process, manufacturers of brand name products submitted data as a supplement to the existing NDAs, confirming the safety and effectiveness of their products. During the implementation of the DESI review program, more than 3400 products and related generics were reviewed and approximately 900 drug products were removed from the market. Many other products were reformulated or relabeled to limit their uses to selected indications only. One effect of the DESI study was the development of the abbreviated new drug application (ANDA) in 1970 for reviewed marketed products that required changes in existing labeling to be in compliance. However, manufacturers of any new drug product (brand name or generic) marketed after 1962 were required to prove both the safety and the efficacy of such products. The 1962 legislation provided an exemption from the NDA approval process for drugs that had been marketed before 1938, based on the assumption that they were generally recognized as safe and effective—the so-called "grandfather" provision. Manufacturers continued to conduct clinical efficacy and safety studies until 1978, when a dispensation was granted to manufacturers whereby the citation of published reports of trials documenting safety and efficacy would suffice.

In 1984, the Drug Price Competition and Patent Term Restoration Act (Hatch–Waxman Act) extended the ANDA process to generic versions of drugs marketed after 1962 (Table 1.2). This Act eliminated the requirement that generic drug manufacturers duplicate expensive, time-consuming clinical and nonclinical studies to demonstrate safety and efficacy. Furthermore, this Act expedites the availability of generic drug products provided that the generic drug manufacturer shows that no patent infringement would occur. The Hatch–Waxman Act also compensated the innovator drug manufacturer for perceived losses due to competition from the generic drug products by extending the patent terms of some brand name drug products for up to an additional 5 years to make up for time lost while their products were going through the FDA's approval process.

The Drug Price Competition and Patent Term Restoration Act was subsequently amended to make provision for a pharmaceutical manufacturer (sponsor) to seek approval from the FDA to market a generic drug product before the expiration of a patent relating to the brand name drug upon which the generic is based. This amendment, known as the "Bolar amendment," allowed the ANDA approval process to begin before the patent on the brand name drug expired. As part of the ANDA submission, the sponsor must consider the pertinent patents and provide a "certification" that, in the opinion of the sponsor and to the best of the sponsor's knowledge

TABLE 1.2
Drug Price Competition and Term Restoration Act of 1984 (Hatch–Waxman Act)

Created a framework for patent term extensions and nonpatent exclusivity periods for brand name drug products
Established for the first time an ANDA approval process specifically for generic manufacturers
Provided for pre-patent expiration testing (Bolar provision) and generic drug product exclusivity