information collection request addresses the burden associated with the completion of the applicable CMS–855A by REHs in order to enroll in Medicare.

As part of this request, and as described in the supporting statement, we also seek approval for additional changes to the CMS–855A. These changes principally (though not exclusively) involve the collection of information related to the provider's ownership. *Form Number:* CMS–855A (OMB control number: 0938–0685); *Frequency:* On occasion; *Affected Public:* Business or other for-profits, not-for-profit institutions; *Number of Respondents:* 1,340; *Total Annual Responses:* 5,881; *Total Annual Hours:* 72,147. (For policy questions regarding this collection contact Frank Whelan at 410–786–1302.)

Dated: December 9, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2022–27166 Filed 12–14–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3728]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Collection of Conflict-of-Interest Information for Participation in Food and Drug Administration Non-Employee Fellowship and Traineeship Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 17, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0882. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Collection of Conflict-of-Interest Information for Participation in Food and Drug Administration Non-Employee Fellowship and Traineeship Programs

OMB Control Number 0910–0882—Extension

Section 742(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379l(b)) allows FDA to conduct and support intramural training programs through fellowship and traineeship programs. Prospective participants in these programs must complete financial disclosure forms to determine if there is a conflict of interest that would preclude participation. These new forms provide FDA with information about financial investments and relationships from non-employee scientists who participate in FDA fellowship and traineeship programs. Participants in FDA fellowship and traineeship programs will be asked for certain information about financial interests and current relationships: (1) description of the financial interest; (2) the type of financial interest (*e.g.,* stocks, bonds, stock options); (3) if the financial interest is an employee benefit from prior employment; (4) value of financial interest; (5) who owns the financial interest (*e.g.,* self, spouse, minor children); (6) employment relationship with an FDA significantly regulated organization (SRO); and (7) service as a consultant to an FDA SRO, and/or proprietary interest(s) in one of more product(s) regulated by FDA, including a patent, trademark, copyright, or licensing agreement. The purpose of the financial information is for FDA to determine if there is a conflict of interest between the Fellow's or Trainee's financial and relationship interests and their activities at FDA. The collection of information is mandatory to participate in FDA's fellowship and traineeship programs.

In the **Federal Register** of July 7, 2022 (87 FR 40537), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Oak Ridge Institute for Science and Education Fellowship	500	1	500	1	500
Traineeship Program	500	1	500	1	500
Reagan Udall Fellowship at FDA	50	1	50	1	50
Total					1,050

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: December 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27194 Filed 12–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1319]

Pulmonary Tuberculosis: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Pulmonary Tuberculosis: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in the clinical development of new antibacterial drugs for the treatment of pulmonary tuberculosis (TB). This draft guidance does not address the development of drugs for latent TB infection or for extrapulmonary TB. This draft guidance revises and replaces the draft guidance for industry of the same name published on November 6, 2013.

DATES: Submit either electronic or written comments on the draft guidance by February 13, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–D–1319 for ''Pulmonary Tuberculosis: Developing Drugs for Treatment.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ramya Gopinath, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6154, Silver Spring, MD 20993–0002, 240–402–5328.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Pulmonary Tuberculosis: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in the clinical development of investigational drugs for the treatment of pulmonary TB. Specifically, this draft guidance provides FDA's current recommendations regarding the overall development program and clinical trial designs for a new investigational drug or drugs to be used in combination with approved drugs or a new treatment regimen that includes one or more investigational drugs to support an indication for the treatment of pulmonary TB.

This draft guidance will revise and replace the draft guidance for industry of the same name issued November 6, 2013 (78 FR 66744). Since the 2013 final guidance was issued, there have been improvements in nonclinical models and further interest in streamlined clinical development programs as well as consideration for combination