approved under section 505 of the FD&C Act (21 U.S.C. 355). On March 23, 2010, the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148). The BPCI Act clarified the statutory authority under which certain protein products will be regulated by amending the definition of a ''biological product'' in section 351(i) of the PHS Act to include a ''protein (except any chemically synthesized polypeptide),'' and describing procedures for submission of a marketing application for certain biological products. The Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) further amended the definition of a ''biological product'' in section 351(i) of the PHS Act to remove the parenthetical exception for ''any chemically synthesized polypeptide'' from the statutory category of ''protein'' (see Division N, section 605, of the Further Consolidated Appropriations Act, 2020). Products containing pancreatin or pancrelipase fall within FDA's interpretation of the term ''protein'' in the statutory definition of a biological product (for additional information, see the final rule entitled ''Definition of the Term 'Biological Product' (85 FR 10057, February 21, 2020)

The BPCI Act requires that a marketing application for a ''biological product'' (that previously could have been submitted under section 505 of the FD&C Act) must be submitted under section 351 of the PHS Act; this requirement is subject to certain exceptions during a 10-year transition period ending on March 23, 2020 (see section 7002(e)(1) to (3) and (e)(5) of the BPCI Act). On March 23, 2020 (*i.e.,* the transition date), an approved application for a biological product under section 505 of the FD&C Act shall be deemed to be a license for the biological product under section 351 of the PHS Act (see section 7002(e)(4)(A) of the BPCI Act; see also section 7002(e)(4)(B) of the BPCI Act). After March 23, 2020, all sponsors seeking approval of a biological product (that previously could have been submitted under section 505 of the FD&C Act) will need to submit a BLA under the PHS Act (see section 7002(e) of the BPCI Act). (For additional information, see FDA's guidance for industry entitled ''Interpretation of the 'Deemed to be a License' Provision of the Biologics Price Competition and Innovation Act of 2009'' (December 2018), available at *https://www.fda.gov/media/119272/download*.)

FDA is withdrawing the guidance because a marketing application for a proposed PEP that contains the ingredients pancreatin or pancrelipase may not be submitted under section 505 of the FD&C Act after March 23, 2020. The guidance included a description of data and information that may support submission of NDAs, including 505(b)(2) applications, for these products. FDA anticipates that there will be different considerations that may inform development of proposed PEPs intended for submission in BLAs under section 351 of the PHS Act. FDA intends to issue guidance regarding how the concepts described in the withdrawn guidance would apply to proposed pancreatic enzyme products submitted under the PHS Act, including the extent of integration of various types of data and information about the use of PEPs into BLAs. In the interim, the Agency encourages sponsors interested in submitting a BLA for a PEP to contact the relevant review division in the Office of New Drugs in FDA's Center for Drug Evaluation and Research with any questions.

Dated: March 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04531 Filed 3–4–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Establishment for the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA), HHS is hereby giving notice that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) has been established as a discretionary advisory committee. The effective date of the establishment is March 20, 2020.

FOR FURTHER INFORMATION CONTACT: Debi Sarkar, Designated Federal Official, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, 18W65, Rockville, Maryland 20857; 301–443–0959; or *DSarkar@hrsa.gov*.

SUPPLEMENTARY INFORMATION: The ACHDNC provides advice and recommendations to the Secretary of HHS on policy, program development, and other matters of significance concerning certain activities described in section 1111 of the Public Health Service (PHS) Act (42 U.S.C. 300b–10), as further described below. The ACHDNC will fulfill the functions previously undertaken by the former Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, which was established under the PHS Act, Title XI § 1111(a) (42 U.S.C. 300b-10(a)). The ACHDNC is also governed by the provisions of the FACA, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. The ACHDNC advises the Secretary of HHS about aspects of newborn and childhood screening and technical information for the development of policies and priorities that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling and health care services for newborns and children having, or at risk for, heritable disorders. The ACHDNC will review and report regularly on newborn and childhood screening practices, recommend improvements in the national newborn and childhood screening programs, as well as fulfill the list of requirements stated in the original authorizing legislation. The ACHDNC charter authorizes the committee to operate until March 20, 2022. A copy of the ACHDNC charter is available on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html*. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is *http://www.facadatabase.gov/*.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–04504 Filed 3–4–20; 8:45 am]

BILLING CODE 4165–15–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: Jeffrey Thruston at 301–594–5179 or *jeffrey.thruston@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:

A Rapid Ultrasensitive Assay for Detecting Prions Based on the Seeded Polymerization of Recombinant Normal Prion Protein (rPrP-sen) Description of Technology

Prion diseases are neurodegenerative diseases of great public concern as humans may either develop disease spontaneously or, more rarely, due to mutations in their prion protein gene or exposures to external sources of infection. Prion disease is caused by the accumulation in the nervous system of abnormal aggregates of prion protein. This technology enables rapid, economical, and ultrasensitive detection of disease-associated forms of prion protein. Specifically, prion aggregates (contained in a biological sample) seed the polymerization of recombinant, monomeric prion protein (rPrP-sen) and the polymerized product is detected as a highly amplified indicator of infectious prions in the sample. This assay differs from the protein-misfolding cyclic amplification assay (PMCA) because it enables the effective use of bacterially expressed rPrP-sen and does not require multiple amplification rounds. In its current embodiment, this assay can be used to detect prions in tissues or fluids from humans (Creutzfeldt-Jakob disease (CJD)), sheep (scrapie), cattle (bovine spongiform encephalopathy), and deer (chronic wasting disease (CWD)). For example, analyses of cerebrospinal fluid and/or nasal brushings from living sporadic CJD patients has allowed for nearly 100% accurate diagnosis.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications:

- A test/screen for infectious prions in live animals and food products
- Cervid CWD monitoring
- A human diagnostic for early detection of prion diseases
- Medical equipment screening
- A monitor for effectiveness of treatments or disease progression
- A high through-put screen for inhibitors of prion replication

Competitive Advantages:

- Uses a consistent, concentrated source of normal prion protein (rPrP-sen)
- Prions are detectable to low levels after a single amplification round
- Demonstrated to be effective at detecting prions from different species
- May be applicable to blood products, nasal brushings, skin, eye components and other accessible biospecimens
- Economical and rapid

Development Stage:

- Research Use

Inventors: Ryuichiro Atarashi (NIAID), Roger Moore (NIAID), Byron Caughey (NIAID).

Publications: Atarashi, Ryuichiro et al. ''Simplified ultrasensitive prion detection by recombinant PrP conversion with shaking.'' *Nature Methods* 5, pages 211–212 (2008).

Licensing Contact: To license this technology, please contact Jeffrey Thruston at 301–594–5179 or *jeffrey.thruston@nih.gov,* and reference E–109–2007–0.

Dated: February 25, 2020.

Wade W. Green,

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

[FR Doc. 2020–04536 Filed 3–4–20; 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.

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: Jeffrey Thruston at 301–594–5179 or *jeffrey.thruston@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:

Tau RT-QuIC: Ultrasensitive Assays for the Detection of Tau Seeding Activity Associated With Tauopathies

Description of Technology:

Tauopathies are a category of neurodegenerative diseases defined by the abnormal accumulation of misfolded tau protein aggregates (often in the form of amyloid filaments) within the brain. Tau proteins exist in six isoforms, three of which contain three microtubule binding regions (3R), and the remainder contain four microtubule binding regions (4R). Tauopathies are characterized, in part, based on the ratio of 3R/4R misfolded tau proteins that make up the aggregates. This technology enables rapid, ultrasensitive and economical differentiation of self-propagating tau aggregates associated with tauopathies in crude biospecimens. The assays use recombinant, truncated 3R, 4R, or 3R+4R tau protein substrates as indicators of tau aggregates. Specifically, misfolded tau aggregates (contained in a biological sample) seed the polymerization of either 3R, 4R, or 3R+4R tau substrates, and the polymers (amyloid fibrils) are detected as an amplified indicator of even extremely low concentrations of tau aggregates within the biological sample and aid in identification of the tauopathy. In its current embodiment, this assay has been used to detect tau seeds in brain tissue from patients with Alzheimer's disease, Pick disease, chronic traumatic encephalopathy, corticobasal degeneration, progressive supranuclear palsy, certain frontotemporal dementias, and other tauopathies. For several of these diseases, tau RT-QuIC assays have also detected tau seeding activity in patients' cerebrospinal fluid.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications:

- Diagnosis of tauopathies, including: Alzheimer's disease, Pick disease,