FDA Releases Draft Guidance on the Approval of Biosimilars

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The United States Food and Drug Administration (FDA) released Draft Guidance on February 9, 2012 for obtaining approval of subsequent-entry versions of biologic drugs (also known as biosimilars). Biologics are substances derived from living organisms such as antibodies, blood products, nucleic acids, and enzymes. Biologics are often much larger and more complex than conventional chemically-synthesized small molecule pharmaceuticals. This makes the comparison of biosimilars to their approved counterparts difficult. Comparative clinical trials are often required. This is a much higher standard than for conventional generic pharmaceuticals which are approved upon showing bioequivalence (no clinical trials).

A new approval pathway for biosimilars in the U.S. was introduced in March 2010 in the *Biologics Price Competition and Innovation Act of 2009 (BPCI Act)*. This is the first detailed FDA interpretation of the BCPI Act. The Draft Guidance is presented as a series of Questions and Answers and includes information on the evidence required to demonstrate biosimilarity or interchangeability with an approved reference product as well as technical details on the approval process.

A 60-day comment period on the Draft Guidance is now open until April 9, 2012. The Draft Guidance will provide valuable information to drug manufacturers interested in developing biosimilar versions of FDA-approved biologics.

The Draft Guidance is available online.