In U.S., Biosimilars Still Await FDA Decision

Officials at the U.S. Food and Drug Administration have yet to announce if and when they plan to begin accepting abbreviated applications for follow-on biologics (referred to as “biosimilar” drugs in Europe), but experts said they do not expect anything from the agency soon.

Generic biologic agents can still be approved through a new-drug application (NDA), but the burden of proof that comes with an NDA undermines some of the cost savings of generic products.

“What do you do all your own research ... or can FDA look at the file from another company’s application? That is the question that is hotly debated,” said Meredith Manning, J.D., a partner with Hogan & Hartson in Washington, D.C.

Even innovator companies are stuck with the current system. When Genentech, South San Francisco, Calif., developed a new version of their flagship biologic agent, Procrit (epoetin), they submitted an NDA rather than the abbreviated application often used for refinements.

The generic industry has urged FDA to move forward with developing a non-NDA mechanism for generic biologics, arguing that the science to demonstrate equivalency to existing agents is already available.

“Generic [biologics] will become a reality, it is just a matter of how and when,” said Andrea Hofelich, director of media relations for the Generic Pharmaceutical Association.

Past statements from FDA officials suggest that they would agree with that assessment. In fact, agency officials had said that they would propose rules for certain biologics, including human growth hormone and insulin, by the end of last year.

That did not happen despite both increasing pressure from members of Congress and a lawsuit brought by Sandoz Pharmaceuticals. The company is still waiting for the FDA to act on an application for approval of its growth hormone Omnitrope that they submitted in July 2003. The company’s application relied on data produced for the innovator product, Pfizer’s Genotropin.

The FDA seems to have stepped back under increasing pressure from industry. However, the agency has continued to hold forums in which experts are helping to build the science needed to better assess the properties of biologics.

While that has helped define what is needed to show equivalency, it has also made it clear that the agency will need to judge generic agents on a case-by-case basis, said Shari Dermer, Ph.D., a former biotech scientist and organizer of a December follow-on biologics workshop cosponsored by the FDA and the New York Academy of Sciences.

But before that can happen, Congress will need to create the legal authority the FDA needs to base the approval of generic proteins on data collected during testing of branded products, she said.

Generic versions of more simple molecules, such as human growth hormone, may require relatively little additional proof to meet FDA’s needs compared with some more complex biologics, but the standards for abbreviated approval of biologics in general are likely to be more stringent than what the agency requires for standard, more easily defined drugs, she said.

“Omnitrope is going to be a bellwether of what might happen in the U.S.,” said Dermer.

—Joel B. Finkelstein