

On the generic side, there is an ongoing battle to obtain the coveted 180-day exclusivity granted by FDA to the first-to-file company of a generic drug product. Also, because of increasing competition among generic manufacturers for market share, monopolistic tendencies have been developing through mergers and locking-in raw material sources through acquisitions or special contracts. A generic company awarded marketing exclusivity by the FDA for a product can market this drug without competition from the other generic companies for 6 months after its patent expiration. As a result, other generic companies cannot recover their development, stability testing, and other costs during this period. These factors are also conducive to increasing the price of generic drugs.

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