

# FDA 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  
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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  
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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  
FURLS FDA Unified Registration and Listing System  
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  
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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  
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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)

OVRV Office of Vaccines Research and Review (CBER)

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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 Enteritidis

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  
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VAERS Vaccine Adverse Event Reporting System  
VAI Voluntary Action Indicated  
vCJD variant Creutzfeldt-Jakob disease  
VEE Venezuelan 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