GLOSSARY OF "FDA ACRONYMS"

(Source: www.fda.gov/ Edited 3/1/2000 sml; subsequently edited 6/26/2003 Dr. Don Green)

510(k) — Pre-market notification for medical devices substantially equivalent to products already on the market

AADA — Abbreviated Antibiotic Drug Application

ADE — Adverse Drug Event

ADAA — Animal Drug Availability Act (of 1996)

ADR — Adverse Drug Report

AERS — Adverse Events Reporting System

AHI — Animal Health Institute

AIDS — Acquired Immune Deficiency Syndrome

ANDA — Abbreviated New Drug Application

ANSI — American National Standards Institute

BLA — Biologic License Application

BIMO — BIo-research MOnitoring (system);
see also Bioresearch Monitoring Information File at: http://www.fda.gov/cder/foi/special/bmis/

BRMS — Biologics Regulatory Management System

BSE — Bovine Spongiform Encephalopathy (Mad Cow Disease)

CABS — Conformity Assessment Bodies

CARS — Compliance Achievement Reporting System

CBER — FDA Center for Biologics Evaluation and Research

CDC — Centers for Disease Control and Prevention

CDER — FDA Center for Drug Evaluation and Research

CDRH — FDA Center for Devices and Radiological Health

CFSAN — FDA Center for Food Safety and Applied Nutrition

CGMPs — Current Good Manufacturing Practices

CJD — Creutzfeldt-Jakob disease

CMC — Chemistry, Manufacturing, and Controls

COMSTAT — Compliance Status Information System

CRADA — Cooperative Research and Development Agreement

CRS — Contamination Response System

CTS — Correspondence Tracking System

CVM — FDA Center for Veterinary Medicine

DHHS — Department of Health and Human Services

DNA — Deoxyribonucleic acid

DOD — Department of Defense

DoL — Department of Labor

DQRS — Drug Quality Reporting System

DRLS — Drug Registration and Listing System

DSHEA — Dietary Supplement Health and Education Act

EDR — Electronic Document Room

EDMS — Electronic Data Management System

EIP — Emerging Infection Program

EIR — Establishment Inspection Report

ELA — Establishment License Application

EPA — Environmental Protection Agency

ERS — Economic Research Service

ETS — Environmental Tobacco Smoke

EU — European Union

FACTS — Field Accomplishment and Compliance Tracking System

FAO — United Nations Food and Agricultural Organization

FAS — USDA Foreign Agriculture Service

FDAMA — Food and Drug Administration Modernization Act of 1997

FD&C Act — Federal Food, Drug and Cosmetic Act

FIS — Field Information System

FLQ — Fluoroquinolone

FORCG — Food Outbreak Coordination Response Group

FPL — Final Printed Label

FPLA — Fair Packaging and Labeling Act

FSI — National Food Safety Initiative

FSIS — Food Safety Inspection Service (USDA)

FTC — Federal Trade Commission

FTE — Full-time equivalents

FY — Fiscal Year (October – September)

GAO — Government Accounting Office

GAPs — Good Agricultural Practices

GATT — General Agreement on Tariffs and Trade

GPRA — Government Performance and Results Act of 1993

GMPs — Good Manufacturing Practices

GRAS — Generally Recognized as Safe food ingredients

GSFA — General Standards for Food Additives

HACCP — Hazard Analysis Critical Control Points (a quality assurance and inspection technique)

HDE — Humanitarian Device Exemption

HIV — Human Immunodeficiency Virus

HUD — Humanitarian Use Device

ICH — International Conference on Harmonization

IDE — Investigational Device Exemption

INAD — Investigational New Animal Drug

INADA — Investigational New Animal Drug Application

IND — Investigational New Drug

IOM — Institute of Medicine

ISO — International Standards Organization

ISRS — Individual Safety Reports

IT — Information technology

JIFSAN — Joint Institute for Food Safety and Applied Nutrition

LACF — Low Acid Canned Foods

LAN — Local Area Network

MATS — Management Assignment Tracking System

MDR — Medical Device Reporting system

MOU — Memorandum of Understanding

MPRIS — Mammography Program Reporting and Information Systems

MQSA — Mammography Quality Standards Act

MRA — Mutual Recognition Agreement

NADA — New Animal Drug Application

NAFTA — North Atlantic Free Trade Agreement

NAFTA TWG — North American Free Trade Agreement Technical Working Group

NARMS — National Antimicrobial Resistance Monitoring System

NASS — National Agricultural Statistics Survey

NCI — National Cancer Institute

NCIE — Notice of Claimed Investigational Exemptions

NCTR — FDA National Center for Toxicological Research

NDA — New Drug Application

NDE/MIS — New Drug Evaluation Management Information System

NIAID — National Institute of Allergy and Infectious Diseases

NIDA — National Institute on Drug Abuse

NIEHS — National Institute for Environmental Health Sciences

NIH — National Institute of Health

NLEA — Nutrition Labeling and Education Act

NME — New Molecular Entity

NPR — National Partnership for Reinventing Government

NRC — National Research Council

NTP — National Toxicology Program

NVPO — National Vaccine Program Office

OASIS — Operational and Administrative System for Import Support

OBRR — Office of Blood Research and Review

OPA — CFSAN, Office of Premarket Approvals

ORA — FDA Office of Regulatory Affairs

ORISE — Oak Ridge Institute for Science and Education

OSHA — Occupational Safety and Health Administration

OTC — Over-the-counter

OTR — Office of Testing and Research (CDER)

PAS — FDA Public Affairs Specialist

PDPs — Product Development Protocols

PDUFA — Prescription Drug User Fee Act of 1992

PIFSI — Produce and Food Safety Initiative

PLA — Product License Application

PMA — Premarket Approval (Application to market medical device that requires premarket approval)

PODS — Project-Oriented Data System

PQRI — Product Quality Research Initiative

QSIT — Quality System Inspection Technique

RA — Rheumatoid Arthritis

RCHSA — Radiation Control for Health and Safety Act

REGO — Reinventing government initiative

RIMS — Regulatory Information Management Staff

RVIS — Residue Violation Information System

SAB — Science Advisory Board

SAMHSA — Substance Abuse and Mental Health Services Administration

SE — Salmonella Enteriditis

SN/AEMS — Special Nutritional Adverse Events Monitoring System

STARS — Submission Tracking and Review System

StmDT104 — Salmonella typhimurium DT 104

TB — Tuberculosis

TRIMS — Tissue Residue Information System

UK — United Kingdom

UMCP — University of Maryland-College Park

USDA — Unites States Department of Agriculture

VAERS — Vaccine Adverse Event Reporting System

VFD — Veterinary Feed Directive

VICH — Veterinary International Conference on Harmonization

WHO — United Nations World Health Organization

WTO — World Trade Organization