prescribing information entitled ''Full Prescribing Information: Contents,'' consisting of a list of each heading and subheading along with its identifying number to facilitate health care practitioners' use of labeling information. Section 201.57(c) specifies the contents of the FPI. Section 201.57(d) mandates the minimum specifications for the format of prescription drug labeling and establishes minimum requirements for key graphic elements such as bold type, bullet points, type size, and spacing.

Older drugs not subject to the revised labeling content and format requirements in § 201.57 are subject to labeling requirements at § 201.80. Section 201.80(f)(2) requires that, within 1 year, any FDA-approved patient labeling be referenced in the ''Precautions'' section of the labeling of older products and either accompany or be reprinted immediately following the labeling.

Annual Burden for Prescription Drug Labeling Design, Testing, and Submitting to FDA for New Drug Applications (NDAs) and Biologics License Applications (BLAs) (§§ 201.56 and 201.57)

New drug product applicants must: (1) Design and create prescription drug labeling containing ''Highlights,'' ''Contents,'' and FPI; (2) test the designed labeling (*e.g.,* to ensure that the designed labeling fits into carton-enclosed products); and (3) submit it to FDA for approval. Based on the projected data used in the January 24, 2006, final rule, FDA estimates that it will take applicants approximately 2,327 hours to design, test, and submit prescription drug labeling to FDA as part of a NDA or a BLA under the revised regulations. Currently, approximately 406 applicants submit approximately 541 new applications (NDAs and BLAs) to FDA annually, totaling 1,258,907 hours.

In the **Federal Register** of July 20, 2018 (83 FR 34596), we published a 60-day notice requesting public comment on the proposed collection of information. We received two comments. One comment encouraged the use of ''provider-neutral language'' in specific regulations. The second comment discussed the distribution of package inserts for prescription drugs via paper labeling. Because these comments do not apply to the regulations associated with the information collection, we have not addressed them here.

Our estimate of the burden for the information collection is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part and activity	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response	Total hours
Labeling Requirements in §§ 201.56 and 201.57	406	1.332	541	2,327	1,258,907

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Estimates may not sum due to rounding.

Our estimated burden for the information collection reflects an overall increase of 602,503 hours and a corresponding increase of 345 records. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: November 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25352 Filed 11–20–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Charter Renewal of the Advisory Committee on Blood and Tissue Safety and Availability

AGENCY: Office of HIV/AIDS and Infectious Disease Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services is hereby giving notice that the charter for the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) has been renewed.

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, Designated Federal Officer for the ACBTSA, Senior Advisor for Blood and Tissue Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L100, Washington, DC 20024. Phone: (202) 795–7697; Fax: (202) 691–2102; Email: *ACBTSA@hhs.gov*.

SUPPLEMENTARY INFORMATION: ACBTSA is a non-discretionary Federal advisory committee. ACBTSA is authorized under 42 U.S.C. 217a, Section 222 of the Public Health Service (PHS) Act, as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees.

The ACBTSA advises, assists, consults with, and makes policy recommendations to the Secretary, through the Assistant Secretary for Health, regarding these broad responsibilities related to the safety of blood, blood products, tissues, and organs. For solid organs and blood stem cells, the Committee's work is limited to policy issues related to donor derived infectious disease complications of transplantation.

To carry out its mission, the ACBTSA provides advice to the Secretary through the Assistant Secretary for Health on a range of policy issues to include: (1) Identification of public health issues through surveillance of blood and tissue safety issues with national biovigilance data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical, and legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors (*e.g.,* product cost and supply) on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues.

On September 25, 2018, the Secretary approved for the ACBTSA charter to be renewed. The new charter was effected and filed with the appropriate Congressional committees and the Library of Congress on October 9, 2018. Renewal of the Committee's charter gives authorization for the Committee to continue to operate until October 9, 2020.

A copy of the ACBTSA charter is available on the Committee's website at *https://www.hhs.gov/ohaidp/initiatives/blood-tissue-safety/advisory-committee/charter/index.html.* A copy of the charter can also be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is *www.facadatabase.gov*.

Dated: October 19, 2018.

James J. Berger,

Senior Advisor for Blood and Tissue Policy, Designated Federal Officer, Advisory Committee on Blood and Tissue Safety and Availability.

[FR Doc. 2018–25374 Filed 11–20–18; 8:45 am]

BILLING CODE 4150–41–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, 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: Heart, Lung, and Blood Initial Review Group; NHLBI Institutional Training Mechanism Review Committee.

Date: December 14, 2018.

Time: 9:30 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 (Telephone Conference Call).

Contact Person: Lindsay M. Garvin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive; Suite 7189, Bethesda, MD 20892, 301–827–7911, *lindsay.garvin@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: November 15, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–25354 Filed 11–20–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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: National Institute on Aging Special Emphasis Panel; Health and Aging Trends.

Date: December 3, 2018.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Room 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Kimberly Firth, Ph.D., National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7702, *firthkm@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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: November 15, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–25351 Filed 11–20–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Review of R35 Research Program Award.

Date: December 3–4, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Alexandria Old Town, Virginia Ballroom A & B, 1900 Diagonal Rd, Alexandria, VA 22314.

Contact Person: Jimok Kim, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH/DHHS, NSC, 6001 Executive Blvd., Suite 3226, MSC 9529, Bethesda, MD 20892–9529, (301) 496–9223, *Jimok.kim@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: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Biomarkers Discovery in Parkinsonism.

Date: December 3, 2018.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Joel A. Saydoff, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH/DHHS, NSC, 6001 Executive Blvd., Suite 3205, MSC 9529, Bethesda, MD 20892–9529, (301) 496–9223, *Joel.saydoff@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. 93.853, Clinical Research