''Cytomegalovirus in Transplantation: Developing Drugs to Treat or Prevent Disease.'' The purpose of this final guidance is to assist sponsors in the clinical development of drugs to treat or prevent CMV disease in patients who have undergone SOT or HSCT. Specifically, this 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 for treating or preventing CMV disease in post-transplant populations. This guidance does not address drug development for treating or preventing congenital CMV infection or CMV infection in patients other than those undergoing SOT or HSCT. This guidance finalizes the draft guidance of the same name issued on May 21, 2018 (83 FR 23463). Changes in this final guidance compared with the previous draft guidance include:

- Clarification of the use of CMV DNAemia as a validated surrogate endpoint for use in certain clinical trials of CMV treatment or prevention
- Clarification that nonclinical combination studies for drugs to be used in combination are generally not needed
- Inclusion of updated background information to reflect the current literature on preventing CMV in transplant recipients

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Cytomegalovirus in Transplantation: Developing Drugs to Treat or Prevent Disease.'' 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 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. 3501–3520). The collections of information in 21 CFR parts 312, 314, and 601 have been approved under OMB control numbers 0910–0014, 0910–0001, and 0910–0038, respectively.

III. Electronic Access

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

Dated: May 1, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–09864 Filed 5–7–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5319]

Notice of Followup to Notice of Public Hearing and Request for Comments on Devices Proposed for a New Use With an Approved, Marketed Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a followup on a **Federal Register** document issued on September 26, 2017, that announced a public hearing and requested comments on a potential approach to enable device sponsors to obtain marketing authorization for their products labeled for a new use with an approved, marketed drug when the sponsor for the approved drug does not wish to pursue or collaborate on the new use, referred to in the notice as devices referencing drugs (DRDs). After further consideration and in light of the comments received, FDA does not intend to pursue the potential approach described in the referenced **Federal Register** document at this time.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5130, Silver Spring, MD 20993, 301–796–8941, *combination@fda.gov.*

SUPPLEMENTARY INFORMATION: FDA issued a **Federal Register** document on September 26, 2017 (82 FR 44803), entitled ''Devices Proposed for a New Use With an Approved, Marketed Drug; Public Hearing; Request for Comments''. The document announced a public hearing and requested comments on a potential approach to enable device sponsors to obtain marketing authorization for their products labeled for a new use with an approved, marketed drug when the sponsor for the approved drug does not wish to pursue or collaborate on the new use. Such new uses generally involve a change in how the drug is used or administered, such as a change in dose, route, or rate of administration, or use of the approved drug for an indication for which it is not approved. As discussed in the document, such DRDs raise unique public health, scientific, regulatory, and legal issues, which the potential approach was intended to address. However, after further consideration and in light of the comments received during the public hearing and submitted to the docket, FDA does not intend to pursue the potential approach described in the document at this time.

Dated: May 1, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–09832 Filed 5–7–20; 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: The Teaching Health Center Graduate Medical Education Program Reconciliation Tool, OMB No. 0915–0342—Extension

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

ACTION: Notice.

SUMMARY: In compliance with of 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 June 8, 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 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: The Teaching Health Center Graduate Medical Education Program Reconciliation Tool OMB No. 0915–0342—Extension.

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 Further Continuing Appropriations Act, 2020, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act extends funding for Fiscal Year (FY) 2020 for the first two months of FY 2021 (until November 30, 2020).

THCGME program awards payment for both direct and indirect expenses to support training for primary care residents in community-based ambulatory patient care settings. Direct medical expense payments are designed to compensate eligible teaching health centers for those expenses directly associated with resident training, while indirect medical expense payments are intended to compensate for the additional costs of training residents in such programs.

A 60-day notice published in the **Federal Register** on January 22, 2020, Vol. 85, No. 14; pp. 3696–97. There were no public comments.

Need and Proposed Use of the Information: THCGME program payments are prospective payments, and the statute provides for a reconciliation process, through which overpayments may be recouped and underpayments may be adjusted at the end of the fiscal year. This data collection instrument will gather information relating to the number of resident full-time equivalents in Teaching Health Center training programs in order to reconcile payments for both direct and indirect expenses.

Likely Respondents: The likely responders to the THCGME Reconciliation Tool are 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.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
THCGME Reconciliation Tool	58	1	58	2	116
Total	58		58		116

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–09906 Filed 5–7–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: Heart, Lung, and Blood Initial Review Group; NHLBI Institutional Training Mechanism Review Committee.

Date: June 4–5, 2020.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, RKL1 6705 Rockledge, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lindsay M. Garvin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6705 Rockledge Drive, Bethesda, MD 20892, 301–827–7911, *lindsay.garvin@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 5, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–09920 Filed 5–7–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; 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