

GLOSSARY OF ACRONYMS

3D	3-Dimensional
ADE	Adverse Drug Experience
ADEPT	Autonomous Diagnostics to Enable Prevention and Therapeutics
ADUFA	Animal Drug User Fee Act
AGDUFA	Animal Generic Drug User Fee Act
AMP	Real Property Asset Management Plan
ANDA	Abbreviated New Drug Application
ARL	Arkansas Regional Laboratory
ARS	Agriculture Research Service
B&F	Buildings and Facilities
BA	Budget Authority
BARDA	Biomedical Advanced Research and Development Authority
BIMO	Bioresearch Monitoring
BLA	Biologic License Application
BMAR	Backlog of Maintenance and Repairs
BPA	Bisphenol A
BPCA	Best Pharmaceuticals for Children Act
BsUFA	Biosimilars User Fee Act
CBER	Center for Biologics Evaluation and Research
CBP	Customs and Border Protection
CBRN	Chemical, Biological, Radiological, and Nuclear
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
cGMP	current Good Manufacturing Practice
CIO	Chief Information Officer
CMS	Centers for Medicare & Medicaid Services

CORE	Coordinated Outbreak Response and Evaluation
CORES	Collaborative Opportunities for Research Excellence in Science
CRADA	Cooperative Research & Development Agreement
CTP	Center for Tobacco Products
CUP	Central Utility Plant
CVM	Center for Veterinary Medicine
CY	Calendar Year
DNA	DeoxyriboNucleic Acid
DOD	Department of Defense
DSC	Drug Safety Communication
DSCSA	Drug Supply Chain Security Act
EADB	Estrogenic Activity Database
EDKB	Endocrine Disruptor Knowledge Base
EDSR	Electronic Document Submission and Review
eMDR	Electronic Medical Device Reporting
E.O.	Executive Order
ESPC	Energy Savings Performance Contract
EUA	Emergency Use Authorizations
FACA	Federal Advisory Committee Act
FATA	Federal Anti-Tampering Act
FCI	Facility Condition Index
FCN	Food Contact Substance Notification
FD&C Act	Federal Food, Drug and Cosmetic Act
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FDAMA	Food and Drug Administration Modernization Act
FDASIA	Food and Drug Administration Safety and Innovation Act
FDA-TRACK	FDA-wide performance management system
FERN	Food Emergency Response Network
FOIA	Freedom of Information Act

FSIS	Food Safety Inspection Service
FSMA	Food Safety Modernization Act
FSVP	Foreign Supplier Verification Programs
FTE	Full Time Equivalent
FVM	Foods and Veterinary Medicine
FY	Fiscal Year
GDUFA	Generic Drug User Fee Amendments
GFI	Guidance for Industry
GIS	Geographic Information System
GMP	Good Manufacturing Practices
GSA	General Services Administration
GUDID	Global UDI Database
HDE	Humanitarian Device Exemption
HHS	Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HQ	FDA Headquarters
HRWG	High Risk Working Group
HSP	Human Subject Protection
HUD	Humanitarian Use Device
HVAC	Heating, Ventilation, and Air Conditioning
ICH	International Conference on Harmonization
ICOR	International Consortium of Orthopedic Registries
IDE	Investigational Device Exemption
IND	Investigational New Drug
IOM	Institute of Medicine
IRB	Institutional Review Board
IT	Information Technology
IVD	In Vitro Diagnostics
JLC	Jefferson Labs Complex

LSBC	Life Sciences-Biodefense Laboratory Complex
MCM	Medical Countermeasure
MCMi	Medical Countermeasures initiative
MDE	Medical Device Epidemiology
MDIC	Medical Device Innovation Consortium
MDR	Medical Device Reporting
MDSAP	Medical Device Single Audit Program
MDUFA	Medical Device User Fee Amendments
MDUFMA	Medical Device User Fee and Modernization Act
MFRPS	Manufactured Food Regulatory Program Standards
MOD	Module
MQSA	Mammography Quality Standards Act
MRI	Magnetic Resonance Imaging
MRTP	Modified Risk Tobacco Product
NADA	New Animal Drug Application
NARMS	National Antimicrobial Resistance Monitoring System
NCTR	National Center for Toxicological Research
NDA	New Drug Application
NGO	Non-governmental Organization
NIH	National Institutes of Health
NME	New Molecular Entity
NSE	Not Substantially Equivalent
NYTS	National Youth Tobacco Survey
OC	Office of the Commissioner
OCI	Office of Criminal Investigations
OFVM	Office of Foods and Veterinary Medicine
OGROP	Office of Global Regulatory Operations and Policy
OMB	Office of Management and Budget
OOPD	Office of Orphan Products Development

ORA	Office of Regulatory Affairs
ORRR	Other Rent and Rent Related
OTC	Over-the-counter
PAC	Pediatric Advisory Committee
PAD	Program Activity Data
PAHPRA	Pandemic and All-Hazards Preparedness Reauthorization Act of 2013
PATH	Population Assessment of Tobacco and Health
PB	President's Budget
PC	Preventive Control
PDC	Pediatric Device Consortia
PDMA	Prescription Drug Marketing Act
PDUFA	Prescription Drug User Fee Act
PMA	Premarket Approval Application
PREA	Pediatric Research Equity Act
PREDICT	Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting
PRISM	Post-Licensure Rapid Immunization Safety Monitoring
REMS	Risk Evaluation and Mitigation Strategy
SE	Substantial Equivalence (when used by Device and Biologics Programs)
SLEP	Shelf Life Extension Program
SP	Strategic Priority
SRL	Southeast Regional Laboratory
SW	Southwest
TB	Tuberculosis
TCORS	Tobacco Centers of Regulatory Science
TPSAC	Tobacco Product Scientific Advisory Committee
TTIMS	Transfusion-Transmitted Infections Monitoring System
UDI	Unique Device Identification

UESC	Utility Energy Service Contract
UF	User Fee
USC	United States Code
USDA	United States Department of Agriculture
VICH	Veterinary International Conference on Harmonization
WD	Withdrawn
WEAC	Winchester Engineering and Analytical Center
WHO	World Health Organization