

Appendix 1

APLB - Advertising and Promotional Labeling Branch
BiMo - Bioresearch Monitoring Branch, Division of Inspection and Surveillance, Office of Compliance and Biologics Quality
BLA - biological license application
BLS - biological license application supplement
CBE - Changes Being Effectuated
CBE-30 - Changes Being Effectuated - 30 Days
CBER - Center for Biologics Evaluation and Research
CE - Categorical Exclusion
CESC - Center electronic submission coordinator
CMC - Chemistry Manufacturing and Control
CR - Complete Response
DB - Division of Biostatistics, Office of Biostatistics and Epidemiology
DBA - Division of Blood Applications, Office of Blood Research and Review
DCC - Document Control Center
DE - Division of Epidemiology, Office of Biostatistics and Epidemiology
DMPQ - Division of Manufacturing and Product Quality, Office of Compliance and Biologics Quality
DR - Discipline Review
EA - Environmental Assessment
EDR - Electronic Document Room
EIR - Establishment Inspection Report
ELA - establishment license application
ELS - establishment license application supplement
ESC - electronic submission coordinator
FONSI - Finding of No Significant Impact
IND - Investigational New Drug Application
IR - Information Request
LARM - Licensing Action Recommendation Memorandum
OBE - Office of Biostatistics and Epidemiology
OBRR - Office of Blood Research and Review
OCBQ - Office of Compliance and Biological Quality
OCTMA - Office of Communication, Training and Manufacturers Assistance
OITM - Office of Information Technology Management
ORA - Office of Regulatory Affairs
PIB - Program Inspection Branch, Division of Inspection and Surveillance, Office of Compliance and Biologics Quality
PLA - product license application
PLS - product license application supplement
PRB - Product Release Branch, Division of Manufacturing and Product Quality, Office of Compliance and Biologics Quality
RIMS - Regulatory Information Management Staff
RMS-BLA - Regulatory Management System - Biologics License Application
RPM - Regulatory Project Manager

SBA - Summary Basis for Approval
STN - Submission Tracking Number