determine whether changes or updates to the currently recognized susceptibility test interpretive criteria are appropriate. FDA will then update the Interpretive Criteria web page to reflect these changes, as needed.

Dated: February 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04175 Filed 2–28–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0627]

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on March 29 and 30, 2018, from 8 a.m. to 6 p.m.

ADDRESSES: 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. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G610, Silver Spring, MD 20993, *patricio.garcia@fda.hhs.gov;* 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 website at *https://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.

SUPPLEMENTARY INFORMATION:

Agenda: On March 29, 2018, the committee will discuss, make recommendations, and vote on information regarding a premarket approval application to market a novel continuous glucose monitoring (CGM) device system, the Senseonics, Inc. Eversense CGM System. This device requires minor surgery to implant and remove, and if approved, would provide 90 days of sensor glucose values from each implanted sensor.

The Eversense CGM System measures patients' glucose concentrations from subcutaneous interstitial fluid similar to approved CGM systems. All CGM devices currently or previously marketed used electrochemistry to measure glucose in interstitial fluids, last for 3 to 11 days and are inserted via a small-gauge needle by the end user. The proposed CGM system uses a fluorescence-based measurement technique, requires minor surgery for subcutaneous implantation, and will have a 90-day sensor wear period. The proposed CGM sensor also includes a drug component (dexamethasone acetate) intended to mitigate negative effects on sensor accuracy and sensor life from the foreign body response at the sensor insertion site. The proposed intended use, as stated by the sponsor, is as follows:

The Eversense CGM System continually measures glucose levels in adults (age 18 and older) with diabetes for the operating life of the sensor.

The system is intended to:

- Aid in the management of diabetes.
- Provide real-time glucose readings.
- Provide glucose trend information.
- Provide alerts for the detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia).

The system is a prescription device. Historical data from the system can be interpreted to aid in providing therapy adjustments. These adjustments should be based on patterns seen over time.

On March 30, 2018, the committee will discuss and make recommendations regarding measuring blood glucose using capillary blood with blood glucose meters in all hospital patients, including those receiving intensive medical intervention/therapy and patients with decreased peripheral blood flow, such as with severe hypotension, shock, hyperosmolar-hyperglycemia and severe dehydration (*e.g.,* patients in intensive care settings). Currently, FDA has cleared one glucose meter for use all over the hospital using venous and arterial blood. FDA understands that being able to make capillary blood measurements in all hospitalized patients using FDA cleared and Clinical Laboratory Improvement Amendments (CLIA) waived (*i.e.,* designated as waived per the standards in the CLIA) glucose meters would be more convenient and timely for hospital staff. FDA would like to present new data from capillary blood measurements on glucose meters in patients receiving intensive medical intervention/therapy to the Clinical Chemistry and Clinical Toxicology Devices Panel. FDA would like to receive feedback from the advisory panel on the benefits and risks of measuring capillary blood using blood glucose meters in this intended use population, and the considerations for CLIA waiver for this use.

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 website 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 website after the meeting. Background material is available at *https://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 March 22, 2018. Oral presentations from the public will be scheduled on March 29 and 30, 2018, between approximately 1 p.m. and 2 p.m. 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 March 14, 2018. 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 March 15, 2018.

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 disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams, at *annmarie.williams@fda.hhs.gov,* 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 website at *https://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: February 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–04167 Filed 2–28–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: Arthritis and Musculoskeletal and Skin Diseases Initial Review Group; Arthritis and Musculoskeletal and Skin Diseases Special Grants Review Committee.

Date: March 15–16, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Nakia C. Brown, Ph.D., Scientific Review Officer, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, 6701 Democracy Boulevard, Suite 816, Bethesda, MD 20817, 301–827–4905, *nikia.brown@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: February 23, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–04119 Filed 2–28–18; 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 Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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; Epidemiology of Chronic and Infectious Disease.

Date: March 5, 2018.

Time: 11:00 a.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: Kate Fothergill, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Room 3142, Bethesda, MD 20892, 301–435–2309, *fothergillke@mail.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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR17–029: Dynamic Interactions between Systemic or Non-Neuronal Systems and the Brain in Aging and in Alzheimer's Disease.

Date: March 8, 2018.

Time: 11:00 a.m. to 6:00 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: Inese Z. Beitins, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7892, Bethesda, MD 20892, 301–435–1034, *beitinsi@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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Collaborative Minority Health and Health Disparities Research with Tribal Epidemiology Centers.

Date: March 8, 2018.

Time: 1:00 p.m. to 3:30 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: Delia Olufokunbi Sam, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, MSC 7770, Bethesda, MD 20892, 301–435–0684, *olufokunbisamd@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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships Overflow: Risk, Prevention and Health Behavior.

Date: March 9, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dupont Hotel, 1500 New Hampshire Avenue NW, Washington, DC 20036.

Contact Person: Lee S. Mann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3224, MSC 7808, Bethesda, MD 20892, 301–435–0677, *mannl@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.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Molecular Sciences and Technology.

Date: March 9, 2018.

Time: 10:00 a.m. to 1:00 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: Raj K. Krishnaraju, Ph.D., Scientific Review Officer, Center for