U.S. FOOD & DRUG ADMINISTRATION

Accelerated Approval Council Activities Report CY 2023

(Required by Section 3210 of FDORA)

Background

The Food and Drug Omnibus Reform Act (FDORA) (Sec. 3210) amended Section 506(c) of the FD&C Act (21 U.S.C. 356(c)). The revisions provided the Food and Drug Administration (FDA) with new authorities, such as the authority to require, as appropriate, that a study or studies be underway prior to approval, or within a specified time period after the approval, of the applicable product. The revisions also specified the creation of a coordinating council within the FDA to ensure the consistent and appropriate use of accelerated approval across the FDA. In addition, Section 3210 requires that FDA publish a report on FDA's website on the activities of the Council within a year of the passage of FDORA. This report is intended to cover activities of the council during the 2023 calendar year.

Activities of the Accelerated Approval Council

As required by FDORA, FDA has established an accelerated approval council, the Accelerated Approval Coordinating Council (AACC). The membership of the AACC includes the Directors (or designees) of the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER) and the Oncology Center of Excellence. The Chair of the AACC will rotate between the three Center Directors (or their designees). Peter Marks, M.D., Ph.D., the Center Director for CBER is serving as the inaugural chair. An executive secretary was also chosen to assist with managing the AACC.

Other standing member of the AACC include Directors (or their designees) of the Office of New Drugs in CDER, the Office of Orphan Products Development, the Office of Therapeutic Products in CBER, the Office of Medical Policy in CDER, the Office of Neuroscience in CDER, the Office of Vaccines Research and Review in CBER, and the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine. In addition to these standing members ad hoc participants have been invited as needed as determined by the AACC Chair.

The AACC has held two meetings during the 2023 calendar year. Those meetings included discussion of policy issues related to the new accelerated approval authorities contained in FDORA to support the development and dissemination of policy to help ensure that accelerated approval is used consistently and appropriately across the FDA. After the AACC meetings, staff in FDA working on accelerated approval policy development documents were informed of the direction that the AACC recommended regarding the policy issues that were discussed.