DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Ophthalmic 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: Ophthalmic 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 September 28, 2012, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900.

Contact Person: Natasha Facey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1544, Silver Spring, MD 20993–0002, *Natasha.Facey@fda.hhs.gov,* 301–796–5290, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On September 28, 2012, the committee will discuss, make recommendations and vote on information regarding the humanitarian device exemption (HDE) application for the Argus II Retinal Prosthesis System sponsored by Second Sight Medical Products, Inc. The proposed Indication for Use for the Argus II (as stated in the HDE) is as follows:

The Argus II System is indicated for use in patients with severe to profound retinitis pigmentosa who meet the following criteria:

- Adults, age 25 years or older.
- Bare light or no light perception in both eyes with Snellen acuity worse than 20/2100 or 2.1 logMAR. If the patient has no residual light perception, the retina must be able to respond to electrical stimulation as evidenced by an electrically evoked response.
- Previous history of useful form vision.

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 meeting 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 September 17, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on September 28, 2012. Those individuals interested in making 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 September 7, 2012. 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 September 10, 2012.

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 at *Annmarie.Williams@fda.hhs.gov* or 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: July 16, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–17668 Filed 7–18–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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 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 Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Science Education Awards (R25).

Date: July 31, 2012.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Richard W. Morris, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700–B Rockledge Drive, MSC–7616, Room 3251, Bethesda, MD 20892–7616, 301–451–2663, *rmorris@niaid.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing

limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 13, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–17492 Filed 7–18–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

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 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: CMIP and MEDI Continuous Submission Review Panel.

Date: July 27, 2012.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301–237–9870, *xuguofen@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: July 13, 2012.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–17512 Filed 7–18–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of a Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in PCT Patent Application No. PCT/US2005/12289, U.S. Patent No. 7,901,881, U.S. Patent Application No. 13/024,845 and foreign equivalents thereof entitled ''Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions'' (HHS Ref. No. E–124–2004/0,1,2) and PCT Patent Application No. PCT/US2008/010139 and U.S. Patent Application No. 12/675,209 entitled ''Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions'' (HHS Ref. No. E–326–2007/0) to Veracyte, Inc., which is located in San Francisco, California. The patent rights in these inventions have been assigned to the United States of America.

Other than license applications submitted as objections to this Notice of Intent to Grant an Exclusive License, no further license applications will be considered for the exclusive field of use set forth below if Veracyte, Inc. is granted an exclusive license pursuant to this Notice of Intent to Grant an Exclusive License. The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the diagnosis and prognosis of thyroid cancer.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before August 20, 2012 will be considered, in addition to the current non-exclusive applications under consideration, for the prospective license territory and field of use to be granted under the contemplated exclusive patent license.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Whitney A. Hastings, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 451–7337; Facsimile: (301) 402–0220; Email: *hastingw@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This technology is based on the discovery of differentially expressed thyroid (DET) genes and their encoded proteins whose expression levels can be correlated to benign or malignant states in a thyroid cell. Specifically, this data arose from a microarray analysis of genes expressed in the eight subtypes of thyroid tumors that are typically difficult to diagnose by cytology of fine needle aspiration (FNA) biopsies. Analysis of the (DET) genes led to the development of 6 gene and 10 gene models that distinguish benign vs. malignant papillary thyroid tumors. Subsequently, a 72 gene model has been developed for diagnosing less common forms of thyroid cancer such as follicular carcinoma. These results provide a molecular classification system for thyroid tumors and this in turn provides a more accurate diagnostic tool for the clinician managing patients with suspicious thyroid lesions. In addition to diagnostics, this invention can be used in the staging of thyroid malignancies by measuring changes in DET gene and protein expression relative to reference cells. Finally, this invention can also be used in the discovery of therapeutic agents through the detection in changes of DET gene and protein levels prior to and after treatment.

The prospective exclusive license and any further license applications received as objections to this Notice of Intent to Grant an Exclusive License, will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Any additional applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license.