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 Thus, in this revised draft guidance more detail is provided for nonclinical models, early phase studies and trial design considerations, including the demonstration of efficacy using superiority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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Pulmonary Tuberculosis: Developing Drugs for Treatment.''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Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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.