December 20, 2019, the appropriations language encouraged ACF ''to convene a working group of federal early childhood program administrators, tribal early childhood stakeholders, and tribal leaders to examine coordination issues that may be impacting early childhood initiatives in tribal communities.'' We are interested in tribal leader input on barriers and opportunities regarding synchronizing early childhood initiatives in their communities.

We invite tribes to provide written testimony, in advance, to the Administration for Children and Families to help guide discussion. Testimonies are to be submitted no later than June 10, 2020 to the following: Jeannie Hovland, Commissioner, Administration for Native Americans, *anacommissioner@acf.hhs.gov.*

For further information and registration details for this Consultation, please visit the following link: *https://www.acf.hhs.gov/ana/2020-acf-tribal-consultation.*

Linda K. Hitt,

Executive Secretariat Certifying Officer.

[FR Doc. 2020–09850 Filed 5–7–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1711]

Cytomegalovirus in Transplantation: Developing Drugs To Treat or Prevent Disease; Final 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 final guidance for industry entitled ''Cytomegalovirus in Transplantation: Developing Drugs to Treat or Prevent Disease.'' The purpose of this guidance is to assist sponsors in all phases of the clinical development of drugs and biological products to treat or prevent cytomegalovirus (CMV) disease in patients who have undergone solid organ transplantation (SOT) or hematopoietic stem cell transplantation (HSCT). This guidance finalizes the draft guidance of the same name issued on May 21, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on May 8, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2018–D–1711 for ''Cytomegalovirus in Transplantation: Developing Drugs to Treat or Prevent Disease.'' 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.gpo.gov/fdsys/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 this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6370, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled

''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.