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FOREWORD

The maintenance of product quality specifications during the entire shelf life of each lot of a product is now recognized as a necessity for a safe and effective pharmaceutical. How to assure this product charactersitic prior to distribution has proved to be no easy task. It should not be surprising that a simple procedure applicable to most dosage forms has not been devised. The complexity and variability of the materials and the methods of manufacture and packaging preclude simplicity. For the same reasons, it should not be too surprising that almost no two experts can agree on the best way to ascertain, prior to distribution, that a product will for sure meet the specifications during it's shelf life. One can say that we are all agreed on the goal we must achieve, but we are not agreed on the route to take.

In practice, a series of stability predicting protocols that best suit the product mix of a given company are selected during the product development phase, and a stability indicating protocol is used to evaluate the product during it's shelf life. The results of the latter either confirm the validity of the former or indicate the need to adjust it.

This issue contains the accumulated wisdom of many respected practitioners of the art of pharmaceutical dosage form stability, both pre-market prediction and post-market evaluation. It includes theoretical treatment of the subject, details of successful programs and experience gained by the United States Food and Drug Administration in reviewing many different programs. Reading the issue should be fruitful both to those setting yp new programs and to those wishing to compare their existing programs with these successful programs.

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