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General Considerations for Stability Testing of Topical Pharmaceutical Formulations

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I. INTRODUCTION

Stability testing is a necessary and vital means to help assure that a formulation will maintain its integrity (i.e., strength, quality, and purity) during its assigned shelf life. It would, however, be futile to attempt to propose a simple, universal stability-testing protocol, which could reasonably be expected to assure the integrity of every topical formulation of every pharmaceutical manufacturer, because there are necessary differences in specific stability protocols between different formulations of the same manufacturer and between similar formulations of different manufacturers.

Although a number of factors may influence the determination of an expiry date for a given product, this discussion will be confined to testing designed to determine the chemical and physical properties critical to the stability of the product, with the assumption that one, or a combination, of these is the limiting factor. Although much of the discussion may be applicable to the testing and dating of nonprescription products, it will be confined to prescription products that progress from investigational new drug (IND) status, through the new drug application (NDA) stage, and on to marketing.

The theme of this chapter is based on the premise that despite the differences in specific stability-testing protocols among products and manufacturers, there are activities that are common to any stability-testing program. The first set of stability-related activities in the development of a new active ingredient into a marketed product generally involves the *profiling* of its physical and chemical