and will support packaging of the product in any *intermediate sizes* of the container–closure system.

V. NEW PRODUCT STAGE

At the time of NDA approval, development enters the new product stage during which the objectives shift from assessment of stability performance and establishment of the initial expiration-dating period to confirmation of the stability performance and expansion of the stability data base. The new product stage is a time of transition to the established product stage and usually lasts from 1 to 2 years. The studies initiated during the proposed product stage are continued and, in general, at least three marketed lots will be placed on stability. These lots are placed on long-term study at label storage conditions. Testing schedules should be selected according to the stability performance of the product.

As the data base for the product matures, the protocol will evolve such that the studies in this stage, although generally less intensive than those of the preceding stage, will be more intensive than those of the succeeding stage. When warranted, any revisions of the expiration dating period for the product are supported by a mature data base.

VI. ESTABLISHED PRODUCT STAGE

The last stage is the established product stage, which continues for as long as the firm manufactures and markets the product. During this stage, concern again shifts. At this point, a comprehensive data base is in place, and the objective becomes one of periodically reassessing the stability of the product.

Because much stability data has been generated on the product during the preceding stages, generally fewer data per product are required in any given time span during this continuation of the stability testing program.

In general, one lot per year should be placed on test. Lot selection should be designed to rotate among the various marketed container–closure systems. The protocol should include tests and assays for significant quality attributes, as established in previous stages. The study design is for full-term studies at label storage conditions. The schedules take into account the relative stability of the product as well as the relative sensitivities of the various stability parameters determined during the previous stages (Table 6).