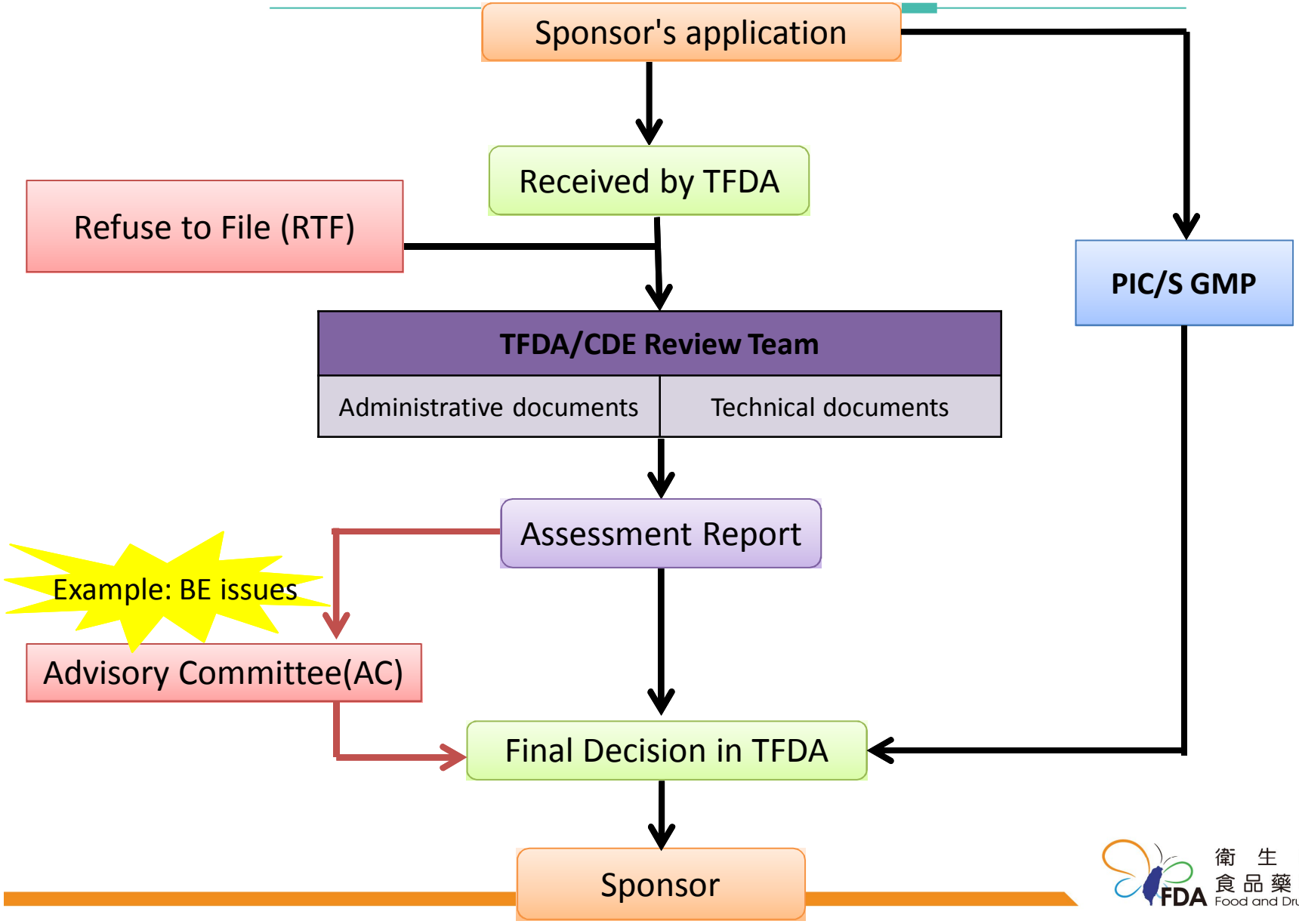
Dossier Requirement

Evaluation	NDA	ANDA	OTC Monograph Drug Application
Reference Drug	Not required	Required	Compiled with Monograph
Safety Efficacy	• Pharm/Tox • PK/PD/BA/BE • Clinical trials	Bioequivalence (BE) as a surrogate to clinical trial	Not required
Quality	• Chemistry, Manufacturing and Controls(CMC) • PIC/S GMP • GLP, GCP		
Labeling	Labeling (direction of use)		

Registration Procedures of Generic Drugs



衛生福利部
食品藥物管理署
FDA Food and Drug Administration