

requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

The ICH guidance entitled "E2B Data Elements for Transmission of Individual Case Safety Reports" was signed off by ICH in July 1997 and issued by FDA in January 1998 (63 FR 2396, January 15, 1998). ICH subsequently issued a revised guidance entitled "E2B(M) Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports" (E2B(M)), to provide additional information and clarification. ICH signed off on E2B(M) in November 2001, and FDA issued the revised guidance in April 2002.

In May 2005, the ICH Steering Committee agreed that the E2B(M) draft guidance should be made available for public comment. The draft guidance is the product of the E2B(R) Expert Working Group of the ICH. Comments about the draft guidance will be considered by FDA and the E2B(R) Expert Working Group.

FDA is announcing the availability of the draft guidance entitled "E2B(R) Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports," which revises the previous E2B guidances to include additional information and clarification for the electronic transmission of individual case safety reports. The draft guidance incorporates adjustments

based on experience gained after implementation of the guidance in the three ICH regions and expands the use of the standard data elements to support vaccine reporting. For electronic transmissions, the draft guidance is intended to be used with the ICH M2 individual case safety report (ICSR) message specification. The draft guidance recommends that electronic transmission of individual case safety reports be implemented using the Medical Dictionary for Regulatory Activities (MedDRA) and ICH M5 data elements and standards where applicable.

FDA has identified in public Docket No. 1992S-0251 (formerly Docket No. 92S-0251) postmarketing individual case safety reports as submission types that the agency can accept in electronic format. FDA believes the ICH recommendations for the electronic transmission of these reports will result in more effective and efficient safety reporting to regulatory authorities worldwide.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/ohrms/dockets/default.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/publications.htm>.

Dated: September 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Waiver of Compliance With Navigation and Inspection Laws; Gulf Coast States

AGENCY: Office of the Secretary, DHS.

ACTION: Notice.

The combined effect of Hurricanes Rita and Katrina is one of the largest natural disasters to ever strike the United States. The hurricanes have significantly disrupted production of oil and gas in the Gulf of Mexico, have caused many Gulf Coast oil refineries to go out of service because of flooding, lack of electric power or other reasons, and have significantly disrupted the pipeline transportation of oil and refined products from the Gulf Coast States. These production losses, outages, and disruptions have caused increases in the price of oil, gasoline and other refined products. The Department of Homeland Security has received reports of threatened or actual shortages of gasoline, jet fuel, and/or other refined products as a result of the hurricanes.

Companies that produce and/or ship petroleum and/or refined petroleum products have submitted to the Department requests for waivers of the Merchant Marine Act of 1920 (the "Jones Act"). See, 46 U.S.C. App. section 1; 46 U.S.C. App. section 883. This and related laws are generally referred to as the "coastwise laws." These laws provide, among other things, that only vessels built and owned by citizens of the United States and flagged in the United States can carry merchandise between U.S. ports.

The Secretary of Homeland Security is vested with the authority and discretion to waive the coastwise laws "to such extent and in such manner and upon such terms as he may prescribe, either upon his own initiative or upon the written recommendation of the head of any other Government agency, whenever he deems that such action is necessary in the interest of national defense." In consultation with and upon the recommendation of the Secretary of Energy, I have determined that such a waiver, in accordance with the terms set forth below, is in the interest of the national defense.

The catastrophic destruction brought about by Hurricanes Rita and Katrina has dramatically impeded, and in some places in the affected region stopped altogether, production and transportation or transmission of oil, refined petroleum products, natural gas, and electricity. Much of the lost oil production is from producing areas in the Gulf of Mexico which have been leased pursuant to programs of the Department of the Interior. This lost production, refining, and transportation capacity has resulted in the actual or threatened unavailability of gasoline, jet fuel and other refined products, and threatens the Nation's economic and national security. I believe that waiver of the coastwise laws would facilitate the transportation of oil and refined petroleum products in and from portions of the United States affected by the hurricanes, and to other regions affected by the disruptions that have occurred in the Gulf Coast area.

Therefore, I am exercising my discretion and authority to waive the coastwise laws generally for the transportation of petroleum and refined petroleum products for the period until 12:01 a.m., October 24, 2005. On September 1, 2005, I exercised my discretion and authority to waive the coastwise laws generally for the transportation of petroleum released from the Strategic Petroleum Reserve, whether pursuant to an exchange, sale or otherwise, undertaken in response to the circumstances arising from Hurricane Katrina. I am today exercising my discretion and authority to extend that waiver of the coastwise laws generally for the transportation of petroleum released from the Strategic Petroleum Reserve, whether pursuant to an exchange, sale, or otherwise, undertaken in response to the circumstances arising from Hurricane Rita. I find, for the reasons set forth above, that such waivers are necessary in the interest of national defense.

Executed this 26th day of September, 2005.

Michael Chertoff,

Secretary.

[FR Doc. 05-19820 Filed 9-29-05; 1:23 pm]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2005-22499]

Integrated Anti-Swimmer System; Draft Programmatic Environmental Assessment

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability and request for comments.

SUMMARY: The Coast Guard announces the availability of the Draft Programmatic Environmental Assessment (PEA) of the Integrated Anti-Swimmer System (IAS). The Coast Guard is proposing to deploy and operate the IAS for temporary periods at various U.S. ports throughout the U.S. Maritime Domain, when necessary. The purpose of the Proposed Action is to increase the Coast Guard's ability to detect, track, classify, and interdict, if necessary, potential underwater threats and as a result, protect personnel, ships, and property from sabotage and/or other subversive acts. Potential threats targeted by the IAS include combat divers and unmanned vehicles. The IAS will be co-located with, and used by, the Coast Guard's newly established Maritime Safety and Security Teams (MSSTs). The IAS is proposed to be used at a range necessary to maintain situational awareness and allow the MSSTs sufficient time to react and counter a detected threat. Extensive research and analysis of alternatives has led to the conclusion that an active sonar system is the only currently available technology that affords this capability.

DATES: Comments and related material must reach the Docket Management Facility on or before November 17, 2005.

ADDRESSES: To make sure that your comments and related material are not entered more than once in the docket, please submit them by only one of the following means:

(1) Electronically through the Web Site for the Docket Management System at <http://dms.dot.gov>.

(2) By mail to the Docket Management Facility, (USCG-2005-22499), U.S. Department of Transportation, room PL-401, 400 Seventh Street SW., Washington, DC 20590-0001.

(3) By fax to the Docket Management Facility at 202-493-2251.

(4) By delivery to room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday

through Friday, except Federal holidays. The telephone number is 202-366-9329.

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public, as well as the draft Programmatic Environmental Assessment (PEA), will become part of this docket and will be available for inspection or copying at room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket, including the PEA, on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, the proposed project, or the associated PEA, call Mr. Kenneth McDaniel at (202) 267-1505 or by e-mail at kmcdaniel@comdt.uscg.mil. If you have questions on viewing or submitting material to the docket, call Andrea M. Jenkins, Program Manager, Docket Operations, telephone 202-366-0271.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to submit comments and related material on the draft Programmatic Environmental Assessment (PEA). If you do so, please include your name and address, identify the docket number for this notice (USCG-2005-22499) and give the reasons for each comment. You may submit your comments and material by mail, hand delivery, fax, or electronic means to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period.

Proposed Action

Domestic port safety and security has long been a core Coast Guard mission. However, in the wake of the terrorist attacks committed on September 11, 2001, emerging threats to the U.S. homeland have prompted an increased Coast Guard focus on protecting domestic ports and the U.S. Maritime Transportation System from terrorist threats.

As part of the U.S. response to these threats, the Coast Guard has undertaken