pilot program in which biologics manufacturers could self-certify conformance to licensing criteria prescribed by FDA. This action was intended to reduce unnecessary burdens for industry without diminishing public health protection.

The guidance is being withdrawn because FDA has determined that there is a lack of industry interest in pursuing the pilot licensing program outlined in the guidance.

Dated: March 31, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5204 Filed 4–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0121]

Guidance for Industry and Food and Drug Administration Staff; In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path.'' FDA is issuing this guidance to inform industry and agency staff of steps that are needed to ensure the safe and effective use of in vitro diagnostic (IVD) devices intended for use in the detection of influenza A (or A/B) virus directly from human specimens. FDA is taking this action because of recent significant public health concerns associated with emergence of an avian influenza A virus strain as a human pathogen in Southeast Asia. This guidance document describes recommendations for fulfilling labeling requirements applicable to all IVDs intended to generally detect influenza A (or A/B) virus directly from human specimens, and outlines the premarket regulatory path for new or modified devices intended to generally detect influenza A virus, or to detect and differentiate, specific novel influenza A viruses infecting humans. This guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices.

DATES: Submit written or electronic comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sally Hojvat, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–0496.

SUPPLEMENTARY INFORMATION:

I. Background

The spread of the influenza A H5N1 virus within bird species, along with sporadic transmission to humans, has heightened awareness of the potential for a novel influenza A virus to cause a pandemic in humans. Novel influenza A viruses are new or re-emergent human strains of influenza A that cause cases or clusters of human disease, as opposed to those human strains commonly circulating that cause seasonal influenza and to which human populations have residual or limited immunity (either by vaccination or previous infection). All of the influenza A (or A/B) devices cleared by FDA under 21 CFR 866.3330 before February 3, 2006, are designed to generally detect influenza A viruses in human respiratory specimens (e.g., washes, aspirates, and swabs). None of these devices is designed or intended to detect a specific influenza A virus, or to detect and differentiate one specific influenza A virus from another (e.g., H5N1 from H3N2). For devices cleared on the basis of performance characteristics established when only influenza A/H3 and A/H1 viruses were circulating, there is no evidence that the devices would reliably detect novel influenza A viruses from human respiratory samples. Also, these testing devices are not intended to detect and differentiate a specific human-infecting novel influenza A virus. FDA is making this guidance document immediately available because prior public participation is not feasible given the national and global public health threat of pandemic influenza. At this time public health officials are expediting plans to prepare for and respond to this threat. Immediate implementation of this guidance is part of this preparedness effort as it clarifies the role of in vitro diagnostic devices for the detection and/or differentiation of novel influenza A viruses.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on labeling and regulatory path for in vitro diagnostic devices to detect influenza A viruses. 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 statute and regulations.

III. Electronic Access

To receive ''In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1549 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.*

fda.gov/cdrh/guidance.html. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. 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 21 CFR part 809 have been approved under OMB Control No. 0910–0485; the collections of information in 21 CFR part 807 have been approved under OMB Control No. 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB Control No. 0910–0078.

V. Comments

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

Dated: March 31, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5203 Filed 4–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2006–24258]

Environmental Assessment for Homeporting of Four National Security Cutters at Alameda, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice; request for public comments.

SUMMARY: The Coast Guard announces its intent to prepare an Environmental Assessment (EA) for the homeporting of four new 418-foot National Security Cutters (NSCs) at Coast Guard Island (CGI) in Alameda, California, and requests public comments. Preparation of the EA is being conducted in accordance with the National Environmental Policy Act and its implementing regulations. The new NSCs will replace the four existing 30-year old 378-foot High Endurance Cutters (HECs) currently homeported at CGI, starting with one in 2007/2008 and continuing with one replacement per year until 2010/2011, under current plans.

DATES: Comments and related material must reach the Docket Management Facility on or before May 10, 2006.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2006–24258 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) Web Site: *http://dms.dot.gov.*

(2) Mail: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001.

(3) Fax: 202–493–2251.

(4) Delivery: 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call LCDR Mike Woolard, Coast Guard, telephone 571–218–3382. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–493–0402.

SUPPLEMENTARY INFORMATION:

Request for Comments

All comments received will be posted, without change, to *http://dms.dot.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.

Submitting comments: If you submit a comment, please include your name and address, identify the docket number for this notice (USCG–2006–24258) and give the reason for each comment. You may submit your comments by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments by only one means. If you submit them by mail or 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 that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments received during the comment period.

Viewing comments and documents: To view comments, go to *http://dms.dot.gov* at any time, click on ''Simple Search,'' enter the last five four digits of the docket number for this rulemaking, and click on ''Search.'' You may also visit the Docket Management Facility in 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.

Privacy Act: Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://dms.dot.gov.*

Background and Purpose

To continue to meet America's 21st century maritime threats and challenges, the United States Coast Guard (USCG) initiated the Integrated Deepwater System (IDS) Program, the largest and most innovative acquisition in the Coast Guard's history. The IDS will significantly contribute to the Coast Guard's maritime domain awareness, as well as the improved ability to intercept, engage, and deter those activities that pose a direct challenge/threat to U.S. sovereignty and security. IDS will provide the means to extend our layered maritime defenses from our ports and coastal areas to hundreds of miles out to sea.

The underlying need for the IDS is to provide upgraded, modern assets for the Coast Guard's Pacific Area (PACAREA) Command, in support of executing the wide range of Coast Guard missions in the Pacific area. PACAREA has operational responsibility for waters as far south as Central America and over 1,000 miles offshore. CGI is the critical facility that currently provides the support functions for meeting Coast Guard missions in the Pacific area. These missions are currently met with aging (Legacy) 378 ft cutters of the *SECRETARY* class whose end of economic service life is 2008.

Under the Coast Guard's Deepwater Program, the NSC will be the flagship of the new fleet of cutters. The sweeping modernization and new assets acquisitions of the Deepwater Program will bring much needed capability and