Explanation of 1999 FDA Ruling on “Changes to an approved NDA or ANDA”

According to an October 1999 FDA ruling entitled “Changes to an Approved NDA or ANDA” (commonly known as PAC PAC), it is permissible for pharmaceutical manufacturers to switch suppliers of primary packaging materials without the need for full stability protocol testing. The FDA only requires that equivalency be proven that meets its requirements on interchangeability of packaging materials

Entitled Changes to an Approved NDA or ANDA, the FDA-issued guidelines (21 CFR 314.70 (d) (6)) require that the materials a company is switching to are:
1) already approved for drug product contact by the FDA;
2) have a current DMF on file with the FDA;
3) have been reviewed elsewhere for other similar dosage forms by the FDA; and
4) they provide a barrier that is as good as if not better than the current material upon which the stability test was conducted.

“If these criteria are met, the change is considered “Minor” and a pharmaceutical company can switch from their current supplier without conducting full stability testing protocols”