REGULATORY ROUNDUP

FDA Releases Long-Awaited Guidances on Biosimilars

CAROL H. DANIELSON *MS, DrPH, RAC has provided regulatory expertise and leadership for more than 25 years for drugs, biologics and Medical devices from discovery through post-marketing. She is the President of Regulatory Advantage in Tucson, AZ and can be reached at regadvantage@att.net or (520) 907-5193.*

On February 9, 2012 FDA released the first 3 in an anticipated series of long-awaited guidances for the development of biosimilars in the United States. These guidances are intended to help define the pathway for approval of biosimilars under an abbreviated licensure pathway allowed under section 351(k) of the Public Health Service Act (PHS Act) as established under the Biologics Competition and Innovation Act of 2009 (BPCI ACT).

The 3 guidance documents now released for comment include: 1) Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009; 2) Scientific Considerations in Demonstrating Biosimilarity for a Reference Product; and 3) Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product.

For a product to be a biosimilar it must be shown to be "highly similar" to an approved reference product and must be interchangeable in clinical practice. Key approaches emphasized in the guidances include a "risk-based totality of the evidence approach" and a "step-wise approach" in developing evidence to support biosimilarity. Sponsors and applicants are encouraged to seek FDA advice early and at important decisions points in the development process. FDA stated that a Federal Register Notice will be issued shortly with a separate docket for submitting comments. ●