Room 100, Wichita, Kansas 67209; phone: 316–946–4174; fax: 316–946–4107; email: *ben.tyson@faa.gov.*

(2) For service information identified in this AD, contact Rockwell Collins, Inc., Collins Aviation Services, 350 Collins Road NE., M/S 153–250, Cedar Rapids, IA 52498–0001; telephone: 888–265–5467 (U.S.) or 319–265–5467; fax: 319–295–4941 (outside U.S.); email: *techmanuals@rockwellcollins.com;* Internet: *http://www.rockwellcollins.com/Services_and_Support/Publications.aspx.* You may review this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on May 16, 2014.

**Earl Lawrence,**

*Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2014–11846 Filed 5–21–14; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 866

**[Docket No. FDA–2014–N–0440]**

## Microbiology Devices; Reclassification of Influenza Virus Antigen Detection Test Systems Intended for Use Directly With Clinical Specimens

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed order.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to reclassify antigen based rapid influenza virus antigen detection test systems intended to detect influenza virus directly from clinical specimens that are currently regulated as influenza virus serological reagents from class I into class II with special controls and into a new device classification regulation.

**DATES:** Submit either electronic or written comments on the proposed order by August 20, 2014. See section XI for the proposed effective date of any final order that may publish based on this proposed order.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA–2014–N–0440, by any of the following methods:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

*Written Submissions*

Submit written submissions in the following ways:

- Mail/*Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name and Docket No. FDA–2014–N–0440 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section.

*Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Stefanie Akselrod, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5517, Silver Spring, MD 20993–0002, 301–796–6188.

**SUPPLEMENTARY INFORMATION:**

### I. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under the FD&C Act, FDA clears or approves the three classes of medical devices for commercial distribution in the United States through three regulatory processes: Premarket approval (PMA), product development protocol, and premarket notification (a premarket notification is generally referred to as a ''510(k)'' after the section of the FD&C Act where the requirement is found). The purpose of a premarket notification is to demonstrate that the new device is substantially equivalent to a legally marketed predicate device. Under section 513(i) of the FD&C Act, a device is substantially equivalent if it has the same intended use and technological characteristics as a predicate device, or has different technological characteristics but data demonstrate that the new device is as safe and effective as the predicate device and does not raise different issues of safety or effectiveness.

FDA determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807). Section 510(k) of the FD&C Act and the implementing regulations in part 807, subpart E, require a person who intends to market a medical device to submit a premarket notification submission to FDA before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use.

In accordance with section 513(f)(1) of the FD&C Act, devices that were not in commercial distribution before May 28, 1976, the date of enactment of the 1976 amendments, generally referred to as postamendment devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless FDA classifies the device into class I or class II by issuing an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval or the device is reclassified into class I or class II. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act and part 807 of FDA's regulations.

Section 513(f)(2) of the FD&C Act establishes procedures for ''de novo'' risk-based review and classification of postamendment devices automatically classified into class III by section

513(f)(1). Under these procedures, any person whose device is automatically classified into class III by section 513(f)(1) of the FD&C Act may seek reclassification into class I or II, either after receipt of an order finding the device to be not substantially equivalent, in accordance with section 513(i), to a predicate device that does not require premarket approval, or at any time after determining there is no legally marketed device upon which to base a determination of substantial equivalence. In addition, under section 513(f)(3) of the FD&C Act, FDA may initiate, or the manufacturer or importer of a device may petition for, the reclassification of a device classified into class III under section 513(f)(1).

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended section 513(e) of the FD&C Act, changing the process for reclassifying a device from rulemaking to an administrative order. Section 608(b) of FDASIA (126 Stat. 1056) amended section 515(b) of the FD&C Act (21 U.S.C. 360e(b)), changing the process for requiring premarket approval for a preamendments class III device from rulemaking to an administrative order.

*Reclassification*

FDA is publishing this document to propose the reclassification of antigen based rapid influenza detection test (RIDT) systems intended to detect influenza virus antigen directly from clinical specimens that are currently regulated as influenza virus serological reagents under § 866.3330 (21 CFR 866.3330) from class I into class II with special controls and into a new device classification regulation.

Section 513(e) of the FD&C Act governs reclassification of classified preamendments device types and postamendments devices that have been classified into class I or II under section 513(f)(2) or (f)(3) of the FD&C Act. This section provides that FDA may, by administrative order, reclassify a device based upon ''new information.'' FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify an eligible device type. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland-Rantos Co.* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see *Bell,* 366 F.2d at 181; *Ethicon, Inc.* v. *FDA,* 762 F.Supp. 382, 388–391 (D.D.C. 1991)), or in light of changes in ''medical science'' (*Upjohn,* 422 F.2d at 951). Whether data before the Agency are old or new data, the ''new information'' to support reclassification under section 513(e) of the FD&C Act must be ''valid scientific evidence,'' as defined in section 513(a)(3) and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Association* v. *FDA,* 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1986).)

FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the ''valid scientific evidence'' upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).) Section 520(h)(4) of the FD&C Act, added by FDAMA, provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This can include information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final order for reclassifying a device. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the **Federal Register**; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket. FDA has held a meeting of a device classification panel described in section 513(b) of the FD&C Act with respect to rapid influenza diagnostic tests, and therefore, has met this requirement under section 513(e).

FDAMA added section 510(m) to the FD&C Act. Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

## II. Regulatory Background of the Device

In the **Federal Register** of April 22, 1980 (45 FR 27204), FDA published proposed regulations containing general provisions applicable to the classification of immunology and microbiology devices and individual proposed regulations to classify 161 immunology and microbiology devices into one or more of three regulatory classes: Class I (general controls), class II (performance standards), and class III (premarket approval). These regulations included the April 22, 1980, proposed rule (45 FR 27204 at 27261) to classify influenza virus serological reagents into class I under § 866.3330 (21 CFR 866.3330) *Influenza virus serological reagents.* In a final rule, on November 9, 1982 (47 FR 50814 at 50823), under the authority of the Medical Device Amendments of 1976, FDA classified influenza virus serological reagents into class I under § 866.3330. At that time, influenza tests conceived to fall under this regulation were laboratory methods to detect antibodies that develop in response to influenza infection while the detection of the influenza virus itself was done primarily by viral culture. As enzyme immunoassay technology developed, tests capable of detecting viral proteins (antigens) directly in human respiratory samples began to come to FDA for clearance. Since then, numerous influenza detection tests based on antigen-antibody binding properties have been developed and cleared for the market. The first RIDT for use directly from clinical specimens was cleared in 1990 and followed by others in the late 1990s. To date, methods utilizing antigens and antibodies as components of an influenza detection device have been regulated under § 866.3330 as class I devices exempt from the premarket notification (510(k)) requirement subject to the limitations in § 866.9 (21 CFR 866.9). RIDTs found under § 866.3330 exceed the limitations to the exemption from premarket notification for influenza virus serological reagents under § 866.9(c)(6) and thus require a 510(k) submission.

There are approximately 12 RIDTs classified under § 866.3330 actively marketed today. Because these devices are easy to use and provide results within 15 to 30 minutes, they are widely used in point-of-care settings where rapid diagnosis of influenza is important for early case identification.

## III. Identification

We are proposing that RIDTs classified under § 866.3330 be identified under the new name of influenza virus antigen detection test system. An influenza virus antigen detection test system is a device intended for the qualitative detection of influenza viral antigens directly from clinical specimens in patients with signs and symptoms of respiratory infection. The test aids in the diagnosis of influenza infection and provides epidemiological information on influenza. Due to the propensity of the virus to mutate, new strains emerge over time that may potentially affect the performance of these devices. Because influenza is highly contagious and may lead to an acute respiratory tract infection causing severe illness and even death, the accuracy of these devices has serious public health implications.

## IV. Background for Proposed Reclassification Decision

On June 13, 2013, FDA convened a meeting of the Microbiology Advisory Panel to discuss the regulation of RIDTs that are currently regulated as class I devices. The primary reasons for convening the panel to discuss this topic were continued reports of poor real world RIDT performance by the RIDTs in the field compounded by the emergence of new influenza strains with a potential to create a public health emergency. The occurrence of the 2009 flu pandemic emphasized that these RIDTs, while widely used by clinicians in point of care settings, performed poorly resulting in misdiagnosed cases and, according to anecdotal reports, sometimes with serious or even fatal consequences.

The panel discussion included a discussion of the labeled performance of the currently available RIDTs and presentations by representatives from the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL) citing the evidence of performance of these tests in real life settings. One of the important issues raised was that the performance of an influenza antigen detecting test is subject to the changes in the virus as it mutates over time. The panel members were asked to discuss whether there is sufficient evidence to suggest that general controls under class I regulation are or are not sufficient to provide a reasonable assurance that current and future RIDTs are safe and effective and whether the addition of special controls would provide reasonable assurance of the device's safety and effectiveness if the general controls alone do not. Panel members provided the opinion that sufficient data and information exist to indicate that special controls are needed to mitigate the risks of false positive and false negative results from RIDTs and provide a reasonable assurance of safety and effectiveness of the device and to identify the special controls needed. The panel members indicated that placing RIDTs into class II with special controls was appropriate.

## V. Classification Recommendation

FDA is proposing that all RIDTs currently regulated under § 866.3330 be reclassified into class II with special controls under the new device name ''influenza virus antigen detection test system.'' FDA believes that special controls that: (1) Identify the minimum acceptable performance criteria; (2) identify the appropriate comparator for establishing performance of new assays; and (3) call for mandatory annual analytical reactivity testing of contemporary influenza strains, including testing of newly emerging strains that pose a danger of public health emergency, would provide reasonable assurance of safety and effectiveness of these devices.

Section 510(m) of the FD&C Act provides that a class II device may be exempt from the premarket notification requirements under section 510(k), if the Agency determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this device, FDA believes that premarket notification is necessary to provide reasonable assurance of safety and effectiveness and, therefore, does not intend to exempt the device from the premarket notification requirements.

## VI. Risks to Health

Although an RIDT is intended for use as an aid in the diagnosis of influenza infection in conjunction with clinical symptoms and other laboratory findings, failure of the device to perform as indicated (producing erroneous or inaccurate results) could mislead the physician and cause inappropriate or delayed medical treatment of a patient. Failure of the test to produce accurate test results can also lead to inaccurate epidemiological information that may contribute to inappropriate public health responses and to facilitate spread of the infection in a community. After considering the information discussed by the Microbiology Devices Panel during the June 13, 2013, meeting in conjunction with the published literature on the subject and the FDA Medical Device Reporting system reports, FDA believes the following risks are associated with RIDTs:

- A false negative result may lead to failure to provide a correct diagnosis and the appropriate treatment of infection caused by influenza virus and may contribute to unnecessary treatment for another suspected condition.
- A false negative result will also provide incorrect epidemiological information leading to failure to initiate appropriate corrective measures to control and prevent additional infections.
- A false positive result on the other hand may lead to delayed treatment of a respiratory infection caused by another etiologic agent, which could potentially result in a more serious patient outcome.
- A false positive result will also provide incorrect epidemiological information on the presence of influenza in a community, which may result in unnecessary patient isolation or contact limitations and in unnecessary close contact investigations.
- A lack of result due to a device malfunction also may lead to a delayed diagnosis and an inadequate treatment regime and, again, lead to delayed epidemiological information on the presence of influenza in a community, contributing to the spread of the infection.

## VII. Summary of the Reasons for Reclassification

Due to the mounting evidence and reports from the scientific community about the poor sensitivity of the RIDTs currently on the market and the corresponding risks to health associated with low sensitivity in combination with a rapidly evolving influenza genome with the potential for a public health emergency, FDA convened a meeting of the Microbiology Devices Panel of the Medical Devices Advisory Committee in order to discuss a proposal to reclassify RIDTs in § 866.3330 from class I to class II with special controls. Consistent with the opinions expressed by the experts on the panel, FDA believes that the establishment of special controls, in addition to general controls, is necessary to mitigate the risks to health not mitigated by the general controls and provide a reasonable assurance of safety and effectiveness for these devices. While we believe that general controls continue to adequately address the risk to health caused by a lack of result due to a device malfunction we believe special controls, in addition to general controls, are needed to control

the other risks of this device, which are: (1) A false negative result may lead to failure to provide a correct diagnosis and the appropriate treatment of infection caused by influenza virus and may contribute to unnecessary treatment for another suspected condition; (2) a false negative result will also provide incorrect epidemiological information leading to failure to initiate appropriate corrective measures to control and prevent additional infections; (3) a false positive result on the other hand may lead to delayed treatment of a respiratory infection caused by another etiologic agent, which could potentially result in a more serious patient outcome; and (4) a false positive result will also provide incorrect epidemiological information on the presence of influenza in a community, which may result in unnecessary patient isolation or contact limitations and in unnecessary close contact investigations.

**VIII. Special Controls**

FDA believes that the following special controls are necessary, in addition to general controls, to mitigate the risks to health described in section VI.

1. The device's sensitivity and specificity performance characteristics must meet one of the following two minimum clinical performance criteria in order to be cleared for marketing and to remain on the market:

- If the manufacturer chooses to compare the device to viral culture:
  - The sensitivity estimate for the device when testing for Influenza A must be at least at the 90 percent point estimate with a lower bound of the 95 percent confidence interval that is greater than or equal to 80 percent. The sensitivity estimate for the device when testing for Influenza B must be at least at the 80 percent point estimate with a lower bound of the 95 percent confidence interval that is greater than or equal to 70 percent.
  - The specificity estimate for the device when testing for Influenza A and Influenza B must be at least at the 95 percent point estimate with a lower bound of the 95 percent confidence interval that is greater than or equal to 90 percent.
- If the manufacturer chooses to compare the device to an appropriate molecular comparator method:
  - The positive percent agreement for the device when testing for Influenza A and Influenza B must be at least at the 80 percent point estimate with a lower bound of the 95 percent confidence interval that is greater than or equal to 70 percent.
  - The negative percent agreement for the device when testing for Influenza A and Influenza B must be at least at the 95 percent point estimate with a lower bound of the 95 percent confidence interval that is greater than or equal to 90 percent.

2. When performing testing to demonstrate the device meets the requirements in paragraph 1 of this section, a currently appropriate and FDA accepted comparator method must be used to establish assay performance in clinical studies.

3. Annual analytical reactivity testing of the device must be performed with contemporary influenza strains. This annual analytical reactivity testing must meet the following criteria:

- The appropriate strains to be tested will be identified by FDA in consultation with CDC and sourced from CDC or a CDC-designated source. If the annual strains are not available from CDC, FDA will identify an alternative source for obtaining the requisite strains.
- The testing must be conducted according to a standardized protocol considered and determined by FDA to be acceptable and appropriate.
- By July 31 of each calendar year, the results of the last 3 years of annual analytical reactivity testing must be included as part of the device's labeling. If a device has not been on the market long enough for 3 years of annual reactivity testing since the device was given marketing authorization, then the results of every designated annual reactivity testing since the device was given marketing authorization by FDA, including the results of annual analytical reactivity testing performed on the viral strains provided that calendar year, must be included. The results must be presented as part of the device's labeling in a tabular format, which includes the detailed information for each virus tested as described in the certificate of authentication, either by:
  - Placing the results directly in the device's § 809.10(b) (21 CFR 809.10(b)) compliant labeling in a section of the labeling devoted to annual analytical reactivity testing; or
  - Providing a hyperlink in a section of the device's labeling to the manufacturer's public Web site where the annual analytical reactivity testing data can be found. If this option is chosen, the manufacturer's home page must publicly provide a hyperlink, which can easily be found and executed, to the annual analytical reactivity testing results and the Web page containing those annual analytical reactivity testing results must allow unrestricted viewing access. This includes being easy to locate the results from the primary part of the manufacturer's Web site that discusses the device.

4. If an emergency, or a potential emergency, is declared by the Secretary of Health and Human Services (HHS) for an influenza viral strain:

- Within 30 days from the date that FDA notifies manufacturers that characterized viral samples are available for test evaluation, the manufacturer must have testing performed on the device with that viral strain in accordance with a standardized protocol considered and determined by FDA to be acceptable and appropriate. The procedure and location of testing may depend on the nature of the emerging virus.
- Within 60 days from the date that CDC first makes characterized viral samples available to manufacturers and continuing until the emergency, or potential emergency, is declared by the Secretary of HHS to be over, the results of the influenza emergency analytical reactivity testing, including the detailed information for the virus tested as described in the certificate of authentication, must be included as part of the device's labeling in a tabular format, either by:
  - Placing the table directly in the device's § 809.10(b) compliant labeling in the section of the labeling devoted to annual analytical reactivity testing and influenza emergency analytical reactivity testing but separate from the annual analytical reactivity testing tables; or
  - Providing a hyperlink in a section of the device's labeling devoted to annual analytical reactivity testing and influenza emergency analytical reactivity testing to a part of the manufacturer's public Web site where the annual and the emergency analytical reactivity testing data can be found. If this option is chosen, the manufacturer's home page must publicly provide a hyperlink, which can easily be found and executed, to the analytical reactivity and emergency testing results and the Web page containing those annual analytical reactivity testing results must allow unrestricted viewing access.

Table 1 shows the special controls set forth in this order that are needed to address the identified risks for this device not sufficiently addressed by the general controls to provide a reasonable assurance of safety and effectiveness of the device.

TABLE 1—IDENTIFIED RISKS TO HEALTH AND REQUIRED MITIGATION MEASURES

| Identified risks to health | Required mitigation measures |
|---|---|
| 1. A false negative result may lead to failure to provide a correct diagnosis and the appropriate treatment of infection caused by influenza virus and may contribute to unnecessary treatment for another suspected condition.. | Special Controls 1–4. |
| 2. A false negative result will also provide incorrect epidemiological information leading to failure to initiate appropriate corrective measures to control and prevent additional infections.. | Special Controls 1–4. |
| 3. A false positive result on the other hand may lead to delayed treatment of a respiratory infection caused by another etiologic agent, which could potentially result in a more serious patient outcome.. | Special Controls 1–4. |
| 4. A false positive result will also provide incorrect epidemiological information on the presence of influenza in a community, which may result in unnecessary patient isolation or contact limitations and in unnecessary close contact investigations.. | Special Controls 1–4. |

If this proposed order is finalized, RIDTs in § 866.3330 will be reclassified into class II with special controls in a new classification regulation at 21 CFR 866.3328. Adherence to the special controls, when finalized, in addition to the general controls, is necessary to provide a reasonable assurance of the safety and effectiveness of the device.

## IX. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of 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.

## X. Paperwork Reduction Act of 1995

This proposed administrative order establishes special controls that refer to previously approved collections of information found in other 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 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 part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

## XI. Proposed Effective Date

FDA proposes that any final order based on this proposed order become effective 1 year after its date of publication in the **Federal Register**.

## XII. Comments

Interested persons may submit either electronic comments regarding this document or the associated Special Controls guideline to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

## XIII. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Transcript of FDA's Microbiology Devices Panel Meeting, June 13, 2013. (Available at: *http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MicrobiologyDevicesPanel/UCM359554.pdf.*)

## List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 866 be amended as follows:

## PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

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

■ 2. Add § 866.3328 to subpart D to read as follows:

### § 866.3328 Influenza virus antigen detection test system.

(a) *Identification.* An influenza virus antigen detection test system is a device intended for the qualitative detection of influenza viral antigens directly from clinical specimens in patients with signs and symptoms of respiratory infection. The test aids in the diagnosis of influenza infection and provides epidemiological information on influenza. Due to the propensity of the virus to mutate, new strains emerge over time which may potentially affect the performance of these devices. Because influenza is highly contagious and may lead to an acute respiratory tract infection causing severe illness and even death, the accuracy of these devices has serious public health implications.

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

(1) The device's sensitivity and specificity performance characteristics must meet one of the following two minimum clinical performance criteria in order to be cleared for marketing and to remain on the market:

(i) If the manufacturer chooses to compare the device to viral culture:

(A) The sensitivity estimate for the device when testing for Influenza A must be at least at the 90 percent point estimate with a lower bound of the 95 percent confidence interval that is greater than or equal to 80 percent. The sensitivity estimate for the device when testing for Influenza B must be at least at the 80 percent point estimate with a lower bound of the 95 percent confidence interval that is greater than or equal to 70 percent.

(B) The specificity estimate for the device when testing for Influenza A and Influenza B must be at least at the 95 percent point estimate with a lower bound of the 95 percent confidence interval that is greater than or equal to 90 percent.

(ii) If the manufacturer chooses to compare the device to an appropriate molecular comparator method:

(A) The positive percent agreement for the device when testing for Influenza A and Influenza B must be at least at the 80 percent point estimate with a lower bound of the 95 percent confidence interval that is greater than or equal to 70 percent.

(B) The negative percent agreement estimate for the device when testing for Influenza A and Influenza B must be at least at the 95 percent point estimate with a lower bound of the 95 percent confidence interval that is greater than or equal to 90 percent.

(2) When performing testing to demonstrate the device meets the requirements in paragraph (b)(1) of this section, a currently appropriate and FDA accepted comparator method must be used to establish assay performance in clinical studies.

(3) Annual analytical reactivity testing of the device must be performed with contemporary influenza strains. This annual analytical reactivity testing must meet the following criteria:

(i) The appropriate strains to be tested will be identified by FDA in consultation with the Centers for Disease Control and Prevention (CDC) and sourced from CDC or a CDC-designated source. If the annual strains are not available from CDC, FDA will identify an alternative source for obtaining the requisite strains.

(ii) The testing must be conducted according to a standardized protocol considered and determined by FDA to be acceptable and appropriate.

(iii) By July 31 of each calendar year, the results of the last 3 years of annual analytical reactivity testing must be included as part of the device's labeling. If a device has not been on the market long enough for 3 years of annual reactivity testing since the device was given marketing authorization, then the results of every designated annual reactivity testing since the device was given marketing authorization by FDA, including the results of annual analytical reactivity testing performed on the viral strains provided that calendar year, must be included. The results must be presented as part of the device's labeling in a tabular format, which includes the detailed information for each virus tested as described in the certificate of authentication, either by:

(A) Placing the results directly in the device's § 809.10(b) of this chapter compliant labeling in a section of the labeling devoted to annual analytical reactivity testing; or

(B) Providing a hyperlink in a section of the device's labeling to the manufacturer's public Web site where the annual analytical reactivity testing data can be found. If this option is chosen, the manufacturer's home page must publicly provide a hyperlink, which can easily be found and executed, to the annual analytical reactivity testing results and the Web page containing those annual analytical reactivity testing results must allow unrestricted viewing access. This includes being easy to locate the results from the primary part of the manufacturer's Web site that discusses the device.

(4) If an emergency, or a potential emergency, is declared by the Secretary of Health and Human Services (HHS) for an influenza viral strain:

(i) Within 30 days from the date that FDA notifies manufacturers that characterized viral samples are available for test evaluation, the manufacturer must have testing performed on the device with that viral strain according to a standardized protocol considered and determined by FDA to be acceptable and appropriate. The procedure and location of testing may depend on the nature of the emerging virus.

(ii) Within 60 days from the date that CDC first makes characterized viral samples available to manufacturers and continuing until the emergency, or potential emergency, is declared by the Secretary of HHS to be over, the results of the influenza emergency analytical reactivity testing, including the detailed information for the virus tested as described in the certificate of authentication, must be included as part of the device's labeling in a tabular format, either by:

(A) Placing the table directly in the device's § 809.10(b) of this chapter compliant labeling in the section of the labeling devoted to annual analytical reactivity testing and influenza emergency analytical reactivity testing but separate from the annual analytical reactivity testing tables; or

(B) Providing a hyperlink in a section of the device's labeling devoted to annual analytical reactivity testing and influenza emergency analytical reactivity testing to a part of the manufacturer's public Web site where the annual and the emergency analytical reactivity testing data can be found. If this option is chosen, the manufacturer's home page must publicly provide a hyperlink, which can easily be found and executed, to the analytical reactivity and emergency testing results and the Web page containing those annual analytical reactivity testing results must allow unrestricted viewing access.

Dated: May 14, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160–01–P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 165

**[Docket Number USCG–2014–0324]**

**RIN 1625–AA08**

## Safety Zones; 9–11 Patriot Festival, Charleston Harbor, Charleston, SC

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish safety zone on the Charleston Harbor in Charleston, South Carolina during the International Outboard Grand Prix (IOGP) 9–11 Patriot Festival, a series of high-speed boat races. The event is scheduled to take place on Friday September 12 through Sunday September 14, 2014. Approximately 25 high-speed race boats are anticipated to participate in the races. This safety zone is necessary to provide for the safety of life and property on navigable waters of the United States during the event. This safety zone would temporarily restrict vessel traffic in a portion of Charleston Harbor. Persons and vessels that are not participating in the races would be prohibited from entering, transiting through, anchoring in, or remaining within the restricted area unless authorized by the Captain of the Port Charleston or a designated representative.

**DATES:** Comments and related material must be received by the Coast Guard on or before June 23, 2014. Requests for public meetings must be received by the Coast Guard on or before June 1, 2014.

**ADDRESSES:** You may submit comments identified by docket number using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* 202–493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.