



Accelerated Approval Council Activities Report CY 2025

(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)), providing the Food and Drug Administration (FDA) with new authorities related to accelerated approval, and requiring 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 and annually thereafter. This report is intended to cover activities of the council during the 2025 calendar year.

Activities of the Accelerated Approval Council

As required by FDORA, in 2023 FDA established an accelerated approval council, the Accelerated Approval Coordinating Council (AACC or the Council). 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 (OCE). The Chair of the AACC for calendar year 2025 was Peter Marks, M.D., Ph.D. (CBER), followed by Richard Pazdur, M.D. (OCE).

Other standing members 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 CDER. In addition to these standing members, ad hoc participants have been invited as needed as determined by the AACC Chair.

The AACC held three meetings during the 2025 calendar year. These meetings included discussion of the different Centers priorities for the year related to accelerated approval, updates on recent trends in accelerated approvals, and updates on guidance related to accelerated approval in development or going through clearance.

The Council also discussed the Rare Disease Innovation Hub and its progress since its initiation as well as the Hub's first RISE Workshop. An overview of Project Confirm, an OCE initiative to promote the transparency of outcomes related to accelerated approval for oncology indication, was presented to the Council Members.

The Council received an update on the submission and review of the progress reports on post-marketing confirmatory studies that sponsors of drugs approved pursuant to accelerated approval are required to submit to FDA approximately every 180 days. The use of overall survival as an endpoint to support accelerated approval was also discussed with the Council members, noting the regulatory and legislative requirements do not provide for the use of overall survival as an endpoint to support accelerated approval. The role of advisory committees in the expedited withdrawal procedures for accelerated approvals and best practices related to this were discussed.



At every meeting, recent accelerated approvals were discussed. As of 12/04/2025, there have been 14 new accelerated approvals between CDER (4), CBER (2) and OCE (8).