

which FDA does not intend to object to the compounding of a drug product from certain bulk drug substances by an outsourcing facility while FDA develops the list of bulk drug substances that can be used in compounding under section 503B(a)(2)(A)(i) of the FD&C Act.

The final guidance "Pharmacy Compounding of Human Drug Products Under Section 503A of the FD&C Act," (503A Final Guidance) published in 2014 (79 FR 37742; July 2, 2014), states, "Until a bulk drug substances list is published in the **Federal Register** as a final rule, human drug products should be compounded using only bulk drug substances that are components of drugs approved under section 505 of the FD&C Act, or are the subject of USP or NF monographs." Because this draft interim guidance proposes to change the Agency's policy relating to compounding with bulk drug substances while FDA develops a list of bulk drug substances that can be used in compounding, FDA is adding a footnote to the 503A Final Guidance referencing this draft interim guidance. Once this draft interim guidance is finalized, FDA intends to remove that footnote from the 503A Final Guidance and cross-reference the final interim guidance as establishing the policy for compounding with bulk drug substances during the development of the 503A bulks list. The footnote is being added to the 503A Final Guidance as a Level 2 change under 21 CFR 10.115 because the final interim guidance, rather than the footnote to the 503A Final Guidance, will set forth the actual change in policy. Accordingly, comments on the proposed change in policy are being solicited as part of this Notice of Availability on the draft interim guidance.

## II. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: October 21, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-27269 Filed 10-26-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute 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 Heart, Lung, and Blood Institute, Special Emphasis Panel; T32 Training Program for Institutions that Promote Diversity.

*Date:* November 16, 2015.

*Time:* 2:30 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Stephanie L Constant, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7189, Bethesda, MD 20892, 301-443-8784, [constantsl@nhlbi.nih.gov](mailto:constantsl@nhlbi.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 22, 2015.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-27325 Filed 10-26-15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Eye Institute 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 Eye Institute Special Emphasis Panel; NEI Clinical and Epidemiological Applications: Retina, Glaucoma and Neuro-Ophthalmology.

*Date:* December 10, 2015.

*Time:* 8:30 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

*Contact Person:* Brian Hoshaw, Ph.D., Scientific Review Officer, National Eye Institute, National Institutes of Health, Division of Extramural Research, 5635 Fishers Lane, Suite 1300, Rockville, MD 20892, 301-451-2020, [hoshawb@mail.nih.gov](mailto:hoshawb@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: October 22, 2015.

**Natasha Copeland,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-27324 Filed 10-26-15; 8:45 am]

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## 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 Clinical Trial Implementation Cooperative Agreement (U01).

*Date:* November 24, 2015.