

# What Statutes and Regulations Govern the Approval and Marketing of Biosimilars?

## **approval and marketing of biosimilars**

Congress passed the Biologics Price Competition and Innovation Act of 2009 (BPCIA) in 2010 an amendment of the Public Health Services Act. The BPCIA is codified at 42 U.S.C. § 262.

### **WHAT IS CONSUMER FRAUD?**