An FDA-approved generic drug product is considered a therapeutic equivalent to the innovator or brand name drug product in terms of quality and performance characteristics and is expected to have the same safety and efficacy. An ANDA checklist for completeness and acceptability of an application is available on the FDA website (http://www.fda.gov/cder/ogd/anda_checklist.doc).

Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)

The FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) lists all approved products, both innovator and generic, approved based on safety and effectiveness by the FDA [3]. The Orange Book is available on the Internet (http://www.fda.gov/cder/ob/default.htm) and is updated monthly. The list contains therapeutic equivalence evaluations for approved multisource prescription drug products. Therapeutic equivalence or inequivalence for prescription products is determined based on the therapeutic equivalence codes provided within that specific dosage form (Table 1.3). The coding system for therapeutic equivalence evaluations is constructed to allow users to determine quickly whether the FDA has

TABLE 1.3
Therapeutic Equivalence Evaluations Codes (Orange Book)

A	Drug products that are considered to be therapeutically equivalent to other pharmaceutically equivalent products. "A" products are those for which actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence
AA	Drug products in conventional dosage forms not presenting bioequivalence problems
AB	Drug products meeting necessary bioequivalence requirements
AN	Solutions and powders for aerosolization
AO	Injectable oil solutions
AP	Injectable aqueous solutions and, in certain cases, intravenous nonaqueous solutions
AT	Topical products
B	Drug products that the FDA, at this time, considers not to be therapeutically equivalent to other pharmaceutically equivalent products
B*	Drug products requiring further FDA investigation and review to determine therapeutic equivalence
BC	Extended-release dosage forms (capsules, injectables, and tablets)
BD	Active ingredients and dosage forms with documented bioequivalence problems
BE	Delayed-release oral dosage forms
BN	Products in aerosol-nebulizer drug delivery systems
BP	Active ingredients and dosage forms with potential bioequivalence problems
BR	Suppositories or enemas that deliver drugs for systemic absorption
BS	Products associated with drug standard deficiencies
BT	Topical drug products with bioequivalence issues
BX	Drug products for which the data are insufficient to determine therapeutic equivalence