

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

| FDA form; survey | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response (hours) | Total hours |
|--|-----------------------|------------------------------------|------------------------|-------------------------------------|-----------------|
| Biosimilar User Fee Cover Sheet (Form FDA 3792) | 60 | 1 | 60 | 0.5 (30 minutes). | 30 |
| Annual Survey | 60 | 1 | 60 | 1 | 60 |
| Request for discontinuation from BPD program | 10 | 1 | 10 | 1 | 10 |
| Request to move products to discontinued section of the Biosimilar List. | 5 | 1 | 5 | 0.5 (30 minutes). | 2.5 |
| Biosimilar product applications (351(k)(2)(A)) | 4 | 2.25 | 9 | 860 | 7,740 |
| Interchangeable product applications (351(k)(2)(B)) | 2 | 1 | 2 | 860 | 1,720 |
| Patent infringement notifications | 4 | 2.25 | 9 | 2 | 18 |
| Formal Meetings GFI Recommendations | 69 | 2.30 | 159 | 21.42 | 3,405 |
| Total | | | 314 | | 12,985.5 |

In anticipation of increased participation in the BPD program, we have increased our estimate to reflect an increase in the number of respondents since last OMB review. We have also made adjustments to reflect information collection consolidated from OMB control number 0910-0719. We invite comment on our estimates and assumptions.

Dated: September 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-20060 Filed 9-16-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0313]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before October 18, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-0313-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: 2021 National Blood Collection & Utilization Survey.

Type of Collection: Revision.

OMB No. 0990-0313: Office of the Assistant Secretary for Health.

Abstract: The 2021 National Blood Collection and Utilization Survey is a biennial survey of the blood collection and utilization community to produce reliable and accurate estimates of national and regional collections, utilization and safety of all blood products. The survey includes a core of standard questions on blood collection, processing, and utilization practices. The rapidly changing environment in blood supply and demand makes it important to have regular, periodic data describing the state of U.S. blood collections and transfusions for understanding the dynamics of blood safety and availability. Two sections were added to the survey to capture information on the impact of the COVID-19 pandemic on the blood supply during the course of 2020. The COVID-19 supplemental sections will only be included on the survey once.

Survey respondents will consist of blood collection centers, cord blood banks, and hospitals that perform blood transfusions, except those reporting fewer than 100 inpatient surgeries per year. For the purposes of this ICR, federal burden is only being placed on facilities located within the fifty states and the District of Columbia.

OMB approval is requested for three years. The total estimated annual burden is 4,532 hours.

ESTIMATED ANNUALIZED BURDEN TABLE

| Type of respondent | Number of respondents | Number responses per respondent | Average burden per response (in hours) | Total burden hours |
|------------------------------------|-----------------------|---------------------------------|--|--------------------|
| Transfusing Hospitals | 2,140 | 1 | 2 | 4,280 |
| Hospital Blood Banks | 76 | 1 | 2 | 152 |
| Community-based blood center | 50 | 1 | 2 | 100 |

ESTIMATED ANNUALIZED BURDEN TABLE—Continued

| Type of respondent | Number of respondents | Number responses per respondent | Average burden per response (in hours) | Total burden hours |
|--------------------|-----------------------|---------------------------------|--|--------------------|
| Total | 2,266 | | | 4,532 |

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2021–20183 Filed 9–16–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 of Neurological Disorders and Stroke Initial Review Group; Neurological Sciences and Disorders C Study Section: Neurological Sciences and Disorders Panel–C (NSD–C).

Date: October 6, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Diana M. Cummings, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Neurological Disorders and Stroke, NIH, NSC, 6001 Executive Blvd., Suite 3208, Rockville, MD 20852, cummingsdi@ninds.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: September 13, 2021.

Tyeshia M. Roberson-Curtis,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–20113 Filed 9–16–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Institute Council of Research Advocates.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov>).

Name of Committee: National Cancer Institute Council of Research Advocates.

Date: September 29, 2021.

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

Agenda: Welcome and Chairwoman's Remarks, NCI Updates, Legislative Update, and Director's Update.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Bethesda, MD 20892–2580 (Virtual Meeting).

Contact Person: Amy Williams, NCI Office of Advocacy Relations, National Cancer Institute, NIH, 31 Center Drive, Building 31, Room 10A28, Bethesda, MD 20892–2850, (301) 496–9723, williamam@mail.nih.gov.

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.

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/ncra/ncra.htm>, where an agenda and any additional information for the meeting will be posted when available.

This notice is being published less than 15 days prior to the meeting due to scheduling difficulties.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 13, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–20075 Filed 9–16–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; Multi-site Clinical Trial Implementation.

Date: November 2, 2021.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Isis S. Mikhail, MD, MPH, DrPH, Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 402–7704, mikhaili@mail.nih.gov.

Name of Committee: National Institute on Aging Special Emphasis Panel Triadic Care.