meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17524 Filed 8–14–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0809]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that CRYSVITA (burosamab-twza), manufactured by Ultragenyx Pharmaceutical, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, Fax: 301–796–9856, email: *althea.cuff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that CRYSVITA (burosamab-twza), manufactured by Ultragenyx Pharmaceutical, Inc., meets the criteria for a priority review voucher. CRYSVITA (burosamab-twza) is indicated for the treatment of X-linked hypophosphatemia in adult and pediatric patients 1 year of age and older.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about CRYSVITA (burosumab-twza), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: August 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17527 Filed 8–14–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0943]

Elemental Impurities in Animal Drug Products—Questions and Answers; Draft Guidance for Industry; Availability; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is reopening the comment period for the notice of availability that published in the **Federal Register** on March 27, 2018. In that document, FDA requested comments on the draft guidance for industry (GFI) #255 entitled ''Elemental Impurities in Animal Drug Products—Questions and Answers.'' The Agency is taking this action in response to requests for an extension to allow interested parties additional time to develop and submit comments.

DATES: FDA is reopening the comment period on the notice of availability published March 27, 2018 (83 FR 13134). Submit either electronic or written comments on the draft guidance by October 15, 2018 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–2018–D–0943 for ''Elemental Impurities in Animal Drug Products—Questions and Answers.'' 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 the draft guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. 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: Michael Brent, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0647, *michael.brent@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 27, 2018, FDA published a notice of availability with a 60-day comment period to request comments on draft GFI #255 entitled ''Elemental Impurities in Animal Drug Products—Questions and Answers.''

This level 1 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 ''Elemental Impurities in Animal Drug Products—Questions and Answers'', providing recommendations to sponsors regarding the control of elemental impurities in animal drug products, including all dosage forms and routes of administration. 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. This guidance is not subject to Executive Order 12866.

The Agency received two requests for an extension of the comment period for the draft guidance. The requestors indicated they needed more time to complete development of comments to submit in response to the draft guidance.

FDA has considered the requests and is reopening the comment period for the draft guidance for 60 days, until October 15, 2018. The Agency believes that a 60-day reopening of the comment period allows adequate time for interested persons to submit comments to ensure that the Agency can consider the comments on this draft guidance before it begins work on the final version of the guidance.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov.*

Dated: August 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17525 Filed 8–14–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Division of Epidemiology and Disease Prevention Epidemiology Program for American Indian/Alaska Native Tribes and Urban Indian Communities

Announcement Type: Competing Supplement

Funding Announcement Number: HHS–2018–IHS–EPI–0002

Catalog of Federal Domestic Assistance Number: 93.231

Key Dates

Application Deadline Date: September 12, 2018

Review Date: September 14–18, 2018

Earliest Anticipated Start Date: September 30, 2018

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Public Health Support, Division of Epidemiology and Disease Prevention (DEDP), is accepting applications for a cooperative agreement for competitive supplemental funds to enhance activities in the Epidemiology Program for American Indian/Alaska Native (AI/AN) Tribes and Urban Indian communities.

This program is authorized under: Section 317(k)(2) of the Public Health Service Act [42 U.S.C. 247(b)(k)(2), as amended]. Funding for this award will be provided by: The Centers for Disease Control and Prevention's (CDC) National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). The authorities will be exercised by CDC and through an Intra-Departmental Delegation of Authority (IDDA) with IHS to create a supplemental funding opportunity for Tribal Epidemiology Centers. The administration will be carried out through an Intra-agency Agreement (IAA) between CDC and IHS. This program is described in the Catalog of Federal Domestic Assistance (CFDA) under 93.231.

Background

The Tribal Epidemiology Center (TEC) program was authorized by Congress in 1998 as a way to provide public health support to multiple Tribes and Urban Indian communities in each of the IHS Areas. Only current TEC grantees serving Arizona Indian Tribes or Urban Indian communities with confirmed cases of Rocky Mountain spotted fever (RMSF) between 2003–2017 are eligible to apply for the competing supplemental funding under this announcement and must demonstrate that they have complied with previous terms and conditions of the TEC program.

Positioned uniquely within Tribes and Tribal or Urban Organizations, TECs are able to conduct disease surveillance, research, prevention and control of disease, injury, or disability. This allows them to assess the effectiveness of AI/AN public health programs. In addition, they can fill gaps in data needed for the relevant Government Performance and Results Act and Healthy People 2020 measures. Some of the existing TECs have already