petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 12, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11176 Filed 5–14–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–E–0132]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for PALLADIA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

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

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: 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 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 animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal 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 Patents and Trademarks 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 an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA has approved for marketing the animal drug product PALLADIA (toceranib phosphate). PALLADIA is indicated for the treatment of Patnaik grade II or III, recurrent, cutaneous mast cell tumors with or without regional lymph node involvement in dogs.

Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PALLADIA (U.S. Patent No. 6,573,293) from Sugen, Inc., and Pharmacia & Upjohn Company LLC, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 3, 2011, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of PALLADIA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for PALLADIA is 2,711 days. Of this time, 2,681 days occurred during the testing phase of the regulatory review period, while 30 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* December 21, 2001. The applicant claims November 23, 2001, as the date the investigational new animal drug application (INAD) became effective. However, Food and Drug Administration (FDA) records indicate that the INAD effective date was December 21, 2001, which was the received date of the first submission that includes a study with substantial data (submission of a major health test) or the first submission containing a Notice of Claimed Investigational Exemption.

2. *The date the application was initially submitted with respect to the animal drug product under section 512 of the FD&C Act (21 U.S.C. 360b):* April 23, 2009. The applicant claims April 22, 2009, as the date the new animal drug application (NADA) for Palladia (NADA 141–295) was initially submitted. However, FDA records indicate that NADA 141–295 was submitted on April 23, 2009.

3. *The date the application was approved:* May 22, 2009. FDA has verified the applicant's claim that NADA 141–295 was approved on May 22, 2009.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this

applicant seeks 827 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 14, 2014. 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 November 12, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (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.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov*, Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11172 Filed 5–14–14; 8:45 am]

BILLING CODE 4160–01–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 inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 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: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Real Time Medical Image Processing Using Cloud Computing

Description of Technology: The invention pertains to a system for reconstructing images acquired from MR and CT scanners in a robust Gadgetron based cloud computing system. A hardware interface connects clinical imaging instruments (e.g., MR or CT scanners) with a cloud computing environment that includes image data reconstruction and processing software not limited by the computational constraints typical of static hardware with finite processor power. Raw imaging data acquired from an MR or CT instrument is evaluated and categorized based on a pre-prioritized dimensionality parameter (e.g., spatial dimension parameter; three- or two-dimensionality, a time parameter, a flow/velocity parameter, an experiment timing dimension parameter, a diffusion encoding parameter, a functional/physiological testing dimension parameter, or a physiologic gating index parameter) and transmitted to a corresponding cloud computing environment for processing and reconstruction. The final processed image is retransmitted to a user interface that can be read by a radiologist or technician.

Potential Commercial Applications:

- MRI imaging
- CT imaging
- Image processing
- Diagnostic radiology

Competitive Advantages:

- Eliminates the need for purchasing expensive data processing equipment that becomes obsolete
- Less equipment leads to lowers costs and space efficiency
- Exponentially more robust computer power, data acquisition and image reconstruction

Development Stage:

- Early-stage
- In vitro data available
- In vivo data available (animal)
- In vivo data available (human)
- In situ data available (on-site)
- Prototype

Inventors: Michael Hansen, Peter Kellman, Hui Xue (all of NHLBI)

Intellectual Property:

- HHS Reference No. E–074–2014/0—U.S. Provisional Application No. 61/934,987 filed 03 Feb 2014
- HHS Reference No. E–074–2014/1—U.S. Provisional Application No. 61/953,017 filed 14 Mar 2014

Licensing Contact: Michael Shmilovich, Esq; 301–435–5019; *shmilovm@mail.nih.gov.*

Collaborative Research Opportunity: The National Heart Lung & Blood Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Gadgetron mediated clinical image processing. For collaboration opportunities, please contact Denise Crooks, Ph.D. at 301–435–0103 or *crooksd@nhlbi.nih.gov.*

Personal Respirator Safety: Flushed Seal for an Improved, More Protective, Negative-Pressure Respirator

Description of Technology: This CDC-developed technology relates to improved, full-face flushed-seal personal respirators for lowering costs, improving user mobility, and ensuring occupational health and safety. Currently, the most common type of respirator in use, the negative pressure respirator, seals to a user's face so that inhaled air is pulled through a purifying filter by inhalation-generated negative pressure; the weakest link in this type of respirator is typically the seal at the face-to-mask interface. When there is face-seal leakage, toxic air will be drawn into the facepiece of the respirator and inhaled by the wearer, though designers and engineers of respirators attempt to minimize this face-seal leakage. Over the last several decades, facepiece design has been optimized by this design approach so that the ambient leakage of half-facepiece respirators and full-facepiece respirators are 10% and 2%, respectively.

This technology incorporates an additional element to reduce face-seal leakage and therefore increases user protection. In the respirator described by this technology, a primary sealing element is situated adjacent to the user's breathing space and a secondary sealing element. Exhaled air (i.e., clean air obtained by filter passage) is passed from the breathing space into a flushing channel formed between the primary and secondary seals. If there is leakage in the primary seal, air from this