

of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 28, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, & C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Neel J. Patel, Center for Devices and Radiological Health (Bldg. 66, rm. 2532), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-5580, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512624. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On October 28, 2009, the committee will discuss, make recommendations, and vote on a premarket approval application for the Alair Bronchial Thermoplasty System sponsored by Astmatx, Inc. The device is indicated for the treatment of severe persistent asthma in adults.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available on the FDA Internet under the appropriate date at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 22, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief

statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 15, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 16, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 301-796-5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 17, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-22819 Filed 9-21-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Public Health Service Act, Section 330A(f)

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of Non-competitive Replacement Award to White River Rural Health Center, Arkansas.

SUMMARY: HRSA has issued a non-competitive replacement award under the Rural Health Network Development Program to White River Rural Health

Center, Inc. (WRRHC). The original grantee, Siloam Springs Memorial Hospital, is no longer eligible to serve as the lead entity for this network of rural health care providers serving a five county area in Arkansas and Oklahoma. This replacement award will ensure that the medically underserved residents of western Benton and Washington counties in Arkansas and Adair, Cherokee, and Delaware counties in Oklahoma continue receiving necessary medical care and services without disruption.

SUPPLEMENTARY INFORMATION: *Intended Recipient of the Award:* White River Rural Health Center, Inc. in Augusta, Arkansas.

Amount of the Fiscal Year 2009 Award: \$179,995.

Anticipated Amount of Fiscal Year 2010 Award: \$179,995.

Original Project Period: May 1, 2008, through April 30, 2011.

Project Period for Replacement Award: August 1, 2009; end date April 30, 2011.

Authority: The Rural Health Network Development Program is authorized under the Public Health Service Act, section 330A(f), 42 U.S.C. 254c(f). The authority for the exception to competition is HHS Grants Policy Directive 2.04, Awarding Grants.

Catalogue of Federal Domestic Assistance Number: 93.912.

Justification for Transfer of Funds:

The network of service providers funded under the original grant award are currently engaged in activities designed to increase access to health care and improve the quality of life for the poverty-stricken residents in the five county service area in Arkansas and Oklahoma, while further decreasing inefficiencies in the health care system, reducing inappropriate emergency room use, helping businesses keep insurance premiums under control, and improving the system for managing patients' long-term health, especially those with conditions like diabetes and heart disease. The service area under this grant award has a limited number of health care providers and a combined population of over 111,131. Of this population, 23,000 (21 percent) lack health insurance, and over 18,000 (16.5 percent) have incomes less than 100 percent of the poverty rate. It is critical that HRSA funding for this network of service providers continues with minimal disruption of services.

Siloam Springs Memorial Hospital is no longer able to serve as the lead entity for this network of rural health care providers in Arkansas and Oklahoma, nor were the other network participants able to assume the lead fiduciary role.

WRRHC is a successful community health center that provides services to 10 counties within Arkansas and has over 22 years of experience in managing State and federally funded programs, including three previous Rural Health Services Outreach grants. The comprehensive services that WRRHC provides and their ability to expand their service area will enable WRRHC to maintain the current scope of service and activities as originally awarded under the grant to Siloam Springs Memorial Hospital. This replacement award will help ensure the continued improvement of health care systems in the targeted service area. WRRHC has a demonstrated record of sound stewardship of Federal funds and can effectively serve as the network lead for the remainder period of support in a manner which minimizes any disruption of services provided by the network. Consequently, White River Rural Health Center has been designated the replacement award recipient.

HRSA is unaware of any other entity that both meets the statutory eligibility requirements and has the ability to carry out these activities.

FOR FURTHER INFORMATION CONTACT: Tom Morris, Associate Administrator, Office of Rural Health Policy, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, MD 20857; phone 301-443-0835; tmorris@hrsa.hhs.gov.

Dated: September 16, 2009.

Mary K. Wakefield,
Administrator.

[FR Doc. E9-22815 Filed 9-21-09; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Actions Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

AGENCY: National Institutes of Health (NIH), Department of Health and Human Services (HHS).

ACTION: Notice of changes to the NIH Guidelines.

SUMMARY: Concerns about the emergence of a pandemic influenza virus have spurred research on influenza viruses that have either caused pandemics or are believed to have the potential to cause a pandemic. These viruses include human H2N2 virus, which circulated from 1957-1968,

the 1918-1919 H1N1, which caused the deadliest pandemic in the past century, and the Highly Pathogenic Avian Influenza (HPAI) H5N1 virus that is thought to have pandemic potential. The public health benefits of this research include developing a better understanding of the pathogenicity of pandemic influenza viruses, their virulence mechanisms, mechanisms of host adaptation, and ultimately the development of vaccines and antiviral drugs. These benefits are balanced against the potential risks that might include the inadvertent release of a highly transmissible and potentially virulent influenza virus. Consequently, explicit and uniform biosafety containment practices are critical to the safe conduct of research with these agents. The *NIH Guidelines* provide a framework for assessing the risks of such research. However, after extensive consultation with the NIH Recombinant DNA Advisory Committee (RAC), experts in biosafety and influenza, the Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA), the NIH Office of Biotechnology Activities (OBA) concluded that more specific guidance in the *NIH Guidelines* is warranted to promote uniform biosafety practices for recombinant research with these viruses.

The resulting amendments are "Minor Actions" under Section IV-C-1-(b)-2 of the *NIH Guidelines* and, therefore, will be implemented immediately upon publication in the **Federal Register**. While a Minor Action only requires consultation with the RAC chair and one or more RAC members, as necessary, as noted above, these changes were developed after extensive consultation with the full RAC and other experts and were discussed at three public RAC meetings. The RAC voted on March 4, 2009 to recommend these changes. They are being published to inform the scientific and biosafety communities, as well as to solicit continued scientific input should further revisions be needed.

The *NIH Guidelines* are being changed to provide the following biosafety guidance for research with potentially pandemic influenza viruses:

- Designation of human H2N2 viruses that circulated from 1957-1968 (human H2N2 (1957-1968)), the fully reconstructed 1918-1919 H1N1 influenza virus (1918 H1N1), and Highly Pathogenic Avian Influenza (HPAI) H5N1 within the Goose/Guangdong/96-like H5 lineage (HPAI H5N1) as Risk Group 3 agents. Risk Group 3 agents have the potential to cause serious or lethal disease in

humans for which preventative and therapeutic measures may be available. Up until this revision, all influenza viruses (Orthomyxoviruses) were Risk Group 2 agents, which are agents that are associated with human disease that is rarely serious and for which preventative and therapeutic agents are often available.

- Requirement for enhanced biosafety practices, including the use of powered air purifying respirators (PAPRs) and other personal protective equipment to prevent laboratory worker exposure and minimize the risk of spread outside of the laboratory.

- Guidance on the containment for research with influenza viruses generated by recombinant methods (*e.g.*, generation by reverse genetics of chimeric viruses with reassorted segments, introduction of specific mutations) containing one or more genes and/or segments from human H2N2 (1957-1968), 1918 H1N1 or HPAI H5N1. For 1918 H1N1, the *NIH Guidelines* will require Biosafety Level 3 enhanced containment for all influenza viruses that contain one of more genes and/or segments from 1918 H1N1 because of the uncertainty about the virulence factors for this agent.

- Guidance on occupational health practices, including policies regarding the use of prophylactic antiviral agents and isolation of laboratory workers who are exposed to one of these viruses.

DATES: The public is encouraged to submit written comments on this action. Comments may be submitted to OBA in paper or electronic form at the OBA mailing, fax, and e-mail addresses shown below under the heading **FOR FURTHER INFORMATION CONTACT**. All comments should be submitted by September 22, 2010. All written comments received in response to this notice will be available for public inspection in the NIH OBA office, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985, weekdays between the hours of 8:30 a.m. and 5 p.m. and may be posted to OBA's Web site.

FOR FURTHER INFORMATION: If you have questions, or require additional information about these changes, please contact OBA by e-mail at oba@od.nih.gov, or telephone at 301-496-9838. Comments may be submitted to the same e-mail address or by fax at 301-496-9839 or by mail to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, Maryland 20892-7985. Background information may be obtained by