GLOSSARY OF ACRONYMS

510(k)	Pre-market notification (Medical devices substantially equivalent to products already on the market)
513(g)	Written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device
AADA	Abbreviated Antibiotic Drug Application
AAFCO	American Association of Feed Control Officials
AAR	After Action Review
ABC	Activity Based Costing
ACE	Angiotensin-converting Enzyme
ADE	Adverse Drug Event
ADAA	Animal Drug Availability Act of 1996
ADR	Adverse Drug Report
ADIMS	Automated Drug Information Management System
ADUFA	Animal Drug User Fee Act
AER	Adverse Event Review
AERS	Adverse Events Reporting System
AFSS	Animal Feed Safety System
AHI	Animal Health Institute
AIDS	Acquired Immune Deficiency Syndrome
AMDUCA	Animal Medicinal Drug Use Clarification Act
ANADA	Abbreviated New Animal Drug Application
ANDA	Abbreviated New Drug Application
ANPR	Advanced Notice of Proposed Rulemaking
ANSI	American National Standards Institute
APHIS	Animal Plant and Health Inspection Service (USDA)
AR	Anti-microbial Resistance
ARL	Arkansas Regional Laboratory
ASAM	Assistant Secretary for Grants and Acquisitions Management
AVMA	American Veterinary Medical Association
BAMSG	Bacteriology and Mycology Study Group
BCCP	Business Continuity and Contingency Plan
BIMO	Bioresearch Monitoring
BIMS	Biological Investigational New Drug Application Management System
BCCP	Business Continuity and Contingency Plan
BLA	Biologics License Application
BLT	Blood Logging and Tracking System
BPCA	Better Pharmaceuticals for Children Act
BSE	Bovine Spongiform Encephalopathy (Mad Cow Disease)
BSL	Biosafety Level
BT	Bioterrorism
CABS	Conformity Assessment Bodies
CAERS	CFSAN Adverse Event Reporting System
CARS	Compliance Achievement Reporting System
CBER	Center for Biologics Evaluation and Research (FDA)
CDC	Centers for Disease Control and Prevention

CDER	Center for Drug Evaluation and Research (FDA)
CDRH	Center for Devices and Radiological Health (FDA)
CERTS	Center for Education and Research Therapeutics
CFO	Chief Financial Officer
CFSAN	Center for Food Safety and Applied Nutrition (FDA)
CGMPs	Current Good Manufacturing Practices
CHD	Coronary Heart Disease
CIP	Critical Infrastructure Protection
CJD	Creutzfeldt-Jakob disease
CLIA	Clinical Laboratory Improvement Amendments
CMC	Chemistry, Manufacturing, and Controls
CMS	Centers for Medicare and Medicaid
CMV	Cytomegalovirus
COMSTAS	Compliance Status Information System
COBOL	Common Business Oriented Language
COOP	Continuity of Operations
CPI	Consumer Price Index
CPI/U	Consumer Price Index/Urban
CRADA	Cooperative Research and Development Agreement
CRO	Contract Research Organization
CRS	Contamination Response System
CT	Counter Terrorism
CTS	Correspondence Tracking System
CVM	Center for Veterinary Medicine (FDA)
CWD	Chronic Wasting Disease
DHHS	Department of Health and Human Services
DHS	Department of Homeland Security
DNA	Deoxyribonucleic Acid
DOD	Department of Defense
DOL	Department of Labor
DQRS	Drug Quality Reporting System
DRLS	Drug Registration and Listing System
DSaRM	Drug Safety and Risk Management
DSHEA	Dietary Supplement Health and Education Act
DTPA	Diaminopropanoltetraacetic acid
eCTD	Electronic Common Technical Document
EDR	Electronic Document Room
EDMS	Electronic Data Management System
EIP	Emerging Infection Program
EIR	Establishment Inspection Report
ELA	Establishment License Application
eLEXNET	Electronic Laboratory Exchange Network
EO	Emergency Operations
EOC	Emergency Operations Center
EPA	Environmental Protection Agency
ERS	Economic Research Service
ETS	Environmental Tobacco Smoke
EU	European Union

FAA	Federal Aviation Administration
FACTS	Field Accomplishment and Compliance Tracking System
FAIR Act	Federal Activities Inventory Reform Act
FAO	Food and Agricultural Organization (United Nations)
FBI	Federal Bureau of Investigation
FAS	Foreign Agriculture Service (USDA)
FD	Food Defense
FDA	Food and Drug Administration
FDAMA	Food and Drug Administration Modernization Act of 1997
FD&C Act	Federal Food, Drug and Cosmetic Act
FERN	Food Emergency Response Network
FES	Financial Enterprise Solutions
FHA	Federal Health Architecture
FIS	Field Information System
FLQ	Fluoroquinolone
FMD	Foot and Mouth Disease
FMFIA	Federal Manager's Financial Integrity Act
FORCG	Food Outbreak Response Coordination Group
FPL	Final Printed Label
FPLA	Fair Packaging and Labeling Act
FSI	Food Safety Initiative (National)
FSIS	Food Safety Inspection Service (USDA)
FSSS	Food Safety and Security Staff (CFSAN)
FTC	Federal Trade Commission
FTE	Full-time Equivalent
FY	Fiscal Year (October - September)
GAO	General Accounting Office
GAPs	Good Agricultural Practices
GATT	General Agreement on Tariffs and Trade
GeMCRIS	Genetic Modification Clinical Research Information System
GGPs	Good Guidance Practices
GLP	Good Laboratory Practices
GMO	Genetically Modified Organisms
GMPs	Good Manufacturing Practices
GphA	Generic Pharmaceutical Association
GPRA	Government Performance and Results Act of 1993
GRAS	Generally Recognized as Safe Food Ingredients
GSA	General Services Administration
GSFA	General Standards for Food Additives
GTIS	Gene Therapy Information System
HACCP	Hazard Analysis Critical Control Points
HCV	Hepatitis C Virus
HDE	Humanitarian Device Exemption
HIV	Human Immunodeficiency Virus
HR	Human Resources
HSPD	Homeland Security Presidential Directive
HUD	Humanitarian Use Device
IAG	Interagency Agreement

ICAAC	Interscience Conference on Antimicrobial Agents and Chemotherapy
ICH	International Conference on Harmonization
IDE	Investigational Device Exemption
IDSA	Infectious Disease Society of America
INAD	Investigational New Animal Drug
INADA	Investigational New Animal Drug Application
IND	Investigational New Drug
IOM	Institute of Medicine
IRB	Institutional Review Board
ISLI	International Life Sciences Institute
ISO	International Standards Organization
ISRS	Individual Safety Reports
IT	Information Technology
IVD	In Vitro Diagnostic
JECFA	Joint Expert Committee on Food Additives
JIFSAN	Joint Institute for Food Safety and Applied Nutrition
JINAD	Generic Investigational New Animal Drug
LACF	Low Acid Canned Foods
LAN	Local Area Network
LBITF	Least Burdensome Industry Task Force
LRN	Laboratory Response Network
MALDI	Matrix Assisted Laser Desorption Ionization
MAB	Metastable Atom Bombardment
MATS	Management Assignment Tracking System
MBM	Meat and Bone Meal
MDAE	Medical Device Adverse Events
MDAER	Medical Device Adverse Event Reports
MDR	Medical Device Reporting System
MDUFMA	Medical Device User Fee and Modernization Act
MedSun	Medical Product Surveillance Network
MEO	Most Efficient Organization
MERS-TM	Medical Event Reporting System for Transfusion Medicine
MFA	Medicated Feed Application
MMBM	Mammalian Meat and Bone Meal
MOU	Memorandum of Understanding
MPRIS	Mammography Program Reporting and Information Systems
MQSA	Mammography Quality Standards Act
MRA	Mutual Recognition Agreement
MUMS	Minor Use/Minor Species
NADA	New Animal Drug Application
NAFTA	North American Free Trade Agreement
NAFTA TWG	North American Free Trade Agreement Technical Working Group
NAHMS	National Animal Health Monitoring System
NARMS	National Antimicrobial Resistance Monitoring System
NAS	National Academy of Sciences
NASS	National Agricultural Statistics Survey
NAT	Nucleic Acid Test

NCCLS	National Committee on Clinical Laboratory Standards
NCFST	National Center for Food Safety and Technology (Moffett Center)
NCI	National Cancer Institute
NCIE	Notice of Claimed Investigational Exemptions
NCTR	National Center for Toxicological Research (FDA)
NDA	New Drug Application
NDE/MIS	New Drug Evaluation Management Information System
NIAID	National Institute of Allergy and Infectious Diseases
NIBSC	National Institute for Biological Standards and Control
NIDA	National Institute on Drug Abuse
NIEHS	National Institute for Environmental Health Sciences
NIH	National Institutes of Health
NLEA	Nutrition Labeling and Education Act
NME	New Molecular Entity
NOA	Notice of Availability
NOH	Notice of Hearing
NPR	National Partnership for Reinventing Government
NPRM	Notice of Proposed Rulemaking
NRC	National Research Council
NSCLC	Non-Small Cell Lung Cancer
NSE	Not Substantially Equivalent
NTP	National Toxicology Program
nvCJD	new variant Creutzfeldt-Jakob disease
NVPO	National Vaccine Program Office
OAI	Official Action Indicated
OARSA	Office of Applied Research and Safety Assessment (CFSAN)
OASIS	Operational and Administrative System for Import Support
OBRR	Office of Blood Research and Review (CBER)
OC	Office of Compliance (CFSAN)
OCD	Obsessive Compulsive Disorder
OCTGT	Office of Cellular, Tissues and Gene Therapies (CBER)
OFAS	Office of Food Additive Safety (CFSAN)
OGD	Office of Generic Drugs (CDER)
OM	Office of Management (FDA)
ONPLDS	Office of Nutritional Products, Labeling, and Dietary Supplements (CFSAN)
OPDFB	Office of Plant and Dairy Foods and Beverages (CFSAN)
OPDiv	Operating Division
OPT	Office of Pediatric Therapeutics
ORA	Office of Regulatory Affairs (FDA)
ORISE	Oak Ridge Institute for Science and Education
OS	Office of Seafood (CFSAN)
OSAS	Office of Scientific Analysis and Support (CFSAN)
OSCI	Office of Science (CFSAN)
OSHA	Occupational Safety and Health Administration
OTC	Over-the-Counter
OTR	Office of Testing and Research (CDER)
OTRR	Office of Therapeutics Research and Review (CBER)
OVRR	Office of Vaccines Research and Review (CBER)

PART	Program Assessment Rating Tool (PART)
PAS	Public Affairs Specialist (FDA)
PAT	Process Analytical Technology
PDPs	Product Development Protocols
PDUFA	Prescription Drug User Fee Act of 1992
PERV	Porcine endogenous retrovirus
PIFSI	Produce and Food Safety Initiative
PISI	Protocol Investigator Site Inspection
PLA	Product License Application
PMA	Premarket Approval (Application to market medical device that requires Premarket approval) or President's Management Agenda *(depending upon context)*
PMN	Premarket Notification
PODS	Project-Oriented Data System
PPP	Pregnancy Prevention Program
PQRI	Product Quality Research Initiative
QSAR	Quantitative Structure Activity Relationship
QSIT	Quality System Inspection Technique
QSR	Quality System Regulation
RA	Rheumatoid Arthritis
RCHSA	Radiation Control for Health and Safety Act
REGO	Reinventing Government Initiative
RIMS	Regulatory Information Management Staff (CBER)
RMS-BLA	Regulatory Management System-Biologics License Application
SAB	Science Advisory Board
SAMHSA	Substance Abuse and Mental Health Services Administration
SBREFA	Small Business Regulatory Enforcement Fairness Act
SCC	Secretary's Command Center
SE	Salmonella Enteriditis
S.M.A.R.T.	System to Manage Accutane Related Teratogenicity
SN/AEMS	Special Nutritional Adverse Events Monitoring System
SSO	Shared Services Organization
STARS	Submission Tracking and Review System
StmDT104	Salmonella Tphimurium DT 104
TB	Tuberculosis
Tof	Time of flight
TRIMS	Tissue Residue Information System
TSE	Transmissible Spongiform Encephalopathy (includes BSE and CJD)
UFMS	Unified Financial Management System
UK	United Kingdom
UMCP	University of Maryland-College Park
USAMRIID	United States Army Medical Research Institute of Infectious Diseases
USC	United States Code
USDA	United States Department of Agriculture
VAERS	Vaccine Adverse Event Reporting System

VAI	Voluntary Action Indicated
vCJD	variant Creutzfeldt-Jakob disease
VEE	Venezuelean Equine Encephalitis
VFD	Veterinary Feed Directive
VICH	Veterinary International Cooperation on Harmonization
VFD	Veterinary Feed Directive
VICH	Veterinary International Conference on Harmonization
WHO	United Nations World Health Organization
WNV	West Nile Virus
WR	Written Request
WTO	World Trade Organization