binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. We anticipate that the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA-required records. The respondents are businesses and other for-profit organizations, State or local governments, Federal Agencies, and nonprofit institutions.

To assist respondents with the information collection we have developed the guidance document entitled ''Guidance for Industry: Part 11, Electronic Records; Electronic Signatures—Scope and Application,'' available on our website at *https://www.fda.gov/media/75414/download.* While we do not believe the guidance creates any attendant burden, it describes the Agency's thinking regarding persons who, in fulfillment of a requirement in a statute or another part of FDA's regulations to maintain records or submit information to FDA, have chosen to maintain the records or submit designated information electronically and, as a result, have become subject to part 11. Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations. Part 11 also applies to electronic records submitted to the Agency under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in Agency regulations (§ 11.1).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 11.100	4,500	1	4,500	1	4,500

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of record per recordkeepers	Total annual records	Average burden per recordkeeping	Total hours
§ 11.10	2,500	1	2,500	20	50,000
§ 11.30	2,500	1	2,500	20	50,000
§ 11.50	4,500	1	4,500	20	90,000
§ 11.300	4,500	1	4,500	20	90,000
Total					280,000

[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: August 5, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17711 Filed 8–12–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1298]

Acute Myeloid Leukemia: Developing Drugs and Biological Products 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 ''Acute Myeloid Leukemia: Developing Drugs and Biological Products for Treatment.'' This draft guidance is intended to assist sponsors in the clinical development of drugs and biological products for the treatment of acute myeloid leukemia (AML). This draft guidance addresses FDA's current thinking regarding the overall development program and clinical trial designs for the development of drugs and biological products to support an indication of treatment of AML, including indications limited to an individual phase of treatment (for example, maintenance, transplantation preparative regimen, etc.). The draft guidance addresses the topics of general drug development, efficacy endpoints, and exploratory and confirmatory trial considerations for AML drug development. In addition, the draft guidance addresses investigational new drug applications, new drug applications, and biologics licensing applications for AML drugs.

DATES: Submit either electronic or written comments on the draft guidance by October 13, 2020 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–2020–D–1298 for ''Acute Myeloid Leukemia: Developing Drugs and Biological Products 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.

• 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.

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 Division of Drug Information, CDER, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development, CBER, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Donna Przepiorka, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2116, Silver Spring, MD 20993–0002, 301–796–5358; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Acute Myeloid Leukemia: Developing Drugs and Biological Products for Treatment.'' This draft guidance is intended to assist sponsors in the clinical development of drugs and biological products for the treatment of AML. This draft guidance includes FDA's current thinking regarding the overall development program and clinical trial designs to support an indication of treatment of AML, including indications limited to an individual phase of treatment.

New classes of drugs are being developed as alternatives to the standard cytotoxic drugs for the treatment of AML. The following factors contribute substantially to the complexity of clinical development programs for such new drugs: The expansion of treatment intent, broadening of the intended population, and development of a wide range of new drug classes as alternatives to cytotoxic drugs. This draft guidance includes FDA's thinking regarding general drug development considerations, efficacy endpoints, exploratory and confirmatory trial considerations, and regulatory submissions for AML drugs to facilitate the development of new drugs for the treatment of AML.

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 ''Acute Myeloid Leukemia: Developing Drugs and Biological Products 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

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR 312 have been approved under OMB control number 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 0910–0338; and 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 either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*, or *https://www.regulations.gov*.

Dated: August 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17714 Filed 8–12–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Teaching Health Center Graduate Medical Education Program Cost Evaluation, OMB No. 0906–XXXX—NEW

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than September 14, 2020.

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: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: *Information Collection Request Title:* Teaching Health Centers Graduate Medical Education Program Cost Evaluation, OMB No. 0906–XXXX—NEW.

Abstract: The Teaching Health Center Graduate Medical Education (THCGME) program, authorized by Section 340H of the Public Health Service Act, was established by Section 5508 of Public Law (Pub. L.) 111–148. The Bipartisan Budget Act of 2018 (Pub. L. 115–123) provided continued funding for the THCGME Program for fiscal years 2018 and 2019 and the Coronavirus Aid, Relief, and Economic Security Act extends funding for FY 2020 and for the first two months of FY 2021 (until November 30, 2020). The THCGME program provides funding support for new and the expansion of existing primary care residency training programs in community-based settings. The primary goals of this program are to increase the production of primary care providers who are better prepared to practice in community settings, particularly with underserved populations, and improve the geographic distribution of primary care providers.

Need and Proposed Use of the Information: Statute requires the Secretary to determine an appropriate THCGME program payment for indirect medical expenses (IME) as well as to update, as deemed appropriate, the per resident amount used to determine the Program's payment for direct medical expenses (DME). To inform these determinations and to increase understanding of this model of residency training, George Washington University (GW), under contract with HRSA, is conducting an evaluation of the costs associated with training residents in the THC model. GW has developed a standardized THCGME Costing Instrument to gather data from all THCGME programs, which they will use to gather costing information related to both DME and IME. The information gathered in the THCGME Costing Instrument includes, but is not limited to, resident and faculty full-time equivalents, salaries and benefits, residency administration costs, educational costs, residency clinical operations and administrative costs, patient visits and clinical revenue generated by medical residents, financial reports, as well as general program information to understand the characteristics of the THCGME program and sponsoring institutions that are involved in residency training.

A 60-day notice published in the **Federal Register** on April 30, 2020, vol. 85, No. 84; pp. 23975–76. One public comment was received. GW also consulted with a GME Expert Panel to provide an external informed review of the THCGME Costing Instrument. Recommendations were received from the GME Expert Panel and minor changes were made. The feedback provided by the public comment and the GME Expert Panel included recommendations to: (1) Collect information on telehealth visits in 2018–2019 as a benchmark for telehealth activity post COVID–19 pandemic; (2) change to academic year 2018–2019 for the data collection period; and (3) further solidify the IME methodology for the non-THC Federally Qualified Health Center comparison group; and (4) enhance the THCGME Costing Instrument instructions.

HRSA is collecting costing information related to both DME and IME in an effort to establish a THC's total cost of running a residency program, to assist the Secretary in determining an appropriate update to the per resident amount used to calculate the payment for DME and an appropriate IME payment. The described data collection activities will serve to inform these statutory requirements for the Secretary in a uniform and consistent manner.

Likely Respondents: The likely respondents to the THCGME Costing Instrument are the THCGME program award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.