PUBLICATION

Recent FDA Plan to Improve Marketplace for Biosimilars

August 10, 2018

The Biologics Price and Competition and Innovation Act (BPCI Act) established an abbreviated pathway for biologics, called biosimilars, in 2010. The FDA has committed to encourage the development of biosimilars in a "Biosimilars Action Plan (BAP): Balancing Innovation and Competition," dated July 2018. These BAP key elements are (1) improving the efficiency of the biosimilar and interchangeable product development and approval process; (2) maximizing scientific and regulatory clarity for the biosimilar product development community; (3) developing effective communications to improve understanding of biosimilars among patients, clinicians and payors; and (4) supporting market competition by reducing gaming of FDA requirements or other attempt to unfairly delay competition.

One of the ways the FDA is improving the efficiency of the biosimilar and interchangeable product development and approval process is transitioning these activities to the newly formed Office of Therapeutic Biologics and Biosimilars (OTBB) which will be dedicated to this type of review. This office has created the Biosimilar Product Development (BPD) Program. Through enrollment in this program, the FDA provides detailed, product-specific advice to manufacturers.

The FDA is committed to maximizing scientific and regulatory clarity for the biosimilar community by holding public meetings and hearings to seek additional input on possible alternative paths and to publish several guidance documents to assist biosimilar applicants. The FDA has published policies and recommendation in a number of guidance documents found here. These guidances are designed to assist biosimilar sponsors in developing high quality biosimilar and interchangeable products.

More webinars, videos and educational material will be conducted and disseminated by the FDA to assist health care professionals and other stakeholders to increase the understanding on the proper use of biosimilars and the interchangeability of medications as outlined in the Biosimilar User Fee Act (BsUFA)program.

The FDA will continue to evaluate whether firms are using FDA statutory or regulatory requirements to inappropriately delay approval of biosimilar or interchangeable competitors as the reference biologic has 12 years of market exclusivity. More clarification is needed in this area. The help of legal counsel can assist to navigate this evolving area of law to introduce these therapies going forward and help maximize market penetration.

If you have any questions about the Biosimilars Action Plan (BAP) or the BPCI Act, please contact any member of Baker Donelson's FDA Group.