Table 10.6 Established Product

Protocol elements	Activities or results
Objectives	Confirmation of stability performance determined in preceding stages
Study design	Long-term studies
Tests	Significant quality attributes as determined in preceding stages
Storage conditions	Consistent with label storage conditions
Schedules	Based on relative stability of the product and the relative sensitivities of the various stability parameters
Samples	Representative of the product; lot selection rotated among the various marketed container–closure systems
Evaluation	Periodic evaluations to allow timely decision-making; evaluation by comparison of results with the established stability profile

VII. PRODUCT REVISION STAGE

The expiration dating periods of established products are assigned or revised based upon a great deal of experience and upon a mature data base. When products are revised, however, there are many instances in which the number of months of stability data are significantly fewer than the number of months of the proposed dating, an event that experience indicates would be entirely reasonable. If the programs previously discussed were conscientiously implemented, treating revised products as entirely new products requiring full, directly supportive data bases would be neither advisable nor necessary. Changes in products occur in several ways and for various reasons. In general, they may be categorized as formulation changes, such as the addition or deletion of excipients; processing changes; changes in the source of active ingredients; or changes in packaging material that comes into direct contact with the dosage form. When such changes are anticipated, a scientific judgment should be made concerning their probable effects on product stability. Such judgments would be based on a sound,