in non-tribal HPOG programs and will include a cost-benefit analysis. Key participant outcomes of interest include (but are not limited to) educational progress, employment, and earnings.

The HPOG 2.0 Long-Term Follow-Up Study will use survey and administrative data to estimate longer-term (approximately 5½ years after random assignment) program impacts at the local and national level and to explore characteristics of local programs that are associated with more favorable outcomes. By extending data collection to include an LTS, OPRE can address important unanswered questions for policymakers and practitioners. The HPOG 2.0 LTS specifically will provide insights into the long-term impacts of HPOG 2.0 for outcomes that are not captured in administrative records, such as details about educational experiences, characteristics of employment, self-employment, and earnings from jobs not covered in administrative data, receipt of public assistance, physical and mental well-being, and child outcomes. There are two versions of the HPOG 2.0 LTS, the full version (Instrument 21) and a shorter version with critical items of interest only (Instrument 21a). Instrument 21a will be offered to reluctant participants who would otherwise not complete the survey to help maximize response rates and reduce item non-response for the most critical outcomes in the study.

Respondents: HPOG 2.0 impact study participants from the 27 non-tribal HPOG 2.0 grantees (treatment and control group members) who enrolled between September 2017 and January 2018.

Annual Burden Estimates: This request is specific to the HPOG 2.0 Long-Term Follow-Up Survey (LTS) (both the full and critical items only versions). Currently approved materials and associated burden, which we plan to continue to use can be found at: *https://www.reginfo.gov/public/do/PRAICList?ref_nbr=201904-0970-006.*

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Instrument 21a: HPOG 2.0 Long-Term Survey	3,064	1	1	3,064	1,021
Instrument 21a: HPOG 2.0 Long-Term Survey Critical Items Instrument	541	1	0.33	179	60
Total	3,605			3,243	1,081

Estimated Total Annual Burden Hours: 1,081.

Authority: Section 2008 of the Social Security Act as enacted by section 5507 of the Affordable Care Act and section 413 of the Social Security Act, 42 U.S.C. 613.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–14580 Filed 7–7–22; 8:45 am]

BILLING CODE 4184–72–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–0388]

Hazard Analysis and Risk-Based Preventive Controls for Food for Animals; 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 #245 entitled ''Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.'' This final guidance document is intended to help animal food facilities comply with the requirements for hazard analysis and risk-based preventive controls under our regulation ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals.'' The guidance announced in this notice finalizes the draft guidance of the same title dated January 23, 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on July 8, 2022.

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–0388 for ''Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.'' 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Jennifer Erickson, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7382, *Jennifer.erickson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 23, 2018 (83 FR 3163) and a correction in the **Federal Register** of February 5, 2018 (83 FR 5106), FDA published the notice of availability for a draft guidance #245 entitled ''Hazard Analysis and Risk-Based Preventive Controls for Food for Animals,'' giving interested persons until July 23, 2018, to comment on the draft guidance. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. We have made some changes and updates. First, we removed Appendix E: ''Aid to Identifying Animal Food Hazards'' based on comments questioning how it should be used and concerns about how to distinguish whether a listed hazard is known or reasonably foreseeable for a facility, specific ingredient, or type of animal food. Second, we provided additional clarity, based on comments, that not all the known or reasonably foreseeable hazard examples in the guidance are applicable to all animal food. Third, we included additional examples of certain hazards in animal food, preventive controls, and situations that would require a reanalysis of a food safety plan. Fourth, we updated some of the references used throughout the guidance. Lastly, editorial and formatting changes were made to improve clarity and consistency. The guidance announced in this notice finalizes the draft guidance dated January 23, 2018.

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 ''Hazard Analysis and Risk-Based Preventive Controls for Food for Animals.'' 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 part 507 have been approved under OMB Control No. 0910–0751.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: June 29, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14567 Filed 7–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–1909; FDA–2020–E–1906; FDA–2020–E–1901; FDA–2020–E–1899]

Determination of Regulatory Review Period for Purposes of Patent Extension; PADCEV

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for PADCEV and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by September 6, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 4, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing