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