

MSC 7854, Bethesda, MD 20892, 301-435-2598, [firrellj@csr.nih.gov](mailto:firrellj@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Topics on Control of Fungal Infections.

*Date:* October 16, 2009.

*Time:* 8 a.m. to 11 a.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Baltimore Marriott Waterfront, 700 Aliceanna Street, Baltimore, MD 21202.

*Contact Person:* Tera Bounds, DVM, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301-435-2306, [boundst@csr.nih.gov](mailto:boundst@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel Fellowships: Biomedical Imaging and Bioengineering.

*Date:* October 16, 2009.

*Time:* 12 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Dharam S. Dhindsa, DVM, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5110, MSC 7854, Bethesda, MD 20892, (301) 435-1174, [dhindsad@csr.nih.gov](mailto:dhindsad@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 14, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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BILLING CODE 4140-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0664]

#### Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Pulmonary-Allergy Drugs 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 November 19, 2009, from 8 a.m. to 5 p.m.

*Location:* Hilton Washington DC/ Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

*Contact Person:* Kristine T. Khuc, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: [Kristine.Khuc@fda.hhs.gov](mailto:Kristine.Khuc@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512545. 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:* The committee will discuss the efficacy supplement for new drug application (sNDA) 21-395, for the approved product Spiriva HandiHaler (tiotropium inhalation powder), manufactured by Boehringer Ingelheim, for the reduction in exacerbations (worsening of symptoms) in patients with chronic obstructive pulmonary disease (COPD).

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 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 November 4, 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 27, 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 28, 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 Kristine Khuc 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. E9-22820 Filed 9-21-09; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0664]

#### Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Anesthesiology and Respiratory Therapy Devices Panel

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 Asthmatx, 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.