Key to the data in: CRLs-NonAppr-FDARelease-04Sept2025.xlsx

Name	Definition
Type	Type of regulatory submission; E.g., BLA, NDA
Number	Regulatory submission number
Date	Date stamp on letter
CompanyName	Company name as specified on the letterhead
Country	Country of addressee as stated on the letterhead
State	U.S. state of addressee as stated on the letterhead
Biopharm	Biopharmaceutical issue in approval; 0 = not an issue, 1= issue
ClinicalPharmacology	Clinical Pharmacology issue in approval; 0 = not an issue, 1= issue
Clinical	Clinical issue in approval; 0 = not an issue, 1= issue
Quality	Quality issue in approval; 0 = not an issue, 1= issue
HumanFactors	Human Factors issue in approval; 0 = not an issue, 1= issue
Statistics	Statistics issue in approval; 0 = not an issue, 1= issue
Nonclinical	Nonclinical issue in approval; 0 = not an issue, 1= issue
Device	Device issue in approval; 0 = not an issue, 1= issue
Facility	Facility issue in approval; 0 = not an issue, 1= issue
Regulatory	Regulatory issue in approval; 0 = not an issue, 1= issue
ControlledSubstance	Controlled Substance issue in approval; 0 = not an issue, 1= issue
AllReasons	All issues in approval mentioned in the letter
ClinPharmAsRecc	Clinical Pharmacology Recommendations provided in letter that are not approval issues; 0 = no, 1 = yes
Drug	Active ingredient
Descriptor	Additional details about drug
TherapeuticArea	Therapeutic area for drug
Condition	Disease treated by drug
Consultant	Submitted by a consultant? Yes or No
Headquarters	Company headquarters as determined by an independent online search
AdditionalClinicalDataRequested	Additional clinical data requested; 0 = No, 1= Yes
PagesInLetter	Number of pages in letter

Leslie Kenna