, or a flow cytometric method utilizing monoclonal CD (cluster designation) markers. The device includes accessory CD markers.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA document entitled “Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA.”

Dated: January 3, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD07–02–001]

Drawbridge Operation Regulations; 63rd Street Bridge, Indian Creek, Mile 4.0, Miami Beach, Miami-Dade County, FL

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Seventh Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the 63rd Street Bridge across Indian Creek, mile 4.0, Miami Beach, Miami-Dade County, Florida. This deviation allows the drawbridge owner or operator to not open the Bridge from January 15, 2002 to January 19, 2002. This temporary deviation is required to allow the bridge owner to safely complete repairs to the Bridge.

DATES: This deviation is effective from 12:01 a.m. on January 15, 2002 until 11:59 p.m. on January 19, 2002.

ADDRESSES: Material received from the public, as well as documents indicated in this preamble as being available in the docket and will be available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 S.E. 1st Avenue, Miami, FL 33131 between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Barry Dragon, Chief, Operations Section, Seventh Coast Guard District, Bridge Section at (305) 415–6743.

SUPPLEMENTARY INFORMATION: The 63rd Street Bridge across Indian Creek, Miami Beach, Miami-Dade County, Florida is a double leaf bridge with a vertical clearance of 11.0 feet above mean high water (MHW) measured at the fenders in the closed position with a horizontal clearance of 50 feet. On December 21, 2001, the Florida Department of Transportation, the drawbridge owner, requested a deviation from the current operating regulation in 33 CFR part 117 which requires the draw of the 63rd Street Bridge, mile 4.04 at Miami Beach, to open on signal. This temporary deviation was requested to allow necessary repairs to the drawbridge in a critical time sensitive manner.

The District Commander has granted a temporary deviation from the operating requirements listed in 33 CFR part 117 to complete repairs to the drawbridge. Under this deviation, the 63rd Street Bridge need not open either span from 12:01 a.m. on January 15, 2002 until 11:59 p.m. on January 19, 2002.

Dated: January 7, 2002.

Greg E. Shapley,

Chief, Bridge Administration, Seventh Coast Guard District.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

CGD01–01–211

RIN 2115–AA97

Safety and Security Zone; Pilgrim Nuclear Power Plant, Plymouth, MA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary safety and security zones around the Pilgrim Nuclear Power Plant in Cape Cod Bay, Plymouth, MA from November 15, 2001 until June 15, 2002. The safety and security zones will temporarily close all waters within an approximate 1000-yard distance from the plant, and will also close shore areas adjacent to the plant. The safety and security zones prohibit entry into or movement within a portion of Cape Cod Bay and adjacent shore