Acronyms that may be used during FDLI's Introduction to Drug Law and Regulation

356h	FDA Form: Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use
482	FDA Form/FD 482: Notice of Inspection
483	FDA Form/FD-483: Inspectional Observances
484	FDA Form/FD-484: Receipt for Samples
505(b)(2)	(previously known as) "Paper" NDAs
2253	FDA Form: Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use
AADA	abbreviated antibiotic drug application
AC	advisory committee
ACCME	Accreditation Council for Continuing Medical Education
ACE	Automated Commercial Environment (CBP)
ACS	automated commercial service
ACUS	Administrative Conference of the United States
ADAA	Animal Drug Availability Act of 1996
ADCOMs	Advisory Committees
ADE	adverse drug experience
ADME	absorption, distribution, metabolism, excretion/elimination
ADR	adverse drug reaction
ADUFA	Animal Drug User Fee of 2003
AE	adverse event
AERS	Adverse Event Reporting System
AHAs	Alpha hydroxy acids
AHFS-DI	American Hospital Formulary Service – Drug Information
AHRQ	Agency for Healthcare Research and Quality (DHHS)
AIP	application integrity policy
AKS	anti-kickback statute
ALJ	administrative law judge
ALS	Amyotrophic Lateral Sclerosis
AMA	American Medical Association
AMP	average manufacturer price
ANADA	abbreviated new animal drug application
ANDA	abbreviated new drug application
ANPRM	advance notice of proposed rulemaking
ANSI	American National Standards Institute
APA	Administrative Procedures Act

APHIS	Animal and Plant Health Inspection Service (USDA)
API	active pharmaceutical ingredient
APLB	Advertising and Promotional Labeling Branch (CBER)
AQSIQ	Administration of Quality Supervision, Inspection and Quarantine (People's Republic of China)
ARC	American Red Cross
ASP	average sales price
ASR	Analyte Specific Reagents
ATLS	analytical testing laboratory sites
AWP	average wholesale price
BACPAC	Bulk Activities Postapproval Changes
BA/BE	bioavailability/equivalent
BATF	Bureau of Alcohol, Tobacco and Firearms (U.S. Department of Treasury)
BHA	Beta Hydroxy acids
BIMO	Bioresearch Monitoring
BLA	biologics license application
BMF	Biological Master File
BPCA	Best Pharmaceuticals for Children Act of 2007
BPCIA	Biologics Price Competition and Innovation Act
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
BTC	Behind the Counter
BW/BT	biowarfare/bioterrorism
CAFE	Court of Appeals for the Federal Circuit
CAFTA-DR	Central American-Dominican Republic Free Trade Agreement
CAN	Counterfeit Alert Network
CANDA	computer assisted new drug application
CAP	Competitive Acquisition Program
CAPA	corrective and preventive actions
CBA	changes being affected
CBE	changes being effected
CBER	Center for Biologics Evaluation and Research (FDA)
CBO	Congressional Budget Office
CBP	U.S. Customs and Border Protection (DHS)
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
CER	Comparative Effectiveness Research
CFR	Code of Federal Regulations

CFSAN	Code for Food Safety & Applied Nutrition
cGMPs	current good manufacturing practices
CHPA	Consumer Healthcare Products Association
CIAs	corporate integrity agreements
CIB	Clinical Investigator Brochure
CIS	Cancer Information Service
CLIA	Clinical Laboratory Improvement Amendments
CMC	chemical, manufacturing and control
CME	Continuing Medical Education
CMO	contract management organization
CMPs	civil money penalties
CMS	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
COLCRYS	colchicine
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
DD	District Director
DDMAC	Division of Drug Marketing, Advertising and Communications (CDER)
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)

DMB	Documents Management Branch
DMF	drug master file
DOs	district offices (FDA)
DOA	drugs of abuse
DOC	documentary sample
DOJ	U.S. Department of Justice
DOT	U.S. Department of Transportation
DP	drug product
DPA	Deferred Prosecution Agreement
DPDD	Division of Pediatric Drug Development
DQRS	Drug Quality Reporting System
DRPM	dispute resolution project manager
DSB	Drug Safety Oversight 'Board (FDA)
DSHEA	Dietary Supplement Health and Education Act
DSI	Division of Scientific Investigations (CDER)
DSMB	data and safety monitoring boards
DTC	direct-to-consumer
DTP	direct-to-patient
DWPE	Detention Without Physical Examination
EAR	Export Administration Regulations
EEA	European Economic Area
EFPIA	The European Federation of Pharmaceutical Industries and Associations
EFTA	European Free Trade Association
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
FACA	Federal Advisory Committee Act
FAR	Field Alert Reports
FCPA	Foreign Corrupt Practices Act of 1977
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 of 1938
FDL	Food and Drug Law
FFDCA	Federal Food, Drug and Cosmetic Act, also spelled FD&C, FFD&CA, FDCA
FIFRA	Federal Insecticide, Fungal, and Rodenticide Act
FOIA	Freedom of Information Act
FM	final monograph
FPL	final printed labeling

FR	Federal Register
FTC	Federal Trade Commission
FTE	full time employees
FY	fiscal year
GAAP	Greater Access to Affordable Pharmaceuticals Act of 2001
GAO	Government Accountability Office
GCPs	Good Clinical Practices
GDEA	Generic Drug Enforcement Act of 1992
GDUFA	Generic Drug User Fee Act
GGPs	good guidance practices
GLPs	good laboratory practices
GMPs	good manufacturing practices
GNLP	Good Naming, Labeling and Packaging
GPhA	Generic Pharmaceutical Association
GPO	group purchasing organizations
GRAS	generally recognized as safe
GRAS/GRAE	generally recognized as safe/effective, also spelled GRAS/E
GRMP	Good Review Management Principles
GRPs	Good Review Practices
GSA	General Services Administration
HCFA	Health Care Financing Administration (DHHS)
HCO	health care organizations
HCP	healthcare provider/health care provider
HDE	Humanitarian Device Exemption
HDMA	Healthcare Distribution Management Association (formally National Wholesale Assocation, NWDA
HEAT	Healthcare Fraud Prevention and Enforcement Action Team
HELP	Health, Education, Labor and Pensions Committee (Senate)
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HPK	human pharmacokinetic
HPUS	Homeopathic Pharmacopeia of the United States
HSP	human subject protection
I&U	indications and usage
IBE	individual bioequivalence
ICD	informed consent document
ICH	International Conference on Harmonization
ICMJE	International Committee of Medical Journal Editors
IFE	import for export
IG	Inspector General
INADA	investigational new animal drug application
INDs	investigational new drug applications
INDA	investigational new animal drug application

INV	investigational sample
IOM	*Investigations Operations Manual*
IPEC	International Pharmaceutical Excipients Counsel
IPO	initial public offering
IQ	installation qualification
IR	immediate release
IRBs	institutional review boards
IRO	independent review organization
IRS	identical, related or similar
ISPE	International Society for Pharmaceutical Engineering
ISE	the Integrated Summary of Efficacy
ISO	International Organization for Standardization
ISS	the Integrated Summary of Safety
ITDS	International Trade Date System
JAMA	*Journal of the American Medical Association*
J/D	judgment for the defendant
JPMA	Japan Pharmaceutical Manufacturers Association
LI	learned intermediary
LIMS	Laboratory Information Management Systems
MAPPs	Manual of Policies and Procedures
MCO	managed care organization
MDD	major depressive disorder
MDL	multidistrict litigation
MECCs	medical education and communication companies
MedPAC	Medicare Payment Advisory Commission
MEDSA	The Medicine Equity and Drug Safety Act of 2000
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
NARA	National Archives and Records Administration
NAF	Notice of Adverse Findings
NAI	No Action Indicated
NAS	National Academy of Sciences
NCCN	National Comprehensive Cancer Network
NCE	new chemical entity

NCI	National Cancer Institute
NCTR	National Center for Toxicological Research
NDA	new drug application
NDC	National Drug Code
NEPA	National Environment Policy Act
NEJM	New England Journal of Medicine
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
NLM	National Library of Medicine
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
NRT	nicotine replacement therapy
NSAIDs	Neurosteroidal anti-inflammatory drugs
NTI	narrow therapeutic index
NVAC	National Vaccine Advisory Committee
OAI	Official Action Indicated
OASIS	operational and administrative system for import support
OCC	Office Chief Counsel
OCI	Office of Criminal Investigations (FDA)
ODA	Orphan Drug Amendments
ODD	Orphan Drug Designation
ODE	Office of Drug Evaluation (CDER)
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
ONDCP	Office of National Drug Control Policy
OOS	out of specification
OPDP	Office of Prescription Drug Promotion (CDER)
OQ	operational qualification
ORA	Office of Regulatory Affairs (FDA)
Orange Book	Approved Drug Products with Therapeutic Equivalence Evaluations
OSHA	Occupational Safety and Health Administration
OSI	Office of Scientific Investigations (CDER)

OTA	Office of Technology Assessment (U.S. Congress)
OTC	over-the-counter
PAC	post approval changes
PAIs	pre-approval inspections
PAP	patient assistance programs
PAPS	Promotional and Advertising Policy Staff (CDRH)
PAS	Prior Approval Supplements
PAT	process analytical technology
PBMs	pharmacy benefit management companies
PCP	principle display panel
PD	pharmacodynamic
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. 30, 2007
PDUFA V	extended act until 2012
PDE	pediatric exclusivity
PdIT	Pediatric Implementation Team
PE	pharmacoeconomics
PHAs	public health advisories
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
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PIPEDA	Personal Information Protection and Electronic Documents Act
PK/PD	pharmacokinetic/pharmacodynamic
PLA	product license application
PM	proposed monograph
PMA	premarket approval application
PMB	pharmacy benefit manager
PPA	phenylpropanolmine
PPACA	The Patient Protection and Affordable Care Act
PPSR	Proposed Pediatric Study Request
PQ	performance qualification
PQG	pharmaceutical quality group
PREA	Pediatric Research Equity Act of 2003
PTEs	Patent Term Extensions
PTR	Patent Term Restoration
PTO	Patent and Trademark Office (U.S. Department of Commerce)
QA	quality assurance
QAU	quality assurance unit

QbR	Question-based Review
QC	quality control
QOL	quality of life
QOSs	quality overall summaries
QS	quality system
QSR	Quality System Regulation
ReGo	reinventing government
REMS	Risk Evaluation and Management Strategy
RFID	radiofrequency identification
RICO	Racketeer Influenced and Corrupt Organizations Act of 1970
RLD	reference listed drug
RMP	Risk Management Plan
RP	reference product
RPM	*Regulatory Procedures Manual*
RPS	Reference Product Sponsor
RTC	Referred to Center
RTF	refuse to file
RTS	Referred to State
Rx	medical prescriptions
S&E	safety and effectiveness
SE	Substantial Evidence
SACX	Secretary's Advisory Committee on Xenotransplantation
SADR	suspected adverse drug reaction
SAER	serious adverse event report
SBA	summary basis of approval
SBREFA	Small Business Regulatory Fairness and Enforcement Act
SEC	Securities and Exchange Commission
SMART	Submission Management and Review Tracking
SMDA	Safe Medical Devices Act of 1990
SMO	site management organization
sNDA	supplemental new drug application
SOP	standard operating procedures
SPA	Special Protocol Assessment
SPL	structured product labeling
SPOOS	significant payments of other sorts
SSA	Social Security Act
SUPAC	Scale-Up and Post-Approval Changes guidance (FDA)
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

TRO	temporary restraining order
TSA	Trade Secrets Acts
TZDs	thiazolidinediones
UCC	Uniform Code Council
URAA	Uruguay Round Agreements Act
USC	United States Code
USDA	U.S. Department of Agriculture
USP	United States Pharmacopeia
USTR	United States Trade Representative
VAERS	Vaccine Adverse Event Reporting System
VAI	Voluntary Action Indicated
VAWD	Verified – Accredited Wholesale Distributers
VIPPS	Verified Internet Pharmacy Practices Site
WAC	wholesale acquisition cost
WAMP	widely available market price
WHO	World Health Organization
WLF	Washington Legal Foundation
WLs	Warning Letters
WR	Written Request

* “untitled” letters were formerly called “notice of violation” letters
** amended and extended PDUFA I to Sept. 30, 2002, published July 1998