timely feedback on service delivery while ensuring that the information collected is useful and minimally burdensome for the public, as required by the Paperwork Reduction Act of 1995. ACF created this generic clearance in response to this effort by OMB.

To work continuously to ensure that the ACF programs are effective and meet our customers' needs, we use this Fast Track generic clearance process to collect qualitative feedback on our service delivery. This collection of information is necessary to enable ACF to garner customer and stakeholder feedback in an efficient, timely manner in accord with our commitment to improving service delivery. The information collected from our customers and stakeholders helps ensure that users have an effective, efficient, and satisfying experience with the programs. This feedback provides insights into customer or stakeholder perceptions, experiences, and expectations; provides an early warning of issues with service; or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections allow for ongoing, collaborative, and actionable communications between ACF and its customers and stakeholders. They also allow feedback to contribute directly to the improvement of program management.

Per Memorandum M–11–26, information collection requests submitted under this Fast Track generic will be considered approved unless OMB notifies ACF otherwise within 5 days.

Respondents: ACF program participants, potential program participants, stakeholders, and other customers.

Annual Burden Estimates

Burden Estimates—Approved Information Collection

The request to OMB will include an extension request for approved information collections that are planned to continue beyond May 2024. Find currently approved information collections here: *https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202305-0970-012.*

Burden Estimates—New Requests

The following table includes burden estimates for new requests under this generic over the next 3 years. Based on the use of this generic clearance over the past 3 years, ACF is requesting an increase to the estimated number of responses per respondent from 1 to 2.

Type of collection	Total number of respondents	Average total number of responses per respondent	Average burden hours per response for types of collections	Total burden hours
Surveys	175,000	2	.5	50,000
Comment Cards/Forms			.25	
Feedback Questions			.083	
Focus Groups, Discussions, Cognitive Studies			1	

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Social Security Act, Sec. 1110. [42 U.S.C. 1310].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–27093 Filed 12–8–23; 8:45 am]

BILLING CODE 4184–88–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2022–E–2095 and FDA–2022–E–2096]

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

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 WELIREG 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 patents which claims that human drug 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 February 9, 2024. 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 June 10, 2024. 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 system will accept comments until 11:59 p.m. Eastern Time at the end of February 9, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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 Nos. FDA–2022–E–2095 and FDA–2022–E–2096 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; WELIREG.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product WELIREG (belzutifan). WELIREG is indicated for the treatment of adult patients with von Hippel-Lindau disease who require therapy for associated renal cell carcinoma, central nervous system hemangioblastomas, or pancreatic neuroendocrine tumors, not requiring immediate surgery. Subsequent to this approval, the USPTO received patent term restoration applications for WELIREG (U.S. Patent Nos. 9,908,845; 9,969,689) from Peloton Therapeutics, Inc, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 13, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of WELIREG represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for WELIREG is 1,752 days. Of this time, 1,541 days occurred during the testing phase of the regulatory review period, while 211 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* October 28, 2016. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 28, 2016.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* January 15, 2021. FDA has verified the applicant's claim that the new drug application (NDA) for WELIREG (NDA 215383) was initially submitted on January 15, 2021.

3. *The date the application was approved:* August 13, 2021. FDA has

verified the applicant's claim that NDA 215383 was approved on August 13, 2021.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 342 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: December 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27044 Filed 12–8–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Theodoric Mattes at 240–627–3827, or *theodoric.mattes@nih.gov*. Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Vaccine for Cats To Block Toxoplasma Gondii Oocyst Shedding and Transmission

Description of Technology:

Toxoplasma gondii is the zoonotic causative agent of toxoplasmosis, a disease of significant concern for pregnant persons and livestock. A member of the phylum Apicomplexa, *Toxoplasma gondii* can infect almost any cell type found in mammals and birds. There are multiple transmission pathways, including consumption of undercooked meat from infected animals, consumption of unwashed plants, contaminated water supplies, blood transfers, and congenital transfer. Felines are considered the definitive host of *Toxoplasma gondii.* Direct or indirect transmission can occur via contact with the stool of infected felines.

Researchers at the National Institute of Allergy and Infectious Diseases (NIAID), the U.S. Department of Agriculture (USDA), and the University of South Bohemia (České Budějovice, Czechia) have demonstrated that *T. gondii* strains lacking expression of either the intracellular transport protein IFT88 or the CYS–6-type surface antigen SRS15B prevent the formation of oocysts and have potential for broad immunity to *T. gondii.* The inventors propose that mass inoculation of felines, specifically wild or feral felines, with a live vaccine developed from these strains could result in a significant reduction in oocyst production and environment contamination, reducing further infection in a geographical area. It is also proposed that loss of IFT88 or SRS15B homologs in other Apicomplexa parasites, like *Neospora, Sarcocystis,* or *Cryptosporidium* could have a similar impact.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Live vaccine for felines against *Toxoplasma gondii* infection
- Reduction in environmental *Toxoplasma gondii* oocysts

Competitive Advantages:

- 100% blocked *Toxoplasma gondii* oocyst shedding in felines
- Detectable seroconversion protective against future *Toxoplasma gondii* infection
- Scalable production strain with predictable inactivation of IFT88 or SRS15B gene
- Materials available for development or licensing

Development Stage:

- Pre-Clinical

Inventors: Michael Grigg (NIAID), Aline Sardinha da Silva (NIAID), Viviana Pszenny (NIAID), Jitender Dubey (USDA), and Julius Lukeš (University of South Bohemia, Czechia).

Intellectual Property: HHS Reference No. E–118–2023–2. U.S. Provisional Patent Application No. 63/470,773 filed June 4, 2023.

Licensing Contact: To license this technology, please contact Theodoric Mattes at 240–627–3827, or *theodoric.mattes@nih.gov.,* and reference E–118–2023–2.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. For collaboration opportunities, please contact Theodoric Mattes at 240–627–3827, or *theodoric.mattes@nih.gov*.

Dated: December 5, 2023.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2023–27113 Filed 12–8–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.