for Drug Development Tools; Guidance for Industry; Availability'' that appeared in the **Federal Register** of November 25, 2020. The document announced the availability of a final guidance for industry and FDA staff that met the 21st Century Cures Act's requirement to issue guidance on this qualification process and elaborated on the new qualification process and transparency requirements and discusses the taxonomy for biomarkers and other drug development tools. The document was published with incorrect information in the Paperwork Reduction Act of 1995 section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Chris Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6461, Silver Spring, MD 20993–0002, 301–796–0017; or Stephen Ripley, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002; 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 25, 2020 (85 FR 75334), in FR Doc. 2020–26051, the following correction is made:

On page 75336, in the first column, under the heading, ''II. Paperwork Reduction Act of 1995'', the paragraph is corrected to read:

''While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information pertaining to submissions of investigational new drug applications have been approved under OMB control number 0910–0014; the collections of information pertaining to submissions of new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001; and the collections of information pertaining to submissions of biologics license applications in 21 CFR part 601 have been approved under OMB control number 0910–0338.''

Dated: December 8, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27288 Filed 12–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0064]

Pre-Submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe Notices; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a final guidance for industry #262 entitled ''Pre-Submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe (GRAS) Notices.'' The guidance provides uniform, consistent process information to industry to facilitate effective and efficient review of pre-consultation submissions for animal food additives or GRAS notices for intended use in animal food.

DATES: The announcement of the guidance is published in the **Federal Register** on December 11, 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–2020–D–0064 for ''Pre-Submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe (GRAS) Notices.'' 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, 240–402–7500.

- 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, 240–402–7500.

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 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: William Burkholder, Center for Veterinary Medicine (HFV–229), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5900, *william.burkholder@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 13, 2020 (85 FR 8297), FDA published the notice of availability for a draft guidance entitled ''Pre-Submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe (GRAS) Notices,'' giving interested persons until April 13, 2020, to comment on the draft guidance.

FDA received two comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated February 2020.

This guidance provides uniform, consistent process information to industry to facilitate effective and efficient review of pre-consultation submissions for animal food additive petitions or GRAS substances and preparation of food use authorization requests.

This level 1 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 the pre-submission consultation process for animal food additive petitions or GRAS notices for intended use in animal food. 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance.

The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 570.17 and 571.1 have been approved under OMB control number 0910–0546; the collections of information under 21 CFR part 570, subpart E have been approved under OMB control number 0910–0342; and the collections of information under 21 CFR part 58 have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 7, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27256 Filed 12–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Standardized Work Plan Form for Use with Applications to the Bureau of Health Workforce Research and Training Grants and Cooperative Agreements OMB No. 0906–0049—Revision

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 have been 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 January 11, 2021.

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.

A 60-day **Federal Register** Notice was published in the **Federal Register** on September 15, 2020, Vol. 85, No. 179, pp.57221–57222. There were no public comments.

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: Standardized Work Plan Form for Use with Applications to the Bureau of Health Workforce Research and Training Grants and Cooperative Agreements, OMB No. 0906–0049—Revision

Abstract: HRSA's Bureau of Health Workforce requires applicants of training and research grants and cooperative agreements to submit work plans via the Standardized Work Plan (SWP) form.

The information in the SWP describes the timeframes and progress required during the grant period of performance to address each of the needs detailed in the Purpose and Need section of the application, as required in the Notice of Funding Opportunity announcement.

Applicants use the SWP form when they submit their proposals, and award recipients and Project Officers use the SWP information to assist in monitoring progress once HRSA makes the awards. HRSA proposes a revision to the SWP to include a Quarterly Progress Update (QPU) for award recipients to provide information to HRSA on a quarterly basis on each activity listed in the SWP.

Need and Proposed Use of the Information: The information collected by the SWP form standardizes and streamlines the data used by HRSA in reviewing applications and monitoring awardees. The form asks applicants to provide a description of the activities or steps the applicant will take to achieve