information on the surface of fresh, intact citrus fruit for commercial marketing as specified in 21 CFR 179.43. Subsequent to this approval, USPTO received patent term restoration applications for CARBON DIOXIDE LASER (U.S. Patent Nos. 5,660,747 and 5,897,797) from Durant Wayland, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated February 13, 2013, FDA advised the USPTO that this product had undergone a regulatory review period and that FDA's granting of the food additive petition for CARBON DIOXIDE LASER represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for CARBON DIOXIDE LASER is 1,950 days. The applicant has not asserted a testing phase. All 1,950 days of the regulatory review period occurred during the approval phase. This period of time was derived from the following dates:

1. *The date a major health or environmental effects test on the food additive was initiated:* No date claimed. The applicant has not asserted a testing period.

2. *The date the application was initially submitted with respect to the food additive under section 409 of the FD&C Act:* February 9, 2007. FDA has determined that the food additive petition (FAP) for Carbon Dioxide Laser for Etching Food (FAP 7M4768) was submitted on February 9, 2007.

3. *The date a regulation for use of the food additive became effective:* June 11, 2012. FDA has verified the applicant's claim that FAP 7M4768 was granted through FDA's issuance of a responsive food additive regulation, effective June 11, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by December 22, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by April 20, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–25032 Filed 10–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, Program on Biosecurity and Biosafety Policy; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the meeting of the National Science Advisory Board for Biosecurity (NSABB).

Name of Committee: National Science Advisory Board for Biosecurity.

Date: October 22, 2014.

Time: 8:00 a.m.–4:00 p.m. Eastern Time (Times are approximate and subject to change).

Agenda: Presentations and discussions regarding: (1) Overview of recent Federal policies regarding biosafety and biosecurity; and (2) other business of the Board.

Place: National Institutes of Health, Building 31; 6th Floor, Conference Room 6, Bethesda, Maryland.

Contact Person: Carolyn Mosby, NSABB Program Assistant, NIH Program on Biosecurity and Biosafety Policy, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892, (301) 435–5504, *carolyn.mosby@nih.gov.*

Under authority 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established the NSABB to provide advice regarding federal oversight of dual use research, defined as biological research that generates information and technologies that could be misused to pose a biological threat to public health and/or national security.

The meeting will be open to the public, however pre-registration is strongly recommended due to space limitations. Persons planning to attend may register online at: *http://palladianpartners.cvent.com/d/KY8f5UlwH0WnoisQD81oFg/8nfg/P1/1Q* or by calling Palladian Partners, Inc. (Contact: Joel Yaccarino at 301–650–8660). Online registration will close at 12:00 p.m. Eastern the day before the meeting. After that time, you will need to register onsite on the day of the meeting, from 7:15 a.m. Eastern. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate these requirements upon registration.

This meeting will also be webcast. To access the webcast and meeting information, including the draft meeting agenda and the registration link, connect to: *http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/nsabb/nsabb-meetings-and-conferences.* Please check this site for updates.

Time will be allotted on the agenda for oral public comment, with presentations limited to three minutes per speaker. Sign-up for oral public comments will begin at approximately 7:45 a.m. on October 22, 2014, and will be restricted to one sign-in per person. In the event that time does not allow for all those interested to present oral comments, any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. In addition, any interested person may submit written comments to the NSABB prior to the meeting by sending the comments to the Contact Person listed on this notice by 5:00 p.m. Eastern on October 20, 2014. Written comments should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Any written comments received after the deadline will be provided to the Committee either before or after the meeting, depending on the volume of comments received and the time required to process them in accordance with privacy regulations and other applicable Federal policies.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Dated: October 16, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–25030 Filed 10–21–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Ancillary Studies: Group 1, Diabetes.

Date: December 3, 2014.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8895, *rushingp@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; U.S.-India Bilateral Collaborative Research Partnerships (CRP) on Diabetes Research (R21).

Date: January 26, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS).

Dated: October 16, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–25045 Filed 10–21–14; 8:45 am]

BILLING CODE 4140–01–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: Microbiology, Infectious Diseases and AIDS Initial Review Group, Acquired Immunodeficiency Syndrome Research Review Committee.

Date: November 18, 2014.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3E70B, 5601 Fishers Lane, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Vasundhara Varthakavi, Ph.D., Scientific Review Officer, Scientific Review Program, NIH/NIAID/DEA/ARRB, 5601 Fishers Lane, Bethesda, MD 20892, 240–669–5010, *varthakaviv@niaid.nih.gov.*

(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: October 16, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–25042 Filed 10–21–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute Meeting

ACTION: Notice of meeting.

SUMMARY: Pursuant to the NIH Reform Act of 2006 (42 U.S.C. 281(d)(4)), notice is hereby given that the National Eye Institute will host a meeting to enable public discussion of the Institute's proposal to rename its Division of Extramural Research to the Division of Extramural Science and establish a new Division of Extramural Activities. The proposal seeks to clearly delineate functions and streamline the services provided by adding focus to scientific programs and extramural operations. This proposed change aligns NEI with the structure of other NIH Institutes and Centers.

DATES: The public hearing will be available to view on October 23, 2014.

ADDRESSES: The public hearing will be recorded at the National Eye Institute, 31 Center Drive, Bethesda, MD 20892. To comment or ask a question about the reorganization, please send an email to the following address: *NEIOrgChangeComment@mail.nih.gov.* To view the webinar, which will be posted on YouTube on October 23, 2014, go to the following Web site: *www.nei.nih.gov/DEROrgChange.*

FOR FURTHER INFORMATION CONTACT: Aytaj Vily, National Eye Institute, NIH, MPAB, 31 Center Drive, Bethesda, MD 20892, at *NEIOrgChangeComment@mail.nih.gov.*

Members of the public wishing to have their questions or comments addressed related to this presentation on the reorganization need to send them to the following email address: *NEIOrgChangeComment@mail.nih.gov.* Individuals will be able to watch the presentation via a YouTube webinar. Please go to the following link to view the webinar: *www.nei.nih.gov/DEROrgChange.*

Any interested person may file written comments by sending an email to the following email address: *NEIOrgChangeComment@mail.nih.gov,* by October 30, 2014. The statement should include the individual's name and, when applicable, professional affiliation. Responses will be sent by November 4, 2014.

SUPPLEMENTARY INFORMATION: The agenda of the public meeting will enable public discussion on the proposed reorganization plans for NEI. This meeting will be in the form of a webinar posted on YouTube on October 23,