to the transition provision. FDA's evaluation of each of these approved NDAs for drug-biologic combination products or complex mixtures was informed by a general consideration of the factors used to determine the appropriate marketing application type for antibody-drug conjugates (see FDA's guidance for industry entitled ''Questions and Answers on Biosimilar Development and the BPCI Act'' (December 2018), available on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*).

To ensure that the Agency considers any additional comments on the list before the statutory transition date, the January 2020 update to the Preliminary List recommended that application holders or other interested persons submit either electronic or written comments no later than February 19, 2020.

This guidance finalizes the draft guidance entitled ''The 'Deemed to be a License' Provision of the BPCI Act: Questions and Answers'' issued on December 12, 2018 (83 FR 63894). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: (1) Providing information on updating the listing information for the biological product in FDA's electronic Drug Registration and Listing System between March 23, 2020, and June 30, 2020; (2) clarifying that, in the absence of other changes made by the application holder that would require a new National Drug Code (NDC) number, biological products approved under the FD&C Act will retain their current NDC number after the NDA is deemed to be a BLA; (3) providing information on establishment standards for ''non-specified biological products'' that are the subject of deemed BLAs; (4) clarifying the process for submitting followup reports on or after March 23, 2020, for any initial field alert report submitted before March 23, 2020; and (5) clarifying certain aspects of FDA's compliance policy for the labeling of biological products that are the subject of deemed BLAs. In addition, technical changes were made for consistency with the revisions to the PHS Act and the BPCI Act enacted in sections 605 and 607 of the Further Consolidated Appropriations Act, 2020, and editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''The 'Deemed To Be a License' Provision of the BPCI Act: Questions and Answers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 have been approved under 0910–0001; the collections of information in 21 CFR parts 601 and 610 have been approved under 0910–0338; the collections of information in 21 CFR 600.80 through 600.90 have been approved under 0910–0308; and the collections of information in 21 CFR 201.56, 201.57, and 201.80 have been approved under 0910–0572. In addition, the collections of information for applications submitted under section 351(k) of the PHS Act have been approved under 0910–0719.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov*.

Dated: March 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–04537 Filed 3–4–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2003–D–0370]

Guidance for Industry: Exocrine Pancreatic Insufficiency Drug Products—Submitting New Drug Applications; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of a guidance for industry entitled ''Exocrine Pancreatic Insufficiency Drug Products—Submitting NDAs,'' which was issued in 2006. The guidance set forth the Agency's thinking on data and information that may support a new drug application (NDA) for a proposed pancreatic enzyme product (PEP) that contains pancreatin or pancrelipase and is intended for the treatment of exocrine pancreatic insufficiency (EPI). FDA is withdrawing the guidance because an NDA for such a product may not be submitted after March 23, 2020. Sponsors interested in submitting a biologics license application (BLA) for a proposed PEP should contact the Agency with any questions.

DATES: The withdrawal is effective March 23, 2020.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6262, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: FDA is withdrawing the guidance for industry entitled ''Exocrine Pancreatic Insufficiency Drug Products—Submitting NDAs,'' which was issued in 2006 (see 71 FR 19524 (April 14, 2006)). The guidance described FDA's thinking regarding the data and information that may support submission of NDAs, including submission of NDAs pursuant to section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (FD&C Act) (21 U.S.C. 355(b)(2)), for products that contain the ingredients pancreatin or pancrelipase and are used to treat EPI.

Pancreatic enzyme preparations of porcine or bovine origin that contain the ingredients pancreatin or pancrelipase have a long history of use for the treatment of EPI in children and adults with cystic fibrosis and chronic pancreatitis. These products have been available in the United States for decades, largely marketed as unapproved drugs. On April 28, 2004 (69 FR 23410), however, FDA announced that all orally administered PEPs are new drugs that must be approved via a marketing application for prescription use only, and explained the conditions for continued marketing of these drug products. The guidance explained FDA's thinking regarding ways in which sponsors of products containing pancreatin and pancrelipase could design drug development programs to demonstrate the safety and effectiveness of their products and satisfy the requirements for approval of an NDA, including an NDA submitted pursuant to section 505(b)(2) of the FD&C Act.

Although most therapeutic biological products have been licensed under section 351 of the Public Health Service Act (PHS) (42 U.S.C. 262), some protein products historically have been

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