FDA Moving Forward On Biosimilars: Setting User Fees

By Jonathan Loeb on May 10, 2011

On May 10, 2011, the FDA published a Request for Comments on its proposal for setting user fees for 351(k) biosimilar applications: "Biologics Price Competition and Innovation Act of 2009; Options for a User Fee Program for Biosimilar and Interchangeable Biological Product Applications for Fiscal Years 2013 Through 2017; Request for Comments."

Among the general principals stated for the proposal, the FDA expressed the desire to keep the 351(k) biosimilar user fees comparable to 351(a) user fees. See Kurt Karst's 5/9/11 Post on the FDA Law Blog for a more detailed synopsis. Of course the industry is still eagerly awaiting the FDA's guidance on establishing biosimilarity.