The FDA Patient Protection and Affordable Care Act (Affordable Care Act) of March 23, 2010, amends the Public Health Service Act or PHS Act to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product [15]. This pathway is provided in the part of the law known as the Biologics Price Competition and Innovation Act. Under the Biologics Price Competition and Innovation Act, a biological product may be demonstrated to be "biosimilar" if data show that, among other things, the product is "highly similar" to an already approved biological product. FDA biosimilars are products that "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product" (http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM292463.pdf).

The FDA is using a stepwise approach to demonstrate biosimilarity that can include a comparison of the proposed product and the reference product with respect to structure, function, animal toxicity, human pharmacokinetics and pharmacodynamics, clinical immunogenicity, and clinical safety and effectiveness. As such, the FDA will consider the totality of the evidence to review applications for biosimilar products. Although biosimilar drug products are currently being developed and a few have been approved, this book only focuses on the development of therapeutic equivalent, generic drug products containing well-characterized, smaller molecules.

SUMMARY

The market for generic drug products continues to increase with the expiration of patents and exclusivities for major brand name drug products and to the demand by consumers and governments for less expensive generic alternatives. From a scientific perspective, generic drug product manufacturers must formulate a drug product that will have the same quality, therapeutic efficacy, safety, and performance as its brand name counterpart. Formulation development of an innovator drug product has minimal constraints with respect to choice of excipients, manufacturing methods, and performance characteristics. In contrast, generic drug manufacturers must demonstrate that their formulation is a pharmaceutical equivalent, is bioequivalent, and has the same quality and performance characteristics as the brand name counterpart. Moreover, the generic drug manufacturer will continue to face a variety of legal, regulatory, and patent challenges from the brand name pharmaceutical industry that may delay the entry of the generic drug in the marketplace. The availability of generic drug products will, nevertheless, continue to play an important role, both nationally and internationally, by providing cost-effective medicines to the wider public, which will bring great benefits to consumers as well as to health authorities in nations around the world in their quest to make medicines more available and affordable. The quest for biotechnology-derived drugs and the manufacture of biosimilar drug products will also expand. However, biotechnology-derived drugs and biosimilar drug products will not be discussed fully in this book.