Use-Related Risk Analysis (URRA) and Human Factor (HF) Protocol Review
FDA and Industry continued discussions about a proposal to enhance the review of HF protocols and URRA submissions by Sponsors, especially during combination product development programs. FDA provided additional details about proposed modifications to current PDUFA timelines associated with HF protocol review, including the potential impact on resources. In addition, FDA provided further details about resources potentially needed to implement PDUFA goals related to URRA review timelines, which are not currently supported by the user fee program.

Medical Product Information
FDA and Industry continued discussions about a proposal to enhance the accessibility of FDA-approved medical product information for patients and healthcare providers. Industry provided additional details about proposed public stakeholder engagement events intended to advance the electronic accessibility of medical product information. Industry also expressed interest in
potentially achieving harmonization with international standards related to electronic labeling. FDA noted that discussions of international harmonization were better suited for other venues outside of PDUFA negotiations, such as the International Council for Harmonisation.

**Bioinformatics Review Expertise**
FDA and Industry continued discussions about a proposal to enhance CBER and CDER’s expertise in various aspects of bioinformatics to support the Agency’s ability to provide detailed and consistently timed feedback to Industry earlier in the development cycle. FDA provided additional details about resource needs associated with bioinformatics review programs in CBER. Industry asked clarifying questions about potential resources required to expand bioinformatics expertise in CBER and CDER, including alignment with other planned or proposed initiatives to advance the information technology infrastructure across the Agency.

**FDA/Sponsor Interactions (Meeting Management)**
FDA and Industry continued discussions about proposals for enhanced interactions between FDA and Sponsors for certain types of product development programs, focusing on a specific proposal related to establishing communication best practices for stakeholders on both sides. Industry asked clarifying questions about FDA’s current and planned internal initiatives to promote the effectiveness and consistency of such interactions across all review divisions within CDER and CBER. Both sides discussed options for updating existing guidances and practices to address the challenges noted.

**Innovative Review Approaches**
FDA and Industry continued discussions about a proposal to enhance the efficiency of efficacy supplement review in order to expedite patient access to treatments that may demonstrate a substantial improvement over currently available therapies. FDA asked clarifying questions about Industry’s proposed framework for expanding the scope and utilization of innovative review approaches to additional product types and review disciplines.

There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.