

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Establishing the Performance Characteristics of Nucleic Acid-Based *In vitro* Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA)." The draft guidance document provides industry and Agency staff with updated recommendations for studies to establish the analytical and clinical performance of nucleic acid-based *in vitro* diagnostic devices (IVDs) intended for the detection and differentiation of methicillin-resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA). This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by *April 5, 2011*.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Establishing the Performance Characteristics of Nucleic Acid-Based *In vitro* Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA)" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Li Li, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5558, Silver Spring, MD 20993-0002, 301-796-6200.

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDA is issuing the draft guidance to provide industry and Agency staff with recommendations for studies to establish the analytical and clinical performance of nucleic acid-based IVDs intended for the detection and differentiation of MRSA and SA. These devices are used to aid in the prevention and control of MRSA/SA infections in healthcare settings. This document is limited to studies intended to establish the performance characteristics of devices that detect the MRSA/SA genome (nucleic acid). It does not address detection of MRSA/SA antigens or serological response from the host to the MRSA/SA antigens, nor does it address establishing performance of non-MRSA/SA components of multi-analyte or multiplex devices.

### II. Significance of Guidance

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 establishing the performance characteristics of nucleic acid-based IVDs for the detection and differentiation of MRSA and SA. 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

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Establishing the Performance Characteristics of Nucleic Acid-Based *In vitro* Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA)," you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1722 to identify the guidance you are requesting.

### IV. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. 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 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR 50.23 have been approved under OMB control number 0910-0586; and the collections of information in 21 CFR 56.115 have been approved under OMB control number 0910-0130.

### V. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: December 30, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-33292 Filed 1-4-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0636]

#### **Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of Antibodies to *Borrelia burgdorferi*; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of Antibodies to *Borrelia burgdorferi*." FDA is issuing this draft guidance to provide industry and agency staff with recommendations for studies to establish the analytical and clinical performance of *in vitro*

diagnostic devices (IVDs) intended for the detection of antibodies to *Borrelia burgdorferi*. These devices are used to aid in the diagnosis of Lyme disease. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 5, 2011.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of Antibodies to *Borrelia burgdorferi*" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Prasadi Rao, Center for Devices and Radiological Health Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5508, Silver Spring, MD 20993-0002, 301-796-6203.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This draft guidance recommends studies for establishing the performance characteristics of in vitro diagnostic devices for the detection of antibodies to *B. burgdorferi* in human serum, plasma, and blood. These devices are used to aid in the diagnosis of Lyme disease. This document does not apply to *B. burgdorferi* nucleic acid amplification assays. A manufacturer who intends to market an in vitro device for the detection of antibodies to *B. burgdorferi* must conform to the general controls of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and, unless exempt,

obtain premarket clearance or approval prior to marketing the device.

**II. Significance of Guidance**

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 establishing the performance characteristics of in vitro diagnostic devices for the detection of antibodies to *B. burgdorferi*. 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**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive "Draft Guidance for Industry and Food and Drug Administration Staff; Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of Antibodies to *Borrelia burgdorferi*," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1721 to identify the guidance you are requesting.

**IV. Paperwork Reduction Act of 1995**

This draft 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 (the PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 42 CFR 493.15 have been approved under OMB control number 0910-0598; the collections of information 21 CFR 50.23 have been approved under OMB control number 0910-0586 and the collections of

information in 21 CFR 56.115 have been approved under OMB control number 0910-0130.

**V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: December 30, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Nursing Research; Notice of Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Nursing Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Advisory Council for Nursing Research.

*Date:* January 18-19, 2011.

*Open:* January 18, 2011, 1 p.m. to 4:45 p.m.

*Agenda:* Discussion of Program Policies and Issues.

*Place:* National Institutes of Health, Building 31, 31 Center Drive, Conference Room 6C, Room 6, Bethesda, MD 20892.