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FRAGILE: HANDLE WITH CARE

Pharmaceutical scientists and others who are involved in drug research and drug product development are quite properly concerned with the many considerations that contribute to the safety and effectiveness of a pharmaceutical product.

After identifying the particular compound with the most favorable therapeutic index from among various possible homologs, analogs, congeners, salt forms, and the like, the next phase involves the complex process of studying and selecting ingredients and manufacturing processes that will result in the most effective dosage form for administering that drug entity to the patient.

Unfortunately, there has sometimes been a mistaken belief that once the elegant tablet, capsule, or other dosage form has been formulated in a pure, bioavailable, and uniformly potent form, the job was over. That is, there was little need for further concern as to the safety and effectiveness of the product.

It is now recognized, however, that the best of products—if not properly packaged to protect its integrity and quality—may undergo changes due to light, moisture, air, or volatilization, which very well might render the product unsafe or reduce its effectiveness, or both.

As in most situations, this problem has been the result of various factors including inadequate research, carelessness, faulty communications, and so on. But one of the major stumbling blocks has been lack of an objective test procedure to conduct the necessary measurements to determine the suitability of a particular container. And in the absence of a test procedure that permits quantitative measurements of reasonable accuracy and precision, it is obvious that no meaningful and enforceable standards or specifications could be developed relative to such container characteristics.

What was probably the first breakthrough in this field came about fifteen years ago with the development and adoption by the official compendia of a specific test procedure and a standard specification for the assessment of light protection afforded by glass containers, based upon spectrophotometric measurements. This procedure and standard subsequently were extended to cover plastic containers also.

But the problem of container "tightness" remained. A well-intentioned effort was made by the compendia to define a "well-closed container" and a "tight container," and to distinguish them from each other as well as from containers affording lesser protection; however, everyone recognized that this effort was more of a pious hope than a scientific standard.

Consequently, the more recent pioneering work of the National Formulary—along with the cooperative involvement of the United States Pharmacopeia and the Food and Drug Administration—has resulted in a very significant step forward. We refer, of course, to the new test procedure, and moisture permeability standards, that appear in the new editions of the compendia and concerning which FDA is currently in the process of establishing regulations to facilitate effective implementation.

In essence, this development serves to plug what has been a gaping hole in our overall system of providing high quality drug products to the patient. As a result, we soon shall be able to rest better assured that the drug product at the point of use by the patient is far more likely to be as safe and as effective as it was at the time of its original manufacture or preparation.