

On February 15, 2000, FDA issued an order to the petitioner classifying the Wallac Neonatal Biotinidase Test Kit, and substantially equivalent devices of this generic type, into class II under the generic name, biotinidase test system. FDA identifies this generic type of device as a biotinidase test system, which is intended to measure the activity of the enzyme biotinidase deficiency, an inborn error of metabolism in infants, characterized by the inability to utilize dietary protein bound vitamin, or to recycle endogenous biotin, and may result in irreversible neurological impairment. This order also identifies the following special control applicable to this device: Sale, distribution, and use of this device are restricted in accordance with the prescription device requirements in § 801.109.

II. Environmental Impact

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. Analysis Impacts

FDA has examined the impacts of the 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 (Public Law 104–121), 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 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 it 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. The agency knows of only one manufacturer of this device. Without this rule, the manufacturer would be required to obtain approval of a premarket approval application from FDA before marketing this device.

Therefore, this rule reduces an economic burden for this manufacturer and any future manufacturers of this type of device. 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 is not required.

IV. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

List of Subjects in 21 CFR Part 862

Medical devices.

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1. The authority citation for 21 CFR part 862 continues to read as follows:

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

2. Section 862.1118 is added to subpart B to read as follows:

§ 862.1118 Biotinidase test system.

(a) *Identification.* The biotinidase test system is an in vitro diagnostic device intended to measure the activity of the enzyme biotinidase in blood. Measurements of biotinidase are used in the treatment and diagnosis of biotinidase deficiency, an inborn error of metabolism in infants, characterized by the inability to utilize dietary protein bound vitamin or to recycle endogenous biotin. The deficiency may result in irreversible neurological impairment.

(b) *Classification.* Class II (special controls). The special control is sale, distribution, and use in accordance with the prescription device requirements in § 801.109 of this chapter.

Dated: March 13, 2000.

Linda S. Kahan,

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

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD08–00–003]

Drawbridge Operating Regulation; Pass Manchac, LA

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Illinois Central Railroad automated bridge, mile 6.7, at Manchac, Tangipahoa and St. John Parishes, Louisiana. This deviation allows the Canadian National/Illinois Central Railroad to close the bridge to navigation continuously from noon on Wednesday, April 12, 2000 until 8 p.m. on Thursday, April 13, 2000. This temporary deviation was issued to allow for the replacement of an electrical cable and to accomplish other general maintenance. Presently, the draw is maintained in the open position and closes for the passage of trains.

DATES: This deviation is effective from noon on Wednesday, April 12, 2000 through 8 p.m. on Thursday, April 13, 2000.

ADDRESSES: Unless otherwise indicated, documents referred to in this notice are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Commander (ob), Eighth Coast Guard District, 501 Magazine Street, New Orleans, Louisiana 70130–3396. The Bridge Administration Branch of the Eighth Coast Guard District maintains the public docket for this temporary deviation.

FOR FURTHER INFORMATION CONTACT: David Frank, Bridge Administration Branch, telephone (504) 589–2965.

SUPPLEMENTARY INFORMATION: The Illinois Central Railroad automated bridge across Pass Manchac, mile 6.7, at Manchac, has a vertical clearance of one foot above mean high water in the closed-to-navigation position and 56 feet above mean high water in the open-to-navigation position. Navigation on the waterway consists of tugs with tows, fishing vessels, sailing vessels, and other recreational craft. The Canadian National/Illinois Central Railroad requested a temporary deviation from the normal operation of the drawbridge in order to accommodate the maintenance work, involving replacement of an underground

electrical cable and other general maintenance work.

This deviation allows the draw of the Illinois Central Railroad automated bridge across Pass Manchac, mile 6.7, at Manchac, Tangipahoa and St. John Parishes, Louisiana to remain closed to navigation continuously from noon on Wednesday, April 12, 2000, until 8 p.m. on Thursday, April 13, 2000.

Dated: March 15, 2000.

K.J. Eldridge,

Capt, USCG, Acting District Commander, Eighth CG District.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP Tampa 00-016]

RIN 2115-AA97

Safety Zone Regulations: Saint Pete Beach, FL

AGENCY: Coast Guard, DOT

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone closing the waters of Blind Pass, Pinellas County, Florida. The zone will be placed into effect and terminated at different times by a broadcast notice to mariners to protect recovery personnel and vessels in the vicinity of pollution response operations. Entry into this zone is prohibited unless authorized by the Captain of the Port.

DATES: This regulation becomes effective at 9 a.m., on March 9, 2000 through 9 a.m., on May 1, 2000.

FOR FURTHER INFORMATION CONTACT: Commanding Officer, Marine Safety Office Tampa, 155 Columbia Drive, Tampa, Florida 33606, Attention: Lieutenant Warren Weedon, or phone (813) 228-2189 ext 101.

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) and 553(d)(3), the Coast Guard finds that good cause exists for not publishing an NPRM and making these regulations effective less than 30 days after the Federal Register publication. Publishing a Notice of Proposed Rulemaking and delaying the effective date would be contrary to national safety interests since immediate action is needed to

minimize potential danger to the public as the updated information concerning the channel blockage was received only one day prior.

Background and Purpose

A permit was granted by the U. S. Army Corp of Engineers to conduct dredging operations in Blind Pass. During the dredging operations it was determined that some oil was buried in the pass. The Coast Guard is now conducting oil recovery operations and has determined that a safety zone is needed to ensure the safety of personnel engaged in recovery operations. The Coast Guard is establishing a temporary safety zone closing the waters of Blind Pass, Pinellas County, Florida. The zone will be placed into effect and terminated at different times by a broadcast notice to mariners to protect recovery personnel and vessels in the vicinity of pollution response operations. Entry into this zone is prohibited unless authorized by the Captain of the Port.

Regulatory Evaluation

This 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 the 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 proposal to be so minimal that a full regulatory evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This regulation will only be in effect in a limited area of Saint Pete Beach.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612 *et seq.*), we considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term "Small entities" comprises small businesses and not for profit organizations that are independently owned and operated and are not dominant in their field and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities as the regulations will only be in effect in a limited area of Saint Pete Beach.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-221), we offer to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. Small entities may contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding and participating in this rulemaking. We also have a point of contact for commenting on actions by employees of the Coast Guard. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism under that order.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) governs the issuance of Federal regulations that require unfunded mandates. An unfunded mandate is a regulation that requires a State, local, or tribal government or the private sector to incur direct costs without the Federal Government's having first provided the funds to pay those unfunded mandate costs. This rule will not impose an unfunded mandate.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking disproportionately affect children.

Civil Justice Reform

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