regimens with treatment-shortening regimens with improved safety and efficacy. Thus, in this revised draft guidance more detail is provided for nonclinical models, early phase studies and trial design considerations, including the demonstration of efficacy using superiority or noninferiority (NI) trial designs. Additionally, updates are made to pediatric patients being included in trials, endpoint and safety considerations, and labeling. The Appendix is also updated with an example of an NI margin justification.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Pulmonary Tuberculosis: Developing Drugs for Treatment.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control numbers 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27186 Filed 12–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2014–N–1048; FDA–2012–N–0386; FDA–2019–N–0430; FDA–2019–N–5553; FDA–2021–N–0555; FDA–2013–N–0242; and FDA–2019–N–1517]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Medical Devices; Humanitarian Use Devices	0910–0332	10/31/2025
Tobacco Product Establishment Registration and Submission of Certain Health Information	0910–0650	10/31/2025
Generic Clearance for Quick Turnaround Testing of Communication Effectiveness	0910–0876	10/31/2025
Right to Try Act: Reporting Requirements	0910–0893	10/31/2025
Medical Device Labeling Regulations	0910–0485	11/30/2025
Current Good Manufacturing Practices for Positron Emission Tomography (PET) Drugs	0910–0667	11/30/2025
Abbreviated New Animal Drug Applications	0910–0669	11/30/2025

Dated: December 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27192 Filed 12–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; 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 Center for Complementary and Integrative Health Special Emphasis Panel; Promoting Research on Music and Health: Phased Innovation Award for Music Interventions (R61/R33) Clinical Trial Optional.

Date: January 13, 2023.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Complementary and Integrative, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shiyong Huang, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, NCCIH/NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20817, *shiyong.huang@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: December 12, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–27216 Filed 12–14–22; 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 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: Center for Scientific Review Special Emphasis Panel; PA Panel: Oncology Fellowships.

Date: January 3, 2023.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nywana Sizemore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6189, MSC 7804, Bethesda, MD 20892, 301–408–9916, *sizemoren@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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 12, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–27219 Filed 12–14–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report; Office of the Director (OD)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the Office of Laboratory Animal Welfare (OLAW) in the Office of Extramural Research will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Jane J. Na, Director, Division of Assurances, Office of Laboratory Animal Welfare, NIH, call (301) 496–7163 or email your request to *olawdoa@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report, OMB #0925–0765, Expiration Date 11/30/2022, REINSTATEMENT WITH CHANGE, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: The Office of Laboratory Welfare (OLAW) is responsible for the implementation, general administration, and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) as codified in 42 CFR 52.8. The PHS Policy implements the Health Research Extension Act (HREA) of 1985 (Pub. L. 99–158 as codified in 42 U.S.C. 289d). The PHS Policy requires entities that conduct research involving vertebrate animals using PHS funds to have an Institutional Animal Care and Use Committee (IACUC), provide assurance that requirements of the Policy are met, and submit an annual report. An institution's animal care and use program is described in the Animal Welfare Assurance (Assurance) document and sets forth institutional compliance with PHS Policy. The purpose of the Assurance (Interinstitutional, Foreign, and Domestic) and Annual Report is to provide OLAW with documentation to satisfy the requirements of the HREA, illustrate institutional adherence to PHS Policy, and enable OLAW to carry out its mission to ensure the humane care and use of animals in PHS-supported research, testing, and training, thereby contributing to the quality of PHS-supported activities.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 9,219.