Therapeutic Equivalence

In the United States, a therapeutically equivalent drug product must meet certain FDA criteria [3,4], which are as follows:

- Approved as safe and effective
- Pharmaceutical equivalent
  - Contain identical amounts of the same active drug ingredient in the same dosage form and route of administration
  - Meet compendial or other applicable standards of strength, quality, purity, and identity
- Bioequivalent
  - Do not present a known or potential bioequivalence problem
  - Meet an acceptable in vitro standard, or if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard
- Adequately labeled
- Manufactured in compliance with current good manufacturing practice regulations

Economic Savings

Generic drug products are typically sold at substantial discounts from their brand name counterparts. The Generic Pharmaceutical Association (GPhA) recently released an independently conducted analysis showing that the savings to consumers and the U.S. health care system from the use of generic prescription drugs rose to a current rate of $1 billion every other day, totaling $193 billion in 2011 and $1.07 trillion over the last 10 years (2002–2011) [5]. The report also revealed that savings from the use of generic drug products in 2011 increased 22% over the prior year, marking the largest year-over-year increase since 1998, and 10% higher than the 10-year average.

Savings from newer generic medicines that have entered the market since 2002 continue to increase exponentially, totaling $481 billion over the past 10 years. In 2011, approximately 80% of the 4 billion prescriptions written in the United States were dispensed using generic medicines, while accounting for only 27% of the total drug spending. The study also predicts that future savings to be achieved through generic prescription medicines will climb at an ever-increasing annual rate. Consumers chose the generic alternative 94% of the time in 2011 and this is a clear indication of the quality, safety, and efficacy of the FDA-approved generic products.

THERAPEUTIC EQUIVALENCE, DRUG PRODUCT QUALITY, AND DRUG PRODUCT PERFORMANCE

Drug product performance, in vivo, may be defined as the release of the drug substance from the drug product leading to bioavailability of the drug substance [6]. Bioavailability is defined as the rate and extent to which the active ingredient or