When an innovative drug product is going off patient, pharmaceutical companies may file an abbreviated new drug application (ANDA) for generic approval. In 1984, the United States Food and Drug Administration (FDA) was authorized to approve generic drug products under the Drug Price Competition and Patent Term Restoration Act. For approval of generic drug products, the FDA requires that evidence of average bioequivalence in drug absorption be provided through the conduct of bioequivalence studies. As indicated in 21CFR320.24, bioequivalence may be established by in vivo (e.g., pharmacokinetic, pharmacodynamic, or clinical) and in vitro studies or with suitable justification by in vitro studies alone. In this presentation, an overview of statistical considerations including study design, criteria, and statistical methods for assessment of bioequivalence will also be discussed. For in vivo bioequivalence testing, in addition to average bioequivalence, the concept of population bioequivalence and individual bioequivalence for addressing drug interchangeability will also be discussed. For in vitro bioequivalence testing, an overview regarding some in vitro tests such as dose or spray content uniformity through container’s life, droplet and drug particle size distribution, spray pattern, plume geometry, priming and repriming, and tail off profile that are commonly employed for local action drug products such as nasal aerosols and nasal sprays products will be provided. Recent development and future research topics will also be discussed.

Keywords: Crossover design; Bioequivalence limit; Drug absorption; Drug release.

sheinchung.chow@duke.edu