

nor an environmental impact statement is required.

#### IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485.

#### List of Subjects in 21 CFR Part 864

Blood, Medical devices, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 864 is amended as follows:

#### PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

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

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

■ 2. Add § 864.1866 to subpart B to read as follows:

#### § 864.1866 Lynch syndrome test systems.

(a) *Identification.* Lynch syndrome test systems are in vitro diagnostic tests for use with tumor tissue to identify previously diagnosed cancer patients at risk for having Lynch syndrome.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Premarket notification submissions must include the following information, as appropriate:

(i) A detailed description of all test components, including all provided reagents, and required but not provided, ancillary reagents.

(ii) A detailed description of instrumentation and equipment, including illustrations or photographs of non-standard equipment or manuals.

(iii) Detailed documentation of the device software, including, but not limited to, standalone software applications and hardware-based devices that incorporate software.

(iv) A detailed description of quality controls including appropriate positive and negative controls that are recommended or provided.

(v) Detailed specifications for sample collection, processing, and storage.

(vi) A detailed description of methodology and assay procedure.

(vii) A description of the assay cut-off (*i.e.*, the medical decision point between positive and negative results) or other relevant criteria that distinguishes positive and negative results, or ordinal classes of marker expression, including the rationale for the chosen cut-off or other relevant criteria and results supporting validation of the cut-off.

(viii) Detailed specification of the criteria for test result interpretation and reporting.

(ix) Detailed information demonstrating the performance characteristics of the device, including:

(A) Data from an appropriate study demonstrating clinical accuracy using well-characterized clinical specimens representative of the intended use population (*i.e.*, concordance to Deoxyribonucleic Acid (DNA) sequencing results of the Lynch syndrome associated genes or method comparison to the predicate device using samples with known alterations in genes representative of Lynch syndrome). Pre-specified acceptance criteria must be provided and followed.

(B) Appropriate device reproducibility data investigating all sources of variance (*e.g.*, for distributed tests, data generated using a minimum of three sites, of which at least two sites must be external sites). Each site must perform testing over a minimum of 5 nonconsecutive days evaluating a sample panel that spans the claimed measuring range, and includes the clinical threshold. Pre-specified acceptance criteria must be provided and followed.

(C) Data demonstrating reader reproducibility, both within-reader and between-reader, assessed by three readers over 3 nonconsecutive days at each site, including a 2 week washout period between reads, as appropriate.

(D) Device precision data using clinical samples spanning the measuring range and controls to evaluate the within-lot, between-lot,

within-run, between run, and total variation.

(E) Analytical specificity studies including as appropriate, western blots, peptide inhibition, testing in normal tissues and neoplastic tissues, interference by endogenous and exogenous substances, and cross-reactivity and cross contamination testing.

(F) Device analytical sensitivity data generated by testing an adequate number of samples from individuals with the target condition such that prevalence of the biomarker in the target population is established.

(G) Device stability data, including real-time stability and in-use stability, and stability evaluating various storage times, temperatures, and freeze-thaw conditions, as appropriate.

(H) The staining performance criteria assessed must include overall staining acceptability, background staining acceptability, and morphology acceptability, as appropriate.

(I) Appropriate training requirements for users, including interpretation manual, as applicable.

(J) Identification of risk mitigation elements used by the device, including a description of all additional procedures, methods, and practices incorporated into the instructions for use that mitigate risks associated with testing.

(2) The device’s § 809.10(b) of this chapter compliant labeling must include a detailed description of the protocol, including the information described in paragraphs (b)(1)(i) through (viii) of this section, as appropriate, and a detailed description of the performance studies performed and the summary of the results, including those that relate to paragraph (b)(1)(ix) of this section, as appropriate.

Dated: February 21, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–03924 Filed 2–26–18; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG–2018–0074]

RIN 1625–AA00

#### Safety Zone; Wando Terminal Crane Movement; Charleston, SC

AGENCY: Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary moving safety zone in the Port of Charleston in Charleston, SC around the vessel, M/V Zhen Hua 16. This temporary safety zone is necessary to provide for the safety of waterway users and the M/V Zhen Hua 16 during the vessel's transit into the Port of Charleston, its stay at Columbus Street Terminal, its transit to and stay at Wando Terminal, and its outbound transit departing the Port of Charleston. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Charleston.

**DATES:** This rule is effective without actual notice from February 27, 2018 through March 31, 2018. For the purposes of enforcement, actual notice will be used from February 23, 2018 through February 27, 2018.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2018-0074 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Lieutenant Justin Heck, Sector Charleston Office of Waterways Management, Coast Guard; telephone (843) 740-3184, email [Justin.c.heck@uscg.mil](mailto:Justin.c.heck@uscg.mil).

**SUPPLEMENTARY INFORMATION:**

**I. Table of Abbreviations**

CFR Code of Federal Regulations  
 DHS Department of Homeland Security  
 FR Federal Register  
 NPRM Notice of proposed rulemaking  
 § Section  
 U.S.C. United States Code

**II. Background Information and Regulatory History**

The Coast Guard is issuing this temporary 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)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. We must establish this safety zone by February 23, 2018 and

lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule because the details of the event were not provided to the Coast Guard until January 24, 2018. It is also contrary to the public interest as it would delay the planning and implementation of safety measures necessary to protect the public and mariners from the hazards associated with the transit of the M/V Zhen Hua 16.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest because immediate action is needed to respond to the potential safety hazards associated with the transit of the M/V Zhen Hua 16.

**III. Legal Authority and Need for Rule**

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port (COTP) Charleston has determined that potential hazards exist and will be associated with navigation and dockside operations of the M/V Zhen Hua 16 while within the Sector Charleston Captain of the Port Zone. Due to the size of the cranes aboard the vessel and the vessel's limited ability to maneuver this temporary safety zone is necessary to ensure the safety of, and reduce the risk to, the public and mariners.

**IV. Discussion of the Rule**

This rule establishes a temporary moving safety zone from 12:00 a.m. on February 23, 2018, through 11:59 p.m. on March 31, 2018, encompassing all navigable waters from the surface to the sea floor within 100 yards of the M/V Zhen Hua 16 while the vessel is underway, moored, or anchored in the Sector Charleston Captain of the Port Zone. No vessel or person is permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. Sector Charleston may be contacted on VHF-FM Channel 16 or (843) 740-7050.

**V. Regulatory Analyses**

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

**A. Regulatory Planning and Review**

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory

alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of the safety zone. The size of the zone is the minimum necessary to provide adequate protection for the waterway users, adjoining areas, and the public. The temporary safety zone will be in place during the vessel's time inside the Sector Charleston Captain of the Port Zone. Any hardships experienced by persons or vessels are considered minimal compared to the interest in protecting the public.

**B. Impact on Small Entities**

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601-612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, 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.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

### C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

### D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

### E. 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.

### F. Environment

We have analyzed this rule under Department of Homeland Security

Directive 023-01, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone that will prohibit entry within a 100-yard radius of the vessel, M/V Zhen Hua 16, during the vessel's transit, mooring and anchoring in the Sector Charleston Captain of the Port Zone. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**.

### G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

### List of Subjects in 33 CFR Part 165

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T07-0074 to read as follows:

### § 165.T07-0074 Safety Zone; Wando Terminal Crane Movement; Charleston, SC.

(a) *Regulated area.* The following regulated area is a moving safety zone: All waters of the Charleston Harbor, Cooper River, and Wando River in Charleston, SC within a 100 yard radius around the outer most points of the M/V Zhen Hua 16 while the vessel is underway, moored or anchored.

(b) *Definition.* As used in this section, "designated representative" means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating

Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Charleston in the enforcement of the regulated areas.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Charleston or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at (843) 740-7050, or a designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative.

(3) The Coast Guard will provide notice of the regulated area by Marine Safety Information Bulletins, Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

(d) *Enforcement period.* This section will be enforced beginning at 12:00 a.m. on February 23, 2018, until 11:59 p.m. on March 31, 2018. This rule will be enforced while M/V Zhen Hua is underway, moored, or anchored in the Sector Charleston Captain of the Port Zone.

Dated: February 21, 2018.

J.W. Reed,

Captain, U.S. Coast Guard, Captain of the Port Charleston.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R06-OAR-2017-0077; FRL-9974-51—Region 6]

### Approval and Promulgation of Implementation Plans; Texas; Approval of Texas Motor Vehicle Rule Revisions

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA)