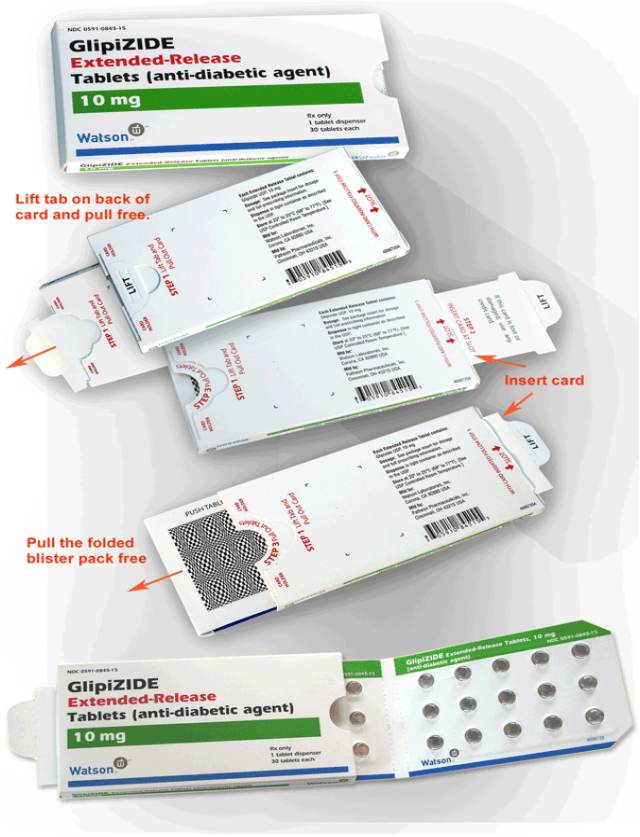
Pharmaceutically Speaking...

Compliance Package Testing



So what are the chances of passing the protocol on the first try, and then failing on the next try.

Of course, this would only be under consideration if a variable were to be changed in packaging or design, or if an inadvertent accidental ingestion occurred.

In the latter event, the Consumer Product Safety Commission would first ask to see documentation of the manufacturer's protocol report. Without documentation, the CPSC would immediately have a protocol administered. Most likely all warehoused product would be quarantined.

To address repeatability of protocol results, it depends on *degree* of success for the first one. If the package passed the "F" rating as required by the toxicity or harmful nature of the product at 86% or above there would be substantial risk that when tested again, failure might occur.

However, if the protocol passed at 98% for children where 85% is passing, the probability is high that results can be replicated. Simultaneously, at least 90% of senior adults must be able to access the product. If either the 85% criteria for children or 90% for adults is not met, the package fails to meet the standards of 16 CFR 1700.

The package should be promoted for the level it is capable of safely passing. When a vendor sponsors administration of a CR package, information gained can only be used for promotional purposes. It does not constitute formal CPSC certification to be commercially distributed.

Final blister package for protocol testing must be run on the commercial line to be used, with commercial materials and structure. Bottle closures can be manually applied to the torque specification. However, prior to senior testing, bottles should be opened and closed the same number of times that matches count per script.

It's the law!