Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) electronic or written comments and written petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with the docket number found in brackets in the heading of this document.

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: February 14, 2011.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2011–6514 Filed 3–18–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–E–0241]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ATRYN 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 human biological product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002. 301–796–3602.

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 human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biologic product ATRYN (antithrombin (recombinant)). ATRYN is indicated for the prevention of peri-operative and peri-partum thromboembolic events in hereditary antithrombin deficient patients. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ATRYN (U.S. Patent No. 6,441,145) from GTC Biotherapeutics, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 17, 2010, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of ATRYN represented the first permitted commercial marketing or use of the recombinant product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ATRYN is 4,468 days. Of this time, 4,285 days occurred during the testing phase of the regulatory review period, while 183 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 (21 U.S.C. 355(i)) became effective:* November 15, 1996. The applicant claims November 14, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 15, 1996, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* August 8, 2008. The applicant claims January 31, 2008, as the date the biologics license application (BLA) for ATRYN (BLA 125284) was initially submitted. However, FDA records indicate that BLA 125284 was submitted on August 8, 2008.

3. *The date the application was approved:* February 6, 2009. FDA has verified the applicant's claim that BLA 125284 was approved on February 6, 2009.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. 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 1,243 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 May 20, 2011. 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 September 19, 2011. 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 petitions. It is only necessary to send one set of comments. It is no longer necessary to send three copies of mailed comments. However, if you submit a written petition, you must submit three copies of the petition. Identify comments with

the docket number found in brackets in the heading of this document.

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: February 14, 2011.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 2011–6509 Filed 3–18–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, 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. 207 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.

ADDRESSES: 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.

UOK 268 Cell Line for Hereditary Leiomyomatosis and Renal Cell Carcinoma

Description of Technology: Hereditary Leiomyomatosis and Renal Cell Carcinoma (HLRCC) is an extremely aggressive cancer syndrome with no effective treatment regimen and currently no cure. The progress of identifying HLRCC treatments and cures has likely been hindered due to the lack of an HLRCC model for studying the cancer syndrome and for screening therapeutic drug candidates.

This technology describes the UOK 268 cell line, a spontaneously immortalized renal tumor cell line that may be of great interest to industry for studying HLRCC, drug screening, and searching for tumor markers related to diagnosis, prognosis, and drug resistance. This cell line is only the second spontaneously immortalized cancer cell line of its kind in the world and is unique in that it is a primary tumor cell model (the other cell line, UOK 262, is from a metastasis cell model). The UOK 268 cell line is an established, clonal, immortalized renal cancer cell line derived from the long-term culture of aggressive tumor tissues of HLRCC in a specially designed culture medium under strict culture conditions. The UOK 268 exhibits an array of HLRCC kidney cancer characteristics that can promote protein and fatty acid biosynthesis and modulate HIF activities in a manner conducive to cancer cell proliferation.

Benefits:

• This is only one of two immortalized HLRCC cell lines, and is unique in that it is from a primary tumor cell model.

• Developing a diagnostic to search for tumor targets and screen for HLRCC and related cancers drug candidates will have significant benefits, including early detection and treatment.

Applications:

• *In vitro* and *in vivo* cell model for understanding the biology of HLRCC and related cancers, including growth, motility, invasion, and metabolite production.

• High throughput screening to test for drug candidates that could be used to treat particular cancers, such as HLRCC.

• Diagnostic tool for the diagnosis, prognosis, and drug resistance of tumor markers.

Advantages:

• *Cell line is derived from a HLRCC patient:* This cell line is anticipated to retain many features of primary HLRCC samples and novel HLRCC antigens identified from this cell line are likely to correlate with antigens expressed on human HLRCC tumors. Studies performed using this cell lines may have a direct correlation to the initiation, progression, treatment, and prevention of HLRCC in humans.

• *Molecular and genetic features are well characterized:* The inventors have elucidated many physical characteristics of the cell lines and their data reveals previously unrecognized coordination between mammalian glucose and iron metabolisms through AMPK signaling, and a novel mechanism for modulating HIF activities in renal cancers.

Inventors: W. Marston Linehan and Youfeng Yang (NCI)

Publications:

1. Youfeng Yang et al. Distinct Mito-transcriptome Profiling in Fumarate Hydratase-deficient Novel Primary Tumor Cell Line UOK268 Leads to Better Understanding of Early Human HLRCC-associated Cancer with Multiple Dysregulated Molecular Events and Metabolic Shunts. *Under submission.*

2. Wing-Hang Tong et al. Hypoactivation of AMPK pathway and remodeling of iron metabolism in hereditary leiomyomatosis and renal cell carcinoma tumorigenesis. *Under resubmission.*

Patent Status: HHS Reference No. E–254–2010/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

Licensing Contact: Whitney Hastings; 301–451–7337; *hastingw@mail.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Urologic Oncology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize UOK268 as human HLRCC primary cell line model to comparing previously established UOK262, which was from metastasis lympho node. UOK 268 is a unique cell model for studying the underlying molecular derangements associated with impaired oxidative phosphorylation in cancer and for evaluating novel therapeutic approaches for this HLRCC-associated kidney cancer. Please contact John Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Agonistic Human Monoclonal Antibodies Against DR4

Description of Technology: The tumor necrosis factor (TNF)-related apoptosis-inducing ligand (TRAIL) and its functional receptors, DR4 and DR5, have been recognized as promising targets for cancer treatment. Therapeutics targeting TRAIL and its receptors are not only effective in killing many types of tumors but they also synergize with traditional therapies, and show efficacy against tumors that are otherwise resistant to conventional treatments.

The researchers at the NIH have developed two human monoclonal antibodies (mAbs) that bind to death receptor 4 (“DR4”). One of the mAbs is agonistic and inhibits the growth of ST486 cells with IC50 of about 10nM. The two mAbs were selected from a human phage-displayed Fab library by panning against a recombinant DR4