''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 This guidance finalizes the draft guidance of the same name issued on May 21, 2018 (83 FR 23463). Changes in this final guidance compared with the previous draft guidance include: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]

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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]

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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.