Acronyms that may be used during FDLI's Introduction to Biological Products, Including Vaccines, Biosimilars, Cell and Gene Therapies, and Advanced Therapies Law and Regulation

356h	FDA Form: Application to Market a New Drug Biologic or an Antibiotic Drug for Human Use
505(b)(2)	(previously known as) "Paper" NDAs
510(k)	Premarket notification
2253	FDA Form: Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use
AADA	Abbreviated antibiotic drug application
ABLA	Abbreviated biological license application
ACE	Automated Commercial Environment (CBP)
ACIPs	Advisory Committee on Immunization Practices (CDC)
ACS	Automated commercial service
ACUS	Administrative Conference of the United States
ADCOMs	Advisory Committees
ADE	Adverse drug experience
ADME	Absorption distribution metabolism excretion/elimination
ADR	Adverse drug reaction
AE	Adverse event
AERS	Adverse Event Reporting System
AHRQ	Agency for Healthcare Research and Quality (DHHS)
AIP	Application integrity policy
ALJ	Administrative law judge
AMA	American Medical Association
AMP	Average manufacturer price
ANDA	Abbreviated new drug application
ANPR	Advance notice of proposed rulemaking
APA	Administrative Procedures Act
APHIS	Animal and Plant Health Inspection Service
API	Active pharmaceutical ingredient
APLB	Advertising and Promotional Labeling Branch (CBER)
ATLS	Analytical testing laboratory sites

AWP	Average wholesale price
BA/BE	Bioavailability/equivalent
BARDA	Biomedical Advanced Research and Development Authority
BATF	Bureau of Alcohol Tobacco Firearms and Explosives (U.S. Department of Treasury)
BIMO	Bioresearch Monitoring
BIO	Biotechnology Industry Association
BLA	Biologics license application
BMF	Biological Master File
BPCA	Better Pharmaceuticals for Children Act of 2002
BPCIA	Biologics Price Competition and Innovation Act of 2009
BPD	Biosimilar Product Development
BPDRs	Biological Product Deviation Reports
BSE	Bovine spongiform encephalopathy (mad cow disease)
BSL	Biological safety level
BTA	Public Health Security and Bioterrorism Preparedness and Response Act of 2002 also known as the Bioterrorism Act
BW/BT	Biowarfare/bioterrorism
CAFE	Court of Appeals for the Federal Circuit
CANDA	Computer assisted new drug application
CAPA	Corrective and preventive actions
CBA	Changes being affected
CBE	Changes being effected
CBER	Center for Biologics Evaluation and Research (FDA)
CBP	U.S. Customs and Border Protection (DHS)
CCI	Confidential commercial information
CDC	Centers for Disease Control and Prevention (DHHS)
CDER	Center for Drug Evaluation and Research (FDA)
CDRH	Center for Devices and Radiological Health (FDA)
CDR	Control document room
CE Mark	French for Conformite Europeene
CFR	Code of Federal Regulations
cGMPs	Current good manufacturing practices
CHPA	Consumer Healthcare Products Association
CIB	Clinical Investigator Brochure

CLIA	Clinical Laboratory Improvement Amendments
CMC	Chemical manufacturing and control
CME	Continuing Medical Education
CMO	Contract management organization
CMPs	Civil money penalties
CMS **CMS**	Centers for Medicare & Medicaid Services (formerly known as HCFA) Centers for Medicare & Medicaid Services (formerly known as HCFA)
	1. Center for Medicare Management 2. Center for Beneficiary Choices 3. Center for Medicaid and State Operations
COI	Conflict of interest
CP	Citizen Petition
CPG	Compliance Policy Guide
CPI	Consumer Price Index
CPSC	Consumer Product Safety Commission
CRA	Clinical research associates
CRADA	Cooperative Research and Development Agreement
CRF	Case report form
CRO	Contract research organization
CSA	Controlled Substances Act
CSI	Consumer Safety Inspector
CSO	Consumer Safety Officer
CT	Clinical trial
CTA	Clinical Trials Agreement
CTD	Common technical document
CVM	Center for Veterinary Medicine
DAL	Defect action level
D and A	Dosage and administration
DBC	Division of Biologics Control
DBS	Division of Biologics Standards (NIH)
DD	District Director
DDMAC	Division of Drug Marketing Advertising and Communications (CDER)
DDRE	Division of Drug Risk Evaluation (ODS)
DEA	Drug Enforcement Administration (U.S. Department of Justice)
DESI	Drug efficacy study implementation
DHHS	U.S. Department of Health and Human Services
DHS	U.S. Department of Homeland Security

DIN	Drug Identification Number
DIOP	Division of Import Operations and Policy (ORA)
DMA	Division of Monoclonal Antibodies (OBP)
DMB	Documents Management Branch
DMETS	Division of Medication Errors and Technical Support (ODS)
DMF	Drug master file
DNA	Deoxyribonucleic acid
DOs	District offices (FDA)
DOA	Drugs of abuse
DOD	U.S. Department of Defense
DOJ	U.S. Department of Justice
DP	Drug product
DPDD	Division of Pediatric Drug Development
DPT	Diphtheria pertussis tetanus vaccine
DQRS	Drug Quality Reporting System
DRPM	Dispute resolution project manager
DSB	Drug Safety Oversight â€˜Board (FDA)
DSHEA	The Dietary Supplement Health and Education Act of 1994
DSI	Division of Scientific Investigations (CDER)
DSMB	Data and safety monitoring boards
DTC	Direct-to-consumer
DTP	Division of Therapeutic Proteins (OBP)
DWPE	Detention Without Physical Examination
EAR	Export Administration Regulations
eCTD	Electronic common technical document
EEA	European Economic Area
EFPIA	The European Federation of Pharmaceutical Industries and Associations
EIR	Establishment inspection report
ELA	Establishment license application
EMEA	European Medicines Evaluation Agency
EPA	Environmental Protection Agency
ERB	Ethical review board
ERISA	Employee Retirement Income Security Act
EU	European Union
EUA	Emergency Use Authorization
FAERS	FDA Adverse Event Reporting
FARs	Field Alert Reports
FDA	Food and Drug Administration (DHHS)

FDAAA	Food and Drug Administration Amendments Act of 2007
FDAMA	Food and Drug Administration Modernization Act of 1997
FDCA	Federal Food Drug and Cosmetic Act also spelled FD&C FFD&CA
FDASIA	Food and Drug Administration Safety and Innovation Act
FIFRA	Federal Insecticide Fungicide and Rodenticide Act
FM	Final monograph
FOIA	Freedom of Information Act
FPL	Final printed labeling
FR	Federal Register
FSH	Follicle Stimulating Hormone
FTC	Federal Trade Commission
FTE	Full time employees
FY	Fiscal year
GAAP	Greater Access to Affordable Pharmaceuticals Act of 2001
GAO	Government Accounting Office
GCPs	Good clinical practices
GDEA	Generic Drug Enforcement Act of 1992
GGPs	Good guidance practices
GLPs	Good laboratory practices
GMPs	Good manufacturing practices
GPhA	Generic Pharmaceutical Association
GPO	Group purchasing organizations
GRAS	Generally recognized as safe
GRAS/GRAE	Generally recognized as safe/effective also spelled GRAS/E
GRPs	Good Review Practices
GSA	General Services Administration
GTPs	Good tissue practices
HBV	Hepatitis B Virus
HCFA	Health Care Financing Administration (DHHS; now named CMS)
HCO	Health care organizations
HCP	Healthcare provider/health care provider
HCT/Ps	Human Cells Tissues and Cellular and Tissue-Based Products
HCV	Hepatitis C Virus
hGH	Human Growth Hormone

HDMA	Healthcare Distribution Management Association (formerly National Wholesale Druggistsâ€™ Association NWDA)
HELP	Health Education Labor and Pensions Committee (Senate)
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIV	Human Immunodeficiency Virus
HPK	Human pharmacokinetic
HPUS	Homeopathic Pharmacopeia of the United States
HSP	Human subject protection
HTS	Harmonized Tariff System
IBE	Individual bioequivalence
ICA	Intercenter agreement
ICC	Interstate Commerce Commission
ICD	Informed consent document
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IFNs	Interferons
IG	Inspector General
INADA	Investigational new animal drug application
INDs	Investigational new drug applications
INDA	Investigational new animal drug application
IOM	Investigations Operations Manual also Institute of Medicine
IP	Intellectual property
IPO	Initial public offering
IPRG	Interdisciplinary Pharmacogenomics Review Group
IQ	Installation qualification
IR	Immediate release
IRBs	Institutional review boards
ISE	The Integrated Summary of Efficacy
ISS	The Integrated Summary of Safety
ITDS	International Trade Date System
IVD	In vitro diagnostic
JAMA	Journal of the American Medical Association
J/D	Judgment for the defendant
JPMA	Japan Pharmaceutical Manufacturers Association
LBC	Laboratory of Biologics Control
LDTs	Laboratory developed tests
LI	Learned intermediary

LIMS	Laboratory Information Management Systems
MAbs	Monoclonal antibodies
MAPPs	Manual of Policies and Procedures
MCO	Managed care organization
MDUFMA	Medical Device User Fee and Modernization Act of 2002
MedPAC	Medicare Payment Advisory Commission
MEDSA	The Medicine Equity and Drug Safety Act of 2000
MedWatch	The FDA Safety Information and Adverse Event Reporting Program
MHLW	Ministry of Health Labour and Welfare (Japan)
MMA	Medicare Modernization Act or Medicare Prescription Drug Improvement and Modernization Act of 2003 (MPDIMA)
MOU	Memorandum of understanding
MPA	Multiple projects (human subjects) assurance
MRA	Mutual recognition agreements
MSJ	Motion for summary judgment
MSLs	Medical Science Liaisons
NACDS	National Association of Chain Drug Stores
NAD	National Advertising Division of the Better Business Bureau
NADA	New animal drug application
NAF	Notice of Adverse Findings
NAS	National Academy of Sciences
NCE	New chemical entity
NCTR	National Center for Toxicological Research
NCVIA	National Childhood Vaccine Injury Act of 1986
NDA	New drug application
NDC	National Drug Code
NEPA	National Environment Policy Act
NF	National Formulary
NIAID	National Institute of Allergy and Infectious Diseases (NIH)
NICHD	National Institute of Child Health & Human Development (NIH)
NIDPOE	Notice of initiation of disqualification proceedings and opposition to explain
NIH	National Institutes of Health (DHHS)
NLR	No license required
NME	New molecular entity
NOH	Notice of hearing

NOOH	Notice offering an opportunity for a hearing
***NOV**	Notice of violations letters
NPR	Notice of Proposed Rulemaking
NRC	National Research Council
NTI	Narrow therapeutic index
NVAC	National Vaccine Advisory Committee
OASIS	Operational and administrative system for import support
OBP	Office of Biotechnology Products (CDER)
OCBQ	Office of Compliance and Biologics Quality (CBER)
OCI	Office of Criminal Investigations (FDA)
OCL	Office of Consumer Litigation (DOJ)
OCP	Office of Combination Products
OCTEC	Office of Counter-Terrorism & Emergency Coordination (OCTEC)
ODA	Orphan Drug Amendments
ODD	Orphan Drug Designation
ODE	Office of Drug Evaluation or Orphan Drug Exclusivity
ODS	Office of Drug Safety
OGD	Office of Generic Drugs (CDER)
OHRP	Office of Human Research Protections (DHHS)
OIA	Official action indicated
OIG	Office of the Inspector General (DHHS)
OMB	Office of Management and Budget
OMP	Office of Medical Policy (OMP)
OND	Office of New Drugs (CDER)
ONDCP	Office of National Drug Control Policy
OOS	Out of specification
OQ	Operational qualification
OPDP	Office of Prescription Drug Promotion (CDER)
OPS	Office of Pharmaceutical Science (CDER)
ORA	Office of Regulatory Affairs (FDA)
Orange Book	Approved Drug Products with Therapeutic Equivalence Evaluations
OSE	Office of Surveillance and Epidemiology (CDER)
OSHA	Occupational Safety and Health Administration
OSI	Office of Scientific Investigations (CDER)
OTA	Office of Technology Assessment (U.S. Congress)
OTC	Over-the-counter
OVID	Office of In Vitro Diagnostic Device Evaluation and Safety (CDRH)

PAC	Post approval changes
PAIs	Pre-approval inspections
PAP	Patient assistance programs
PAPS	Promotional and Advertising Policy Staff (CDRH)
PAT	Process analytical technology
PBMs	Pharmacy benefit management companies
PCP	Principle display panel
PD	Pharmacodynamic
PDE	Pediatric exclusivity
PdIT	Pediatric Implementation Team
PDMA	Prescription Drug Marketing Act of 1987
PDUFA I	Prescription Drug User Fee Act of 1992 (1992-1997)
PDUFA II	Extended act until Sept. 30 2002 by FDAMA
PDUFA III	Extended act until Sept. 302007
PE	Pharmacoeconomics
PG	Pharmacogenomic
PHI	Protected health information
PhRMA	Pharmaceutical Research and Manufacturers of America
PHS	Public Health Service (DHHS)
PHSA	Public Health Service Act
PI	Principal investigator or preliminary injunction or product/package insert
PIPEDA	Personal Information Protection and Electronic Documents Act
PK/PD	Pharmacokinetic/pharmacodynamic
PLA	Product license application
PLI	Prelicense inspection
PMA	Premarket Approval
PMB	Pharmacy benefit manager
PMOA	Primary mode of action
PPI	Patient package insert
PPSR	Proposed Pediatric Study Request
PQ	Performance qualification
PREA	Pediatric Research Equity Act of 2003
PTEs	Patent Term Extensions
PTO	Patent and Trademark Office (U.S. Department of Commerce)
QAU	Quality assurance unit
QOL	Quality of life
QOSs	Quality overall summaries

QS	Quality system
rDNA	Recombinant DNA
RAC	Recombinant DNA Advisory Committee
ReGo	Reinventing government
REMS	Risk Evaluation and Mitigation Strategies
RFD	Request for designation
RFID	Radiofrequency identification
RMATs	Regenerative Medicine Advance Therapies
RLD	Reference listed drug
RNA	Ribonucleic acid
ROA	Route of administration
RP	Reference product
RPM	Regulatory Procedures Manual
RTF	Refuse to file
Rx	Prescription
S&E	Safety and effectiveness
SACX	Secretary's Advisory Committee on Xenotransplantation
SADR	Suspected adverse drug reaction
SAE	Serious adverse event
SBA	Summary basis of approval
sBLA	Supplemental biologics license application
SBREFA	Small Business Regulatory Fairness and Enforcement Act
SE	Substantial equivalency
SEC	Securities and Exchange Commission
SMART	Submission Management and Review Tracking
SMO	Site management organization
sNDA	Supplemental new drug application
SOPs	Standard Operating Procedures
SOPP	Standard Operating Procedures and Policies
SPAs	Special Protocol Assessments
SPC	Supplementary Protection Certificates
SRCS	Division of Surveillance Research and Communication Support (ODS)
SUPAC	Scale-Up and Post-Approval Changes guidance (FDA)
TBPs	Therapeutic biological products
TE	Therapeutic equivalence
TEA	Time and extent application
TESS	Treatment Emergent Signs and Symptoms

TFM	Tentative final monograph
TMO	Trial management organization
Trial: SJ/D	Summary judgment for defendants at trial
TRIPS	Trade Related Aspects of Intellectual Property
TRO	Temporary restraining order
TSA	Trade Secrets Acts
TSE	Transmissible Spongiform Encephalopathies
UCC	Uniform Code Council
URAA	Uruguay Round Agreements Act
USAs	United States Attorneys (DOJ)
USC	United States Code
USDA	United States Department of Agriculture
USP	United States Pharmacopeia
USTR	United States Trade Representative
VA	U.S. Department of Veteran Affairs
VAERS	Vaccine Adverse Event Reporting System
VGDS	Voluntary Genomics Data Submission
VIPPS	Verified Internet Pharmacy Practices Site
WHO	World Health Organization
WL	Warning letter
WLF	Washington Legal Foundation