marketed products, the cost of ongoing stability studies is independent of the number of batches produced in a given year. If only one batch is produced in a given year, that batch still must go on annual stability. If 100 batches are produced for a certain product, only one batch needs to be set up for stability testing. Clearly, the cost of stability is proportionately greater for low volume products. There is no regulation requiring that the first lot produced in a particular year needs to be on stability. Because the stability workload can be substantial, it is important to spread the workload throughout the year to prevent overloading the first few months of a year with stability testing. This will also spread the cost of stability testing evenly throughout the year.

With the growth of the generic industry, the stability testing workload and thus its cost are destined to grow as well. Ultimately, the cost is borne by the consumers (i.e., patients). Creativity will be required to control the cost of stability. Usually, the stability protocol requires testing at 0, 3, 6, 9, 12, and 18 months and yearly thereafter until the expiry period. For stable products with a documented history of at least 5 years, the stability workload can be reduced significantly through deletion of the intermediate short-term test points of 3, 6, 9, and 18 months. For products with multiple strengths and package sizes, the stability protocol should be amended to reduce testing requirements via justifiable reduction of intermediate time points and appropriate bracketing and matrixing designs. Of course, the amended protocol needs to be submitted to the FDA as a PAS. Upon approval, the reduced time points can be immediately implemented, which will reduce the cost of stability testing and also bring down the price of generic drugs. To further control costs, the stability samples for a given product should be set up in a manner to allow batch processing for laboratory testing.

CONCLUSIONS

Patients depend on high quality and affordable generic drugs that are safe and efficacious. The generic drug industry must make every attempt to lower the cost of drugs without compromising their quality, safety, or efficacy. Raw material, research and development, production, quality control and stability testing, storage, and distribution costs all contribute to the cost of medicines. To control these costs on an ongoing basis, which include the significant costs of stability testing, and concomitantly maintain compliance, creativity will be required to keep up with the evolving regulatory requirements and guidances, competitive industrial practices, technological developments, and changing market demands.

It is common knowledge that brand companies, faced with an ever increasing prospect of many drugs losing their patent protection, have been resorting to court actions to gain one or more 30-month stays of FDA approvals for many generic drug products. Often, just before patent expirations, these companies have employed the tactic of filing pediatric clinical studies to gain an additional 6 months' patent extension, which has effectively blocked FDA approvals of generic equivalents during this period. Meanwhile, the generic industry continues to bear the cost of product development and ongoing stability testing during the exclusivity periods, which ultimately increases the cost of sale.