DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0118]

Guidances for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Documents: Respiratory Viral Panel Multiplex Nucleic Acid Assay; and Testing for Human Metapneumovirus Using Nucleic Acid Assays; and Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Nucleic Acid Assays; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the special controls guidance document entitled ''Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay,'' and two companion special controls guidance documents entitled ''Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays'' and ''Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Nucleic Acid Assays.'' These guidance documents describe a means by which respiratory viral panel multiplex nucleic acid assays may comply with the requirement of special controls for class II devices. The guidance documents include recommendations for performance evaluation, labeling, and measures to address the effects of ancillary reagents (specific reagents required under instructions for use of the assay but not provided) on safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule codifying the classification of the respiratory viral panel multiplex nucleic acid assay into class II (special controls), and establishing these guidance documents as the special controls for those devices.

DATES: Submit written or electronic comments on the guidances at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance documents entitled ''Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay,'' ''Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays,'' or ''Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Nucleic Acid Assay'' 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. 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 written comments concerning these guidances 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.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Zivana Tezak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5550, Silver Spring, MD 20993, 301–796–6204.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule codifying the classification of the respiratory viral panel multiplex nucleic acid assay 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)), and establishing these guidance documents as the special controls for respiratory viral panel multiplex nucleic acid assay devices classified under that regulation. 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), request FDA to classify the device under the criteria set forth in section 513(a)(1). 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.

Under this authority, on January 3, 2008, FDA by order classified into class II, subject to these special control guidance documents, the Luminex Molecular Diagnostics, Inc., xTAG™ RVP (Respiratory Viral Panel).

II. Significance of Special Controls Guidance Documents

FDA believes that adherence to the recommendations described in these guidance documents, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of respiratory viral panel multiplex nucleic acid assays classified under § 866.3080. In order to be classified as a class II device under § 866.3080, an RVP device must comply with the requirement of special controls; manufacturers must address the issues requiring special controls as identified in the guidance documents, either by following the recommendations in the guidance documents or by some other means that provides equivalent assurances of safety and effectiveness.

III. Electronic Access

Persons interested in obtaining a copy of any of the guidance documents may do so by using the Internet. To receive ''Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay,'' (document number 1669); ''Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays,'' (document number 1673); or ''Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Nucleic Acid Assays,'' (document number 1672); you may either send an e-mail request to *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 numbers shown in parentheses in the previous sentence to identify the guidance you are requesting.

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/MedicalDevices/default.htm*. 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 on the Division of Dockets Management Internet site at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule establishing as special controls for the respiratory viral panel multiplex nucleic acid assay the three guidance documents that are the subject of this notice. The preamble to that rule addresses the application of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) to the information collection provisions referenced in these guidance documents.

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 paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Revised comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 1, 2009.

Jeffrey Shuren,

Acting Director, Center for Devices and Radiological Health.

[FR Doc. E9–24431 Filed 10–8–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; Molecular, Cellular and Developmental Neurobiological Small Business.

Date: November 16–17, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting)

Contact Person: Eugene Carstea, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5199, MSC 7846, Bethesda, MD 20892, (301) 435–0634.

Name of Committee: AIDS and Related Research Integrated Review Group; Behavioral and Social Consequences of HIV/AIDS Study Section.

Date: November 16–17, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Palomar Hotel, 2121 P Street, NW., Washington, DC 20037.

Contact Person: Mark P. Rubert, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1775, *rubertm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Developmental Biology and Aging.

Date: November 16, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Joseph G. Rudolph, PhD, Chief and Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7844, Bethesda, MD 20892, 301–435–2212, *josephru@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–OD–09–008 BRDG–SPAN and RFA–OD–09–009 Catalyst ARRA Review Panel #1.

Date: November 16, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco, 700 F Street, NW., Washington, DC 20001.

Contact Person: David Balasundaram, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5189, MSC 7840, Bethesda, MD 20892, 301–435–1022, *balasundaramd@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Diseases and Microbiology Fellowships.

Date: November 16–17, 2009.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.

Contact Person: Alexander D. Politis, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3210, MSC 7808, Bethesda, MD 20892, (301) 435–1150, *politisa@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Musculoskeletal Rehabilitation.

Date: November 16, 2009.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call)

Contact Person: Aftab A. Ansari, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, 301–594–6376, *ansaria@csr.nih.gov.*

Name of Committee: AIDS and Related Research Integrated Review Group; AIDS Clinical Studies and Epidemiology Study Section.

Date: November 17–18, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Hilary D. Sigmon, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7852, Bethesda, MD 20892, (301) 594–6377, *sigmonh@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–OD–09–008 BRDG–SPAN and RFA–OD–09–009, Catalyst ARRA Review Panel #5.

Date: November 17, 2009.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Mary Custer, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7850, Bethesda, MD 20892, (301) 435–1164, *custerm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Orthopedic and Skeletal Biology SBIR/STTR.

Date: November 17, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott Washingtonian Center, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Kan Ma, PhD, Scientific Review Officer, National Institute of Arthritis, Musculoskeletal Scientific Review Branch, One Democracy Plaza Suite 800, Bethesda, MD 20892–4872, 301–451–4838, *mak2@mail.nih.gov.*