

of the PHS Act and has published a draft guidance addressing certain exclusivity issues (see FDA's draft guidance for industry on *Reference Product Exclusivity for Biological Products Filed under Section 351(a) of the PHS Act*, available at <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm407844.pdf>). An applicant may include in its BLA submission a request for reference product exclusivity under section 351(k)(7) of the PHS Act, and the FDA will consider the applicant's assertions regarding the eligibility of its proposed product for exclusivity. The draft guidance describes the types of information that reference product sponsors should provide to facilitate FDA's determination of the date of the first licensure for their products.

*Q. III.2:* How can a prospective biosimilar applicant determine whether there is unexpired orphan exclusivity for an indication for which the reference product is licensed?

*A. III.2:* A searchable database for Orphan Designated and/or Approved Products and indications is available on FDA's Web site and is updated on a monthly basis (see <http://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm>). The FDA will not approve a subsequent application for the "same drug" for the same indication during the seven-year period of orphan exclusivity, except as otherwise provided in the FD&C Act and 21 CFR part 316.

### **3.13 FDA's explicit views on development of biosimilars**

While there is a longer history of approvals of biosimilar products in Europe and certainly in the developing countries, the FDA has taken a more calculated, more conservative view. Surprisingly, the first biosimilar-like products were approved by the FDA long before EMA began a formal biosimilar product program, but this was done under the statutory authority that the FDA enjoys. Now the challenges that the FDA faces are more regulatory. A keen understanding of the thinking of the FDA will greatly contribute to the biosimilar product developers because the United States still represents about 50% of the world market and still securing the FDA approval is the standard that most biosimilar product companies would like to earn.

Recently, Dr. Steven Kozlowski, director of Biotechnology Products in the Center for Drug Evaluation and Research at the FDA, testified before a congressional committee and shared the thinking of the FDA regarding the development of biosimilar products. This testimony that focused on therapeutic proteins reveals many interesting and subtle directions in