

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 2006D-0099]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses: Availability**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses". This guidance document describes a means by which Reagents for detection of specific novel influenza A viruses may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify Reagents for detection of specific novel influenza A viruses into class II (special controls). This guidance document is immediately in effect as a special control for Reagents for detection of specific novel influenza A viruses, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

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

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses" 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:

Claudia Gaffey, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0496.

SUPPLEMENTARY INFORMATION:**I. Background**

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying Reagents for detection of specific novel influenza A viruses into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This notice announces the guidance document that will serve as a special control for Reagents for detection of specific novel influenza A viruses. An additional special control is established in 21 CFR 866.3332. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the agency's current thinking on Reagents for detection of specific novel 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 "Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses" 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 1596 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 contains information collection provisions that 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 this guidance were approved under OMB control numbers 0910-0485, 0910-0120, 0910-0073 and 0910-0584 and expires on September 30, 2006.

V. Comments

Interested persons may submit to the Division of Dockets Management (See **ADDRESSES**), written or electronic comments regarding this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit 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 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06-2743 Filed 3-21-06; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[CGD01-06-016]

Implementation of Sector Southeastern New England

AGENCY: Coast Guard, DHS.

ACTION: Notice of organizational change.

SUMMARY: This notice explains the details associated with the establishment of Sector Southeastern New England. The date on which the boundaries of the areas of responsibility discussed herein shifted was February 28, 2006, the date of the official stand-up of Sector Southeastern New England. The Sector Commander has the authority, responsibility, and missions of Group Woods Hole, Captain of the Port (COTP) and Marine Safety Office Providence in the zone identified in this notice. The Coast Guard has established continuity of operations whereby all previous practices and procedures will remain in effect until superseded by an authorized Coast Guard official or document.

DATES: The effective date of the Sector stand-up was February 28, 2006.

ADDRESSES: Documents associated with this notice are part of docket CGD01-06-016 and are available for inspection or copying at Commander, First Coast Guard District (dm), 8th Floor, 408 Atlantic Ave., Boston, MA 02110, between 7:30 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: The First Coast Guard District Resource and Performance Management Office at (617) 223-8248, between 7 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Discussion of Notice

This notice confirms the stand-up of Sector Southeastern New England. This is the final Sector being established in the First Coast Guard District. Information concerning the stand-up of other Sectors within the First Coast Guard District was published via a similar Notice of Organizational Change in the **Federal Register** on June 27, 2005 (70 FR 36942).

The boundaries of the areas of responsibility for Sector Southeastern New England discussed herein changed on the date of stand-up, February 28, 2006. The restructuring described in this notice is internal to the Coast Guard. The purpose of this organizational change is to strengthen unity of command in our port, waterway and coastal areas of operation.

Sector Southeastern New England will contain a single integrated command center, which provides a common operating picture. The Sector is composed of three departments, namely: The Response Department, the Prevention Department, and the Logistics Department.

The Search and Rescue (SAR) boundary formally associated with Group Woods Hole has been changed to align with the Marine Inspection and COTP zone formerly associated with Marine Safety Office Providence, as described in this notice. The new Sector's area of responsibility for SAR will be maintained in accordance with the District SAR Plan.

The Sector Commander is vested with all the rights, responsibilities, duties, and authority of a Group Commander and a Commanding Officer, Marine Safety Office, as provided for in Coast Guard regulations, and is the successor in command to the Commanding Officer of Marine Safety Office Providence and the Commander of Group Woods Hole. The Sector Southeastern New England Commander is designated: (a) Captain of the Port (COTP); (b) Federal Maritime Security Coordinator (FMSC); (c) Federal On-Scene Coordinator (FOSC) consistent with the National Contingency Plan; (d) Officer In Charge, Marine Inspection (OCMI); and (e) Search and Rescue Mission Coordinator (SMC).

The First District Commander may also designate the Sector Commander as mission coordinator for search and rescue and law enforcement operations beyond the exclusive economic zone. The Deputy Sector Commander has been designated alternate COTP, FMSC, FOSC, SMC, and acting OCMI. A separate continuity of operations order has been issued providing that all previous Marine Safety Office and Group practices and procedures will remain in effect until superseded by the Sector Commander. The continuity of operations order addresses existing COTP regulations, orders, directives and policies.

Sector Southeastern New England (Sector SENE) is located at Little Harbor Rd., Woods Hole, Massachusetts. Sector SENE is responsible for all Coast Guard missions in the following Marine

Inspection and Captain of the Port Zone. The zone starts on the Massachusetts coast at Manomet Point at 41°55' N latitude, 70°33' W longitude and proceeds northeast to 42°08' N latitude 70°15' W longitude; thence east along 42°08' N latitude to the outermost extent of the EEZ; thence southerly along the outermost extent of the EEZ to a line bearing 132° T from Watch Hill Light, Rhode Island; thence northwest along a line bearing 132° T from Watch Hill Light, Rhode Island, to Watch Hill Light; thence northeast to 41°21' N latitude, 71°48.5' W longitude at Westerly, Rhode Island; thence north to 41°25' N latitude, 71°48' W longitude; thence north along the Connecticut-Rhode Island boundary, including the waters of Beach Pond, to the Massachusetts boundary; thence east along the Massachusetts-Rhode Island boundary to 42°01.5' N latitude, 71°28.0' W longitude; thence east to 42°04' N latitude, 71°06' W longitude; thence southeasterly to the point of origin.

All existing missions and functions performed by MSO Providence, and Group Woods Hole have been realigned under this new organizational structure as of February 28, 2006, and MSO Providence, and Group Woods Hole no longer exist as separate organizational entities.

The following is updated address and point of contact information to facilitate requests from the public:

Name: Sector Southeastern New England.

Address: Commander, U.S. Coast Guard Sector Southeastern New England, 1 Little Harbor Road, Woods Hole, MA 02543-1099.

Contact: General Number, (508) 457-3272.

Dated: March 12, 2006.

David P. Pekoske,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

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DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Agency Information Collection Activities; Declaration of Persons Who Performed Repairs or Alterations

AGENCY: Bureau of Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: Proposed collection; comments requested.