## FDA Glossary Compiled by: Yawtsong Lee Last updated: September 16, 2016 [Top] [Laws & Regulations] [FDA Organization] [SFDA 国食药监]

食品和药物管理局局长 Robert M. Califf, MD

食品和约物官理句句太 Robert M. Califf, MD	
2-(4-hydroxyphenyl) acetamide	2-(4-羟qiǎng苯基)乙酰胺
AAA = abdominal aortic aneurysm	腹主动脉瘤
ABCs = airways, breathing, circulation	气道、呼吸、循环
ABI/ACS = Automated Broker Interface of the	自动商业系统下的自动经纪人界面(CBP 的自动
Automated Commercial System	商业系统)
ABMS = American Board of Medical Specialities	美国医学专业委员会
absorbable collagen sponge	吸收性胶原海绵
absorption rate constant/absorption rate coefficient Ka	吸收速率常数/吸收速率系数
abstinence symptoms	戒断症状
ACA = Patient Protection and Affordable Care Act; Obamacare	患者保护与平价医疗法案; 奥巴马医改
Accelerated Approval regulation <sup>1</sup>	加速批准
access to medicine (ATM)	有药品可使用
ACCF = American College of Cardiology Foundation	美国心脏病学会基金会
accredited school	备案,立案学校
accuracy	准确度
Accutane, a brand of isotretinoin	异维(生素) A 酸;异维甲酸;保肤灵
ACE inhibitors = angiotensin converting enzyme inhibitors = ACEI	血管紧张素转化酶抑制剂
acetaminophen	扑热息痛;醋氨酚;对乙酰(xian)氨基酚
acid reflux	胃酸逆流
acidified food	酸化食品
ACO <sup>2</sup> : Accountable Care Organization	责任制医疗组织
ACR-20 improvement criteria (American College of	美国风湿病学会类风湿关节炎改善的基本定义要
Rheumatology)	求触痛关节数减少≥20% 肿胀关节数减少≥20%
	加上以下五条中三条好转≥20%
acrylamide	丙烯酰胺
ACS <sup>3</sup> = Automated Commercial System	自动商业系统
ACTH = adrenocorticotropic hormone	促肾上腺皮质激素
Actimmune (Interferon gamma-1 b) <sup>4</sup>	干扰素微克— 1b
action letter	决定通知
active comparator	活性对照药物;活性药物对照组
active control = AC	阳性对照,活性对照;阳性药
active ingredient	有效成分
Active Substance Master File (ASMF)	欧洲药物主文件
Actos (pioglitazone)	艾可拓(匹格列酮) (日本武田制药公司 Takeda
	的糖尿病药物)
acute myocardial infarction	急性心肌梗死
acute tibial fractures	急性胫骨骨折
Adalat XL <sup>5</sup> (Nifedipine Extended Release Tablets) by Bayer	硝苯地平缓释片;拜新同,心痛定、艾克地平
adalimumab (Humira) <sup>6</sup>	阿达木单抗

adaptive design	自适应设计
adaptive randomization	自适应随机
ADC <sup>7</sup> Antibody Drug Conjugates	抗体-药物偶联剂
ADE = adverse drug event	药物不良事件
adenosine	腺苷
adenoviral vectors	腺病毒载体
adequate and well-controlled studies	充分严格的对照研究
ADHD = Attention-deficit hyperactivity disorder	注意力缺陷多动障碍;注意力不足过动症;多动 症
adhesion barrier product	防黏著产品
adjuvant	助剂; 佐剂 auxiliary;
adjuvant therapy	佐药疗法,辅助疗法
ADL = activities of daily living	日常生活活动能力
ADME = absorption, distribution, metabolism, and excretion	药物的吸收、分布、代谢和排泄
administrative detention	行政扣留权
ADP Adenosine diphosphate <sup>8</sup>	腺嘌呤核廿二磷酸
ADR = adverse drug reaction	药物不良反应
adrenal cortex	肾上腺皮质
adrenal cortical hormone	肾上腺皮质激素
adrenal gland	肾上腺
adrenaline	肾上腺素
adrenoceptor	肾上腺受体
adrenocortical steroids	肾上腺皮质类固醇 me
adulterant	掺杂物
adulterated devices	掺假器械
AdvaMed = Advanced Medical Technology Association, medical technology (medical devices) trade association	先进医疗技术协会
adventitious infectious agents <sup>9</sup>	外来感染物
adverse drug reaction = ADR	药物不良反应
adverse effect	副作用
adverse event = $AE$	不良事件
adverse medical events	不良医学事件
adverse reaction (adverse event) <sup>10</sup>	药物不良反应
advisory	提醒
Advisory Committee on Medical Uses of Isotopes ACMUI	(美国)同位素医用咨询委员会
advocacy and support groups <sup>11</sup>	倡导和支持团体
$AE = adverse event^{12}$	不良事件
AERS = Adverse Event Reporting System; now FDA Adverse Event Reporting System (FAERS)	不良事件报告系统;
aflatoxin	黄曲霉素;黄曲霉毒素
Aflibercept <sup>13</sup>	阿柏西普
african sleeping sickness	非洲昏睡病;非洲锥虫病
AFSSAPS = Agence Française de Sécurité Sanitaire des Produits de Santé	法国卫生安全和健康产品委员会;法国医疗产品
	安全局
after effect	后遗效应

agency	审理部门(指FDA)
agonist	兴奋剂,激动剂,刺激物;竞争剂;拮抗剂
agonist, partial	部分激动药
AHA = American Heart Association	美国心脏病协会
AI = aromatase inhibitor	芳香酶抑制药
$AIP = Application Integrity Policy^{14} also Fraud$	防伪政策
Policy	
air embolism	气体栓塞
air handling	空气处理
air lock	阻隔室
alanine aminotransferase = $ALT^{15}$	丙氨酸氨基转移酶
ALARP region (as low as reasonably practicable)	尽合理可行程度的低
Alb = albumin	白蛋白
Alcohol and Tobacco Tax and Trade Bureau TTB	烟酒税务和贸易局
ALD = Approximate Lethal Dose	近似致死剂量
ALF = acute liver failure	急性肝功能衰竭
alkaline phosphatase <sup><math>16</math></sup> = ALP	碱性磷酸酶
alkylating agent	烷化剂
allele <sup>17</sup>	等位基因
allergenicity	致敏性
allergic shock	过敏性休克
allogeneic hematopoietic stem cell	异基因造血干细胞
allograft <sup>18</sup> transplantation	同种异体移植
allosteric AKT inhibitor	变构 Akt 抑制剂
ALOP = Appropriate Level of Protection	适当的保护水平
ALP = Alkaline phosphatase	碱性磷酸酶
alpha spending function	消耗函数
ALS = amyotrophic lateral sclerosis; Lou Gehrig's Disease	肌萎缩性脊髓侧索硬化;渐冻症
ALT = alanine aminotransferase	丙氨酸氨基转换酶
Alzheimer's Disease	老年痴呆症;阿尔茨海默氏病
Ambien (Zolpidem)	唑吡坦, 赛诺菲研制安眠药
amino acid sequence	氨基酸序列
aminoglycoside antibiotics	氨基糖苷类抗生素
amphetamines	安菲他明;苯丙胺
amyotrophic lateral sclerosis = ALS	肌萎缩侧索硬化
$ANA^{19} = antinuclear antibodies$	抗核抗体
analysis of covariance (ANCOVA) <sup>20</sup>	协变量分析
analysis sets	统计分析的数据集
analyte	待测物;分析物
Analyte specific reagents ASRs	分析物特异性试剂
anaphylaxis	过敏性反应; 过敏休克
ANDA = abbreviated new drug application	简化新药申请
angina pectoris	心绞痛
angioplasty	血管成形术
angioplasty balloons	血管修复气囊
animal trial	动物试验
Annual Product Reviews (APR)	年度产品审查

anotia	无耳;又称"无耳畸形"
antibiotic prophylaxis	预防性抗生素使用
antibiotic propriytaxis	抗生素抗性
antihistamine	抗组胺剂
Anti-Infective	抗退於药物
anti-inflammatory agents	抗炎药
anti-metabolites	抗代谢物;干扰代谢药物
antimicrobial resistance	耐药性
anti-neoplastic agent	抗肿瘤药
anti-nutrients	抗营养素
antipyretic, analgesics and anti-inflammatory drugs	解热镇痛抗炎药
anti-TNF agent; TNF blocker drugs	抗肿瘤坏死因子抑制剂
anti-TNF therapy	抗 TNF-a 治疗
AORN = Association of Perioperative Registered	美国围手术注册护士协会
Nurses	
aortic disease	主动脉疾病
aortic dissection	主动脉夹层
aortic stenosis	主动脉瓣狭窄
APEC	亚太经济合作组织
APHIS = Animal and Plant Health Inspection Service	动植物卫生检验局
APIC = Association of Professionals of Infection Control and Epidemiology	美国感染控制和流行病专业协会
APIs = active pharmaceutical ingredients / Drug Substance (bulk drug substances)	原料药 / 活性药用成分
aplastic anemia = pancytopenia	再生障碍性贫血
apoptotic	细胞凋亡的
Appropriate Level of Protection (ALOP)	适当的保护水平
approval	批准
approved drugs	已批准药物
approximate lethal dose = $ALD$	近似致死剂量
aprotinin	抑肽酶
AQSIQ = China's General Administration for Quality Supervision, Inspection and Quarantine	国家质量监督检验检疫总局;质检总局
arachidonic acid	花生四烯酸
Arava = leflunomide	爱若华(来氟米特)
archival copy	存档用副本
Area Under the Curve = AUC; area under the	药时曲线下面积/血药浓度-时间曲线下面积
plasma concentration-time curve	
ARGNB = antibiotic-resistant gram-negative bacilli	耐药革兰阴性杆菌
ARM <sup>21</sup>	组
arrhythmia	心律不齐
arsenicals = arsenic compounds	砷化合物
artery infusion	动脉滴注
artificial discs	人造脊椎
artificial heart valve	人工心脏瓣膜
artificial pancreas	人工胰脏
AS = ankylosing spondylitis	强直性脊柱炎
no – unkyrosnie spondynus	历且任何狂火

ASCO = American Society of Clinical Oncology	美国临床肿瘤学会
ASD = atrial septal defect	房间隔缺损
aseptic packaging	无菌包装
Asian Harmonization Working Party = AHWP	医疗器械法规亚洲协调会
aspartate aminotransferase = $AST^{22}$	天门冬氨酸氨基转移酶
aspergillin	曲霉菌素
aspergillus flavus	黄曲霉
aspergillus ochraceus	赫曲霉
ASR = alternative summary reports	
assay	化验
assay constancy CA	检验恒定性
assay sensitiviy AS	检验灵敏度
assistant investigator = AI	助理研究者
assurance <sup>23</sup>	临床试验许可
AST = antimicrobial susceptibility test	药敏试验 = 抗菌药物敏感性试验
AST = aspartate aminotransferase	天门冬酸氨基转换酶
ASTM International (ASTM), originally known as	美国材料与试验协会
the American Society for Testing and Materials	
AstraZeneca	阿斯利康
as-treated analysis <sup>24</sup>	接受治疗分析
atopic dermatitis = AD	异位性皮炎
atorvastatin	阿托伐他汀非诺贝特片 cholesterol-lowering
	drug
ATP adenosine triphosphate	腺嘌呤核甘三磷酸
ATR = attenuated total reflection	衰减全反射法
attenuated total reflection = ATR	衰减全反射法
AUCss = area under the plasma concentration-time	稳态血药浓度-时间曲线下面积
curve at steady-state audit <sup>25</sup>	the total and to
	稽查
audit or inspection	稽查 / 视察
audit report auditor	稽查报告
autoimmune disease, AID	稽查员
	自身免疫病
autologous marrow stem cell transplantation	自体骨髓干细胞移植
autologous structural cells Automated Broker Interface of the Automated	自体结构细胞
Commercial System = ABI/ACS	自动商业系统下的自动经纪人界面
Automated Commercial System	自动商业系统
autonomic neuropathy	自主神经病变
autophosphorylation	自体磷酸化
availability of water	有效水分
Avandia (rosiglitazone) <sup>26</sup>	商品名: 丈迪雅; 通用名: 罗格列酮
Avastin = Bevacizumab	阿瓦斯丁; 贝伐单抗; 抗血管内皮生长因子单克
	隆嵌合抗体
Avelox (Moxifloxacin) by Bayer	莫西沙星;拜复乐
Aventis Pharma	安万特医药
average concentration/average concentration value = Cav	平均浓度
B. Cereus = Bacillus cereus	蜡状芽孢杆菌

B.atrophaeus	草芽孢杆菌黑色变种
bacilli	芽孢杆菌
Bacillus anthracis	炭疽芽胞杆菌
bacterial endospores	细菌芽孢
bacterial spore	细菌孢子
bar code	条(形)码
barbiturates	巴比妥盐
basal metabolic rate	基础代谢率
baseline	基线
basiliximab (trade name Simulect)	一 至 3 舒 菜;治疗肾移植排斥药
batch production	批量生产;分批生产
batch release	批放行
Baycol ( cerivastatin sodium )	拜斯亭;西立伐他汀;降血脂新药
Bayer Schering Pharma	拜耳先灵医药
BCG Boston Consulting Group	波士顿咨询公司
BCPNN (Bayesian Confidence Neural Network)	贝叶斯置信传播神经网络法
bench test	实验室试验
benefit	受益
benzodiazepine <sup>27</sup>	苯重氮基盐;苯二氮卓类抗焦虑药28
benzoic acid	安息香酸
Best Pharmaceuticals for Children Act 2002	《最好的儿童医药品法案》
beta-blocker	β-受体阻滞剂
Betaferon/ Betaseron <sup>29</sup> (Interferon Beta-1B) by Bayer	倍泰龙(干扰素 β-1b)
Bextra (valdecoxib)	伐地考昔(镇痛类药物)
BfARM = Bundesinstitut für Arzneimittel und	德国联邦药品和医疗器械管理局
Medizinprodukte	
BHC = Bayer HealthCare	拜耳医药保健有限公司
bias <sup>30</sup>	偏倚
bicohort study	双队列研究
bilirubin	胆红素
BIMO Bioresearch Monitoring Program <sup>31</sup>	生物研究监测(监督)项目
binding antibody	结合抗体
bioassay	生物检定
bioavailability (F) <sup>32</sup>	生物利用度
bioburden <sup>33</sup>	菌落总数
biochemical drugs	生化药品
biocides	生物杀灭剂;杀生物剂
biocompatibility <sup>34</sup>	生物相容性;
biodegradable	生物分解
bio-engineered, transgenic food	转基因食物
bioequivalence; bioequivalent i.e., performs in the same manner as the innovator drug	生物等效
biofilm <sup>35</sup>	细菌薄膜, 生物膜
biologic <sup>36</sup>	生物制品
biological response modifiers BRM <sup>37</sup>	生物应答调节剂
biological therapeutic agents	生物治疗药剂
Biologics Price Competition and Innovation Act	《生物药价格竞争及创新法》
21010gres Trice Competition and Infortation field	

(BPCI Act)	
biomarker <sup>38</sup>	生物标志物
biometrics	生物统计;生物识别技术
bion stimulator	生物体刺激器
bionic knee	仿生膝关节
biopharma: biopharmaceutical products	生物药物产品
biopharmaceutic study <sup>39</sup>	
biosimilar <sup>40</sup>	生物仿制药,生物类似物,生物拟似物
bipolar	双极燥郁症
birth defect	出生缺陷,新生儿缺陷,先天缺陷
bisphosphonate	双磷酸盐
BiTEs (Bi-specific T-cell engagers) <sup>41</sup>	
BLA = biologic license application	生物制品许可申请
blank control	空白对照
blend uniformity analysis <sup>42</sup>	
blind <sup>43</sup>	
blind codes	
blind review <sup>44</sup>	
blinding method	
blinding/ masking	
blister packaging	
block	泡罩包装;水泡眼       分段;层
block size	
blocked randomization	
blood biochemistry	
blood thinner	
blood urea nitrogen = BUN	
Blue Book Memoranda <sup>45</sup> , ODE	
BMP = bone morphogenetic proteins	马取卡皮ム
101	骨形成蛋白 百时美施贵宝公司
BMS ( Bristol-Myers Squibb )	
BNF = biotechnology notification file	生物工程通报档案
Board Certified	专科认证
Board Certified rheumatologist	美国专科认证的风湿病学家
Body Mass Index = BMI	体质指数
bolus amounts	大剂量
bone grafting	骨移植
bone marrow suppression	骨髓抑制
bone turnover marker BTM	骨转换标志物
botulinum	肉毒杆菌
botulism	肉毒中毒
boxed warnings	黑框警告
brachytherapy seeds	放射性粒子源近距离治疗
bradycardia	心动过缓
Breakthrough Therapy Designation <sup>46</sup>	突破性疗法认定
breast implants, Polyurethane-coated	乳房植入物, 聚亚安酯包囊;隆胸
bridging study <sup>47</sup>	桥接研究
bromfenac	溴 xi ù 酚酸

Def = Def no opening of the computery interest BUFA (Biosimilar User Fee Act) BUFA (Biosimilar User Fee Act) Calibration CABC = corneary attrey bypass graft CAD cornary attrey bypass graft CAD cornary attrey bypass graft CAD cornary attrey bypass graft Calibration CAD (Carrent Blockers = CCB Gialtration Calibration Calibration Calibration CAP = corrective action plan by drug sponsor DLF (Birth Al) CAPA (Corrective & Preventive Action) system Cardiac Er (Cetrophysiology) Cardia EP (Cetrophysiology) Cardia EP (Cetrophysiology) Cardia CP (Cornective & Breventive Action) system Cardiac resynchronization thrapy Cardia CP (Corrective & Def Age Action Carel Ink & Ba Cardiac resynchronization thrapy Cardiac P (Corrective & DE Age Action Carel Ink & Ba Cardiac Cornective (CE Age Age) Cardiac Cornective (CE Age Age) CE Cornective (CE Age	BSE = Bovine Spongiform Encephalopathy; mad	疯牛病;牛海绵状脑病
BsUFA (Biosimilar User Fee Act)         生物相似药品用户費用法           BU = Business Units         等业单位           BU = Business Units         等业单位           BUR = blood urea nitrogen         尿素氮           Bureau of Customs and Border Protection = CBP         美国海美台边技能が局           CABG = corronary artery bypass graft         見状助泳身路移植木: 冠状动脉海路移植木: 冠状动脉海路移植木: 冠状动脉海路手           CAG = Compound Annual Growth Rate         各均复合增长单           calcium antagonists         好枯杭剤           calcium channel blockers = CCB         好這距滑剤           calibration         校准: 标定: 校验           campylobacter         夏歯井菌           campylobacter fetus         胚胎旁面杆菌           cannulas         委管           CAPA (Corrective & Preventive Action) system         約正行动計划           CAPA (Corrective & Preventive Action) system         約正行动计划           Cardiac arbythmia         -公羅大衛愛           carcinogenic risk assessment, procedures for         技術人参加           carcinogenic risk assessment, procedures for         技術人参加           cardiac arbythmia         -公羅大衛愛           cardiac arbythmia         -Saturd*           carbythmia         -Saturd*           carcinogenic risk assessment, procedures for         技術人参加           careriskoft         Carbitof		派了 所; 7 母师 1人 阳 府
BU = Business Units         事业单位           Bubb elak test         満理气泡測成           BUN = blood urea nitrogen         尿素気           Bureau of Customs and Border Protection = CBP         美国海关与边境保护局           C. botulinum (proteolytic) = Clostridium botulinum, 内参板状芽胞杆菌 (蛋白质水解型)         CABG = cornary artery bigsas graft           CAB Coronary artery bigsas graft         短北动脉旁路移植木; 延沢动脉搭檐手木           CAD coronary artery disease         短心病           calcium channel blockers = CCB         钙道阻滞剂           calcium channel blockers = CCB         钙道阻滞剂           calcium channel blockers = CCB         钙道阻滞剂           campvlobacter fetus         医胎弯曲杆菌           campvlobacter fetus         医胎弯曲杆菌           campulobacter legini         空肠弯杆菌           carinogeneicity study         黄瘤杜病兒           carinogenic risk assessment, procedures for         黄海人屋市体花           Cardiac arshytchronization therapy         心脏長力を塗           cardia respichronization therapy         心脏長力を塗           carticel         坦源火道板砂           cartisel antix         転音基素           care record form         黄術报書表           cardiar espichronization therapy         动此所可 少症所引きえ/病例記表           care link Monitor         Carel ink 监が           care record form         病例祖	BsUFA (Biosimilar User Fee Act)	生物相似药品用户费用法
BUN = blood urea nitrogen $\bar{R} \pm \bar{s}_{i}$ Bureau of Customs and Border Protection = CBP $\bar{\xi}$ 图 $\bar{k} \pm \bar{k}_{i} $		
Bureau of Customs and Border Protection = CBP $\xi$ [ $ijk$ , $\xi$ , $jjk$ , $\xi$ , $jjk$ , $\xi$ , $jkk$ , $kk$ ,	bubble leak test	漏泄气泡测试
Bureau of Customs and Border Protection = CBP         美国海关与边境保护局           C. botulinum (proteolytic) = Clostridium botulinum         内毒板状芽孢杆菌(蛋白质木解型)           CABG = coronary artery bypass graft         冠北动脉旁路移植木; 冠状动脉搐桥手木           CAD coronary artery disease         冠之动病           Calcar         平均复合増禾車           calcium antagonists         钙拮抗剤           calcium antagonists         钙拮抗剤           calcium channel blockers = CCB         钙道阻滞剤           calibration         核准: 标定;核验           campylobacter Feus         運動背菌           campylobacter Flyini         空肠骨杆菌           campulobacter Jejuni         空筋骨杆菌           campulobacter Jejuni         空筋骨杆菌           carinulas         春管           CAP a (corrective & Dreventive Action) system         刘丘贞病防潜施系统           Caritation <sup>48</sup> 壮人头付費           carcia carnylthmia <sup>calk</sup> 建木           cardiac arbythmia <sup>calk</sup> 建木           cardiac arbythmia <sup>calk</sup> 建木           cardiac arbythmia <sup>calk</sup> 建木           cardia resynchronization therapy <sup>calk</sup> 生           cardia resynchronization therapy <sup>calk</sup> 生           cardiac respectronization therapy <sup>calk</sup> 生           cardia resphotionary therap = <td>BUN = blood urea nitrogen</td> <td>尿素氮</td>	BUN = blood urea nitrogen	尿素氮
C. botulinum (proteolytic) = Clostridium botulinum 内泰被決芽絶杆菌(蛋白质水解型)         CABC coronary artery bypass graft       現北动脉旁路移植木; 冠北动脉溶格桥手木         CAD coronary artery bypass graft       現北动脉旁路移植木; 冠北动脉溶格桥手木         CAD coronary artery disease       現心病         Calberation       年均复合增长率         calibration       校准: 抗定: 校验         calibration       枝准: 抗定: 校验         campylobacter fetus       医胎旁歯杆菌         campylobacter fetus       医胎旁肉甘菌         campylobacter fetus       長子切打动         CAP corrective action plan by drug sponsor       纠正方动防潜地系统         Carliation <sup>18</sup> ベ人久骨         Carci study, carcinogenecity study       成点水解明空         carcinogenic risk assessment, procedures for       双胞小動骨を放行         Cardiac EP (electrophysiology)       心離長常         cardia resynchronization therapy       心脏長子の         carticel       组织工程软骨移植疗法         caraliage matrix       転行基度         case report form       病例报告表         case report form       病例报告表         case report form       東側报書和         cash istory       第         Gardia EP       金属門         Carlia EP (electrophysiology)       心離天常         carticel       组织工程序设定         cartiage matr	Bureau of Customs and Border Protection = CBP	
CABG = coronary artery bypass graft         規載劫脉旁路移植术; 稅狀劫脉搭桥手术           CAGR = Compound Annual Growth Rate         年均复合增长车           calcium atagonists         钙拮抗剂           calcium channel blockers = CCB         钙道阻滞剂           calcium atagonists         钙拮抗剂           calcium atagonists         钙结抗剂           calcium atagonists         钙拮抗剂           calcium atagonists         ビドン           campylobacter         宮由井首           campylobacter Jejuni         空助弯杆首           campylobacter Jejuni         空助弯杆首           carbin atagonists         村工行动计划           CAP = corrective action plan by drug sponsor         利工与预防措施系统           Capacitation <sup>18</sup> 校人头付費           carcinogeneic risk assessment, procedures for         发点火付費           carcinogenic risk assessment, procedures for         公律失常           cardiac arrhythmia         心律失常           cardiac resynchronization therapy         心脏电力生理           cardiac resynchronization therapy         心能常力           carrinogenic risk assessment, procedures for         近常成点           cardiac arrhythmia         心律未常           cardiac resynchronization therapy         心能見思力           cardiac resynchronization therapy         心能電力           carelin K Mon	C. botulinum (proteolytic) = Clostridium botulinum	
CAD coronary artery disease       短心病         CAGR = Compound Annual Growth Rate       年均复合增长率         calcium antagonists       钙拮抗剂         calcium antagonists       钙拮抗剂         calcium channel blockers = CCB       钙适阻溶剂         calibration       枝准:标定:枝脸         campylobacter fetus       胚胎弯歯杆菌         campylobacter Jejuni       空肠弯杆菌         cannulas       套管         CAP = corrective action plan by drug sponsor       纠正行动计划         Capitation <sup>45</sup> 桜人头代費         carc study, carcinogenecity study       玻慮性研究         carcinogenic risk assessment, procedures for       炎瘡风風い骨が         cardiac EP (electrophysiology)       心脏中力生理         cardiac EP (electrophysiology)       心脏中力生理         cardiac resynchronization therapy       心脏 和量素         carryover effect       延滞成点         Carriele       组织工程软骨移植疗法         caratilage matrix       軟骨基         case report form       病例报告表/病例记表表/         case report form       病例报告表/         cash curve       現金時所         case report form       病例报告表         cash curve       現金指示         Cardia FP (electrophysic)       第         Caretiset       分素受量		
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calcium antagonists       钙结杭剂         calcium channel blockers = CCB       钙道阻滞剂         calibration       枝准:标定;校验         campylobacter       弯曲杆菌         campylobacter Jejuni       空肠弯杆菌         cannylobacter Jejuni       空肠弯杆菌         cannulas       套管         CAP = corrective action plan by drug sponsor       纠正与预防措施系统         Captation <sup>48</sup> 接人头付费         carcinogenic risk assessment, procedures for       炭瘟风险评估程序         cardiac resynchronization therapy       心脏并受索         Carticel       组织工程软骨移植疗法         cartilage matrix       軟骨基质         case record form = CRF       病例根書素/病例记录素         cash curve       現金輸現         cash curve       現金管室         cathers       等量         cathab bypass       导管室搭桥         Cav       平均浓度         CBE cupplement "Changes Being Effected"       "正在进行修改" 补充申请         supplement (FDA)       CBRN chemical, biological, radiological and         culcar       CarGa and Border Protection)       美国海关与边境保护局         Care invexita, 就有, 标载, 核 (威夸)       (aclear         care cord form       CRF       公前核小教局         cash curve       現金          cash curve		
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CCFAC = Codex Committee on Food Additives and 食品添加剂和污染物法典委员会 Contaminants		公司核心数据表
Contaminants		
CCFH = Codex Committee on Food Hygiene	Contaminants	
	CCFH = Codex Committee on Food Hygiene	食品卫生法典委页会

CCT = controlled clinical trial	对照临床试验
$CCyR^{50}$ = complete cytogenetic response	细胞遗传学完全应答
CD = circular dichroism	圆二色谱
CDER = Center for Drug Evaluation & Research	药品审评和研究中心
CDR <sup>51</sup> Challenge-dechallenge-rechallenge	给药-停药-再次给药
CDRH = Center for Devices and Radiological	器械与辐射保健中心
Health	
CE mark <sup>52</sup>	CE 认证标记
Celebrex (celecoxib)	西乐葆; COX-2 特异性抑制剂; 塞来考昔
cell bank	细胞库
cell line	细胞株
censored data	删失数据
censoring	【统计】 - 删截
Center for Biologics, Food and Drug Administration	生物制品中心
Center For Food Safety and Applied Nutrition =	食品安全与应用营养中心
CFSAN	Ku XIJZMAN I
CEP = Certificate of Suitability to the Monograph of the European Pharmacopoeia; Certificate of Suitability to the EP	欧洲药典适应性证书
cephalosporins	头孢菌素类抗生素;
cerebellar atrophy	小脑萎缩
cerebellar malformation	小脑畸形;小脑发育畸形
cerebral infarction	脑梗塞
cerezyme	伊米苷酶,治疗罕见戈谢病(高雪氏病)
Certificate of Suitability to the EP (CEP)	欧洲药典适用性证书
cetuximab; Erbitux <sup>53</sup>	爱必妥
CFG = Certificate for Foreign Government	致外国政府证书
CFR = code of federal regulations	(美国)联邦法规;《美国联邦管理条例》
CFSAN = Center For Food Safety and Applied	食品安全与应用营养中心
Nutrition	
CFU = colony forming unit	菌落形成单位
cGMP's = current good manufacturing practice	现行生产质量管理规范
CGMS = continuous glucose monitoring system	动态血糖监测
Chagas disease (also called American	美洲锥虫病;恰加斯病
trypanosomiasis)	
Challenge-dechallenge-rechallenge = CDR	给药-停药- 再次给药
Change Control	A formal system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect the validated status of facilities systems, equipment or processes
channeling bias <sup>54</sup>	facilities, systems, equipment or processes 渠道偏倚
CHB = customs house broker	* 坦 個 何 报关行
chemotherapeutics in seafood (aquaculture drug	- 扱大门 - 药
residues)	Σ.Λ Ξ
CHF congestive heart failure	充血性心力衰竭
Child-Pugh	Child-Pugh 分级标准
Chi-square test/Chi-Square Goodness-of-Fit Test	卡方检验
chlorambucil	苯丁酸氮芥
CHMP = Committee for Medicinal Products for	
CHIVIF = COMMITTUEE FOR IVIEURCINAL PRODUCTS FOR	人用药品委员会

Human Use	
cholestatic hepatitis	胆汁郁积型肝炎
Cholestyramine	考来烯胺
CHR = Complete hematologic response55	血液学完全应答
chromatography	色谱
chronic myelocytic leukemia, chronic granulocytic	慢性粒细胞白血病
leukemia, CML, CGL	
chronic obstructive pulmonary disease = COPD	慢性阻塞性肺疾病
Chronic Wasting Disease (CWD)	鹿慢性消耗性疾病
CIOMS = Council for International Organizations	国际医学科学组织委员会
of Medical Sciences	
circular dichroism <sup>56</sup> = CD	圆二色谱;
cirrhosis	肝硬化
cirrhosis of liver without mention of alcohol	未提及酒精的肝硬化
citation	传唤
CJD = Creutzfeld-Jakob disease	克-雅病
CL = clearance rate	清除率
	宣示
CLASS (Celecoxib Long-term Arthritis Safety Study) 57	塞来考昔长期关节炎安全研究
class effect <sup>58</sup>	药物类效应
clearance rate = CL	清除率
cleft palate	7月15千 腭裂
CLIA Clinical Laboratory Improvement	临床实验室改进修订案
Amendments	加水大拉主议近时以来
clinical (human) data	临床数据
clinical equivalence	
clinical hold	临床试验暂停(通知)
clinical investigator <sup>60</sup>	临床研究者
Clinical Pharmacists	临床药师
Clinical Research Coordinator = CRC	临床研究协调者
clinical study	临床研究
Clinical Study Application = CSA	临床研究申请
clinical study report	
clinical trial <sup>61</sup>	临床试验
clinical trial application = CTA	
clinical trial exemption = CTX	
clinical trial protocol = CTP	
Clinical Trial Report = CTR	临床试验报告
clinically inactive pituitary adenoma, CIPA	临床无活性垂体腺瘤
clinically significant results	有临床意义
Clopidogrel	氯吡格雷 抑制血小板药物 保栓通
closed loop system	闭路系统
Clostridium botulinum	
Clostridium difficile <sup>62</sup>	
Clostridium sporogenes	
clinical equipoise <sup>59</sup> clinical equivalence clinical hold clinical investigator <sup>60</sup> Clinical Pharmacists Clinical Research Coordinator = CRC clinical Research Coordinator = CRC clinical study Clinical study Application = CSA clinical study report clinical study report clinical trial application = CTA clinical trial application = CTA clinical trial protocol = CTP Clinical trial protocol = CTP Clinical Trial Report = CTR clinically inactive pituitary adenoma , CIPA clinically significant results Clopidogrel closed loop system Clostridium botulinum	临床研究者 临床药师 临床研究协调者 临床研究申请 临床试验的总结报告 临床试验申请 临床试验免责 临床试验免责 临床试验无案 临床试验报告 临床式验报告 临床无活性垂体腺瘤 有临床意义 氯吡格雷 抑制血小板药物 保栓通

峰浓度
化学、生产和控制
相互认可和分散化规程合作组织
继续医学教育
美国老年医疗保险基金中心与穷人医疗救助基金
服务中心;美国医疗保险和医疗补助服务中心
(拜耳医药保健有限公司的)规范管理系统
有关成员国
巨细胞病毒
中枢神经系统异常
脉络膜新生血管
分析证书
合并用药; 与其它药物联合使用
涂层
国际食品法典委员会
并存生理状况
分析证明书
主营业务成本
队列
队列研究
合作研究者
胶原
胶原酶
寄殖
集落刺激因子
结直肠癌
复合产品
组合用药;联合用药治疗
商业发行
社区获得性细菌性肺炎
基于社区的临床试验
并存疾病;共患病;合并疾病
罕用药委员会
对照
体恤使用
竞争性抑制
优越标签
补充性和非传统治疗
完全有效
完全答复函(FDA 不批准通知)
合规; 遵守; 对遵守法规情况的监管
病人顺从性,依从性
复合变量
复方药房;调剂药房
压缩试验
原子计算机建模

computer-assisted trial design = CATD	计算机辅助试验设计
con meds = concomitant medications	F 并机辅助试验设计 联合用药
concentration = C	浓度
concurrent control	平行对照
condemnation	117月7月 报废
condemnation cone beam CT, CBCT	
confidence interval = CI	锥形束CT
	可信区间;置信区间
confidence level	置信水平
confidentiality regarding trial participants <sup>67</sup>	为试验参与者保密
confirmatory trial	验证性试验
confounding variable	混淆变量
congenital analgesia	先天无痛
congenital anomaly	先天性异常
congenital long QT syndrome	先天性长QT综合征
conjugate <sup>68</sup>	结合物
consent decree	服罪判决书;同意判决书
consignee	收货人
consistency test	一致性检验
contagious disease	接触传染病
context of vulnerability <sup>69</sup>	肿瘤的薄弱基因环境
Continuous Process Verification	An alternative approach to process
	validation in which manufacturing process
	performance is continuously monitored and
	evaluated
contract research organization = CRO	合同研究组织
contraindication <sup>70</sup>	禁忌;禁忌症
contrast agent	造影剂
control	对照
control group <sup>71</sup>	对照组
controlled clinical trials	临床对照实验
controlled substance	管控物质;管制药物
controlled substance scheduling	管控物质归类(调度);
controlled trials <sup>72</sup>	对照试验
convulsion	惊厥;又叫抽风
coordinating committee	协调委员会
coordinating investigator = COI	协调研究者
CO-Oximeter, pulse	脉搏血氧计
COPD = chronic obstructive pulmonary disease	慢性阻塞性肺疾病
COPE = International Coalition of Pacing and	国际整律与电生理学组织联盟
Electrophysiology Organizations	
coronary artery disease	冠状动脉疾病
coronary heart disease = CHD	冠心病
coronary stents	血管支架
coronary vascular disease	冠状血管疾病
cortical stimulation	刺激皮层
corticosteroid	皮质甾类(的),皮质类固醇
cortisol; glucocorticosteroid	糖皮质激素
cost overrun	成本超支;费用超支
	1八个人之义,贝川人之义

coumadin	苄丙酮香豆素钠[抗凝血药];香豆定,3-(α-丙酮基苄基-4-羟基香豆素)
Covington and Burling, LLP limited liability	科温顿•柏灵律师事务所
partnership	
COX = cyclooxygenase	环氧化酶
COX-2 inhibitor	COX-2 抑制剂; e.g. 罗非昔布
coxachie virus	柯萨奇病毒
$Cp = Process Capability^{73}$	工序能力
CPAP = Continuous Positive Airway Pressure	持续气道正压通气治疗(仪); for sleep apnea;
CPDER = Center For Post-market Drug Evaluation	上市后药品评价研究中心
and Research	
CPG (Compliance Policy Guides) <sup>74</sup>	合规政策指南 (CPG)
CPGM Compliance Program Guidance Manuals <sup>75</sup>	合规项目指导手册
CPIC = Clinical Pharmacogenetics Implementation	临床药物基因组学实施联盟
Consortium	
Cpk = Process Capability Index <sup>76</sup>	工序能力指数
CPMP = Committee for Proprietary Medicinal Product	专卖医疗产品委员会
CPP = Critical Process Parameter	关键工序参数
CQA = critical quality attribute77	· 关键质量属性
cranial nerve	· 大碇坝里偶住 · · · · · · · · · · · · · · · · · · ·
CRC = colorectal cancer	70/1+52 结直肠癌
$creatine^{78} = Cr$	肌酸
creatine kinase = CK	肌酸激酶
creatinine <sup>79</sup> = $Cr/Crea$	
CRF = case report form	肌酐 gan 病例报告表
Crimean-Congo haemorrhagic fever virus	· 对问报 古衣 克里米亚 — 刚果出血热病毒
critical path <sup>80</sup>	<u> </u>
Crizotinib <sup>81</sup> (Xalkori)	
CRM = continual reassessment method	克里唑蒂尼胶囊 连续重新评估方法
crossover design	· 廷瑛里制许佰万法
cross-over study <sup>82</sup>	
crossover therapy	交叉研究
CRP (C-reactive protein) <sup>83</sup>	交义治疗 血清 C-反应蛋白
CRPC <sup>84</sup> castration-resistant prostate cancer	
cryptosporidium parvum	去势抵抗性前列腺癌
Css = steady-state concentration	小球隐孢子虫
-	稳态血药浓度; 稳浓度
CT Computed tomography CTCAE = Common Terminology Criteria for	计算机断层技术 不良事件的通用术语标准
Adverse Events	个尺争仟的週州不诺标准
$CTD = Common Technical Document^{85}$	通用技术文件
CTLA4 (Cytotoxic T-Lymphocyte Antigen 4)	────────────────────────────────────
CTP = Comprehensive Toxicological Profile	全面毒理学综述
Ctrough,ss	稳态谷值浓度
cure	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
CV = cardiovascular event	· 心血管事件
CVMP = Committee for Medicinal Products for	<ul><li>总监督书件</li><li>兽用药品委员会</li></ul>
Veterinary Use	
CVTE = cardiovascular thrombolic events	心血管血栓事件

CYA <sup>86</sup> mentality (Cover Your Ass)         銀清貴任:明郁保身的心态           CYA <sup>86</sup> mentality (Cover Your Ass)         銀清貴任:明郁保身的心态           cyanosis <sup>73</sup> 常母           cyclopport dependent kinase; CDK         週期素濃輝           cyclopport acyctanesis         圓孢子&火           cyclosport acyctanesis         圓孢子&火           CYP 50         corn metabolizer           CYP box metabolizer         CYP box fita.%           cytokine         mb应月子           cytokine storm         mb应月子           cytokine storm         mb应月不           cytostatic         mb应月不           cytostatic         mb应月子           cytostatic         mb应月           cytostatic         mb应月           cytostatic         mb应月           cytostatic         mb应月           cytokine storm         mb应月           cytokine storm         mb应月           cytokine storm         mbc月	CyA = cyclosporin A	环孢素 A;
cyanosis <sup>87</sup> 常細       cyclin-dependent kinase; CDK     週期素激酶       cyclopsprin A= CyA     环孢素A;       CYP <sup>85</sup> = Cyclorhrome P450 (abbreviated P450, infrequently CYP450)     知胞色素 P450 @       CYP 90 Corbrrome P450 (abbreviated P450, infrequently CYP450)     知胞色素 P450 @       CYP 90 Corbrrome P450 (abbreviated P450, infrequently CYP450)     知胞色素 (CYP 006 弱代谢者       CYP probe substrates     CYP 66 孩代说者       CYP probe substrates     CYP 66 孩代说者       cytokine storm     如胞色素       cytokine storm     如胞色素       cytokine storm     如胞色素(性)药物       Data pdata     法比加年額; 新型口服抗凝苛, 由徳間勃林格殼       Adward for and Safety Monitoring Board = DSMB <sup>50</sup> 数据及金金鉴测奏员会       Data and Safety Monitoring Board = DSMB <sup>50</sup> 数据基進調委員会       Data and Safety Monitoring Boards     数据能量、Chased       DMAC = Division of Drug Marketing, Advertising, and Communications     費品領售, 广告和信息处       DMAC = Division of Drug Marketing, Advertising, and Communications     費品領售, 广告和信息处       De novo process <sup>44</sup> (Kri Saki) 全新分表表成進尽       De novo process <sup>44</sup> (Kri Saki) 全新公表       DEA = Drug Enforcement Administration     美国維泰局       DEA core letters     女医疗足生人員的一封信       dear octor letters     女医疗足生人員的一封信       dear octor letters     女医疗足生人員的一封信       dear doctor letters     女医疗足生人員的一封信       dear	CYA = cyanocycline A	蓝环素A
cyclin-dependent kinase; CDK         週期素激酶           cyclophosphamide (Cytoxan)         环場税股           Cyclospora cayctanesis         週池子球虫           cyclospori A = CyA         环絶素 A;           CYP <sup>59</sup> = Cytochrome P450 (abbreviated P450, infrequently CYP450)         細胞色素 P450 時           CYP D26 poor metabolizer         CYP B6 poor metabolizer         CYP P06 substrates           CYP probe substrates         CYP B6 poor metabolizer         CYP B6 poor metabolizer           Cytokine         細胞色素         空性太気射化塩炎比、素粉丸気性纤维化、素肿性纤维 支性太気射化塩炎比、素化           cytokine         細胞目子         eytokine           cytokine         細胞点引         eytokine           cytokine         細胞目子         eytokine           cytokine         細胞点引         eytex           cytokine         細胞点引         eytex           cytokine         細胞目子         eytokine           cytokine         細胞目子         eytokine           cytokine         細胞目子         eytokine           cytokine         細胞に <td< td=""><td></td><td>撇清责任;明哲保身的心态</td></td<>		撇清责任;明哲保身的心态
cyclin-dependent kinase; CDK         週期素激酶           cyclophosphamide (Cytoxan)         环場税股           Cyclospora cayctanesis         週池子球虫           cyclospori A = CyA         环絶素 A;           CYP <sup>59</sup> = Cytochrome P450 (abbreviated P450, infrequently CYP450)         細胞色素 P450 時           CYP D26 poor metabolizer         CYP B6 poor metabolizer         CYP P06 substrates           CYP probe substrates         CYP B6 poor metabolizer         CYP B6 poor metabolizer           Cytokine         細胞色素         空性太気射化塩炎比、素粉丸気性纤维化、素肿性纤维 支性太気射化塩炎比、素化           cytokine         細胞目子         eytokine           cytokine         細胞点引         eytokine           cytokine         細胞目子         eytokine           cytokine         細胞点引         eytex           cytokine         細胞点引         eytex           cytokine         細胞目子         eytokine           cytokine         細胞目子         eytokine           cytokine         細胞目子         eytokine           cytokine         細胞に <td< td=""><td>cyanosis<sup>87</sup></td><td>紫绀</td></td<>	cyanosis <sup>87</sup>	紫绀
cyclophosphamide (Cytoxan)         坏磷酰胺           Cyclospora cayetanesis         國港子球点           cyclosporin A = CyA         环稳素 A:           CYP DS = Cytochrome P450 (abbreviated P450, infrequently CYP450)         环胞急素 P450 節           CYP Drop on metabolizer         CYP Bix F4x, a           CYP Drop on metabolizer         CYP Bix F4x, a           CYP Drop on metabolizer         CYP Bix F4x, a           cytochrome         500 Bix City A           cytochrome         500 Bix City A           cytokine storm         500 Bix City A           cytostatic         500 Bix City A           Data And Safety Monitoring Board = DSMB <sup>401</sup> 500 Bix City A           Data Monitoring Committees <sup>91</sup> (DMCs) (also know as Data and Safety		週期素激酶
Cyclospora cayetanesis         関抱子球虫           cyclosporin A = CyA         环孢素 A;           CYP8 <sup>55</sup> = Cytochrome P450 (abbreviated P450, infrequently CYP450)         細胞色素 P450 戶           CYP D0 poor metabolizer         CYP 2D6 前代謝者           CYP pois substrates         OYP 商塚社&A           cytokine         如胞包素           cytokine         如胞目子风暴 <sup>m</sup> cytokine         如胞目子风暴 <sup>m</sup> cytokine         如胞見子风暴 <sup>m</sup> cytokine storm         如胞肉子           cytokine drugs         細胞素           Data and Safety Monitoring Board = DSMB <sup>90</sup> & 基准及全全监测表员会           data mining         数基及全全监测表员会           Data And Safety Monitoring Boards         数据鉴之观           DBS = deep brain stimulation         脑深部电刺激技术           DBMS = deep brain stimulation         脑深部电刺激技术           DBA = Drug Enforcement Administration )         美国蜂毒局           DEA (Drug Enforcement Administration )         美国蜂毒局		
cyclosporin A = CyA     环稳素 A;       CYP <sup>95</sup> = Cytochrome P450 (abbreviated P450, infrequently CYP450)     如胞色素 P450 師       CYP Dob substrates     CYP 026 弱代謝者       CYP probe substrates     CYP Mark1&&       CYD probe substrates     CYP Mark1&&       Cytochrome     如胞色素       cytochrome     如胞日子       cytockine     如胞日子       cytotxine     如胞子八暴 <sup>m</sup> cytotxic drugs     如胞母子八暴 <sup>m</sup> Data and Safety Monitoring Board = DSMB <sup>60</sup> 发掘公室金盆测委员会       data mining     費揚老組       Data and Safety Monitoring Board = DSMB <sup>60</sup> 数据监测委员会       Committees (DSMCs))     和baffs, Jr 告和信息处       Data And Safety Monitoring Boards     数据公金金盆测委员会       Committees (DSMCs))     和baffs, Jr 告和信息处       DBS = deep brain stimulation     脑家部电刺激技术       DDMAC = Division of Drug Marketing, Advertising, and Communications     Astalis, Jr 告和信息处       de novo process <sup>64</sup> (Enst Sak) 更新分支程序       DEA (Drug Enforcement Administration )     美国鮮毒局       DEA = Drug Enforcement Administration     美国蜂毒局       DEA = Drug Enforcement Administration <td></td> <td></td>		
CYP <sup>38</sup> = Cytochrome P450 (abbreviated P450, infrequently CYP450)         知胞色素 P450 篩           CYP 2D6 約代谢者         CYP pope substrates         CYP 2D6 約代谢者           CYP probe substrates         CYP 四海菜牡底物         変性纤维化、赤称为囊性纤维化、囊肿性纤维 变性发囊纤维变性;囊性纤维化、囊肿性纤维           cytochrome         細胞息子            cytokine storm         細胞周子风暴 <sup>m</sup> cytokine storm         細胞周子风暴 <sup>m</sup> cytotxic drugs         細胞者(性)药物            Daligatran (Pradaxa)         这比か群酯; 新型口服抗凝药, 由德国勃林格般 格输公司开发            Daraprim (pyrimethamine)         乙烯定定 過季定, 多定定            Data And Safety Monitoring Board = DSMB <sup>50</sup> 数据定委全差調委員会            data mining         数据友安全差調委員会             Data And Safety Monitoring Boards         数据率             Data And Safety Monitoring Boards         数据意報過費会             DMAC = Division of Drug Marketing, Advertising, and Communications              DBMA = Drug Enforcement Administration )         美国雄泰局              DFA = Drug Enforcement Administration )         美国雄泰局                 DFA = Dru		
infrequently CYP450)         CYP 2D6 poor metabolizer         CYP D6 Bit Alpha Bit CYP poor metabolizer           CYP probe substrates         CYP mark Aga           cystic fibrosis = CF		
CYP probe substrates         CYP 酶核针底物           cystic fibrosis = CF         囊肿性纤维化、亦称为囊性纤维化、囊肿性纤维 变性达量式囊纤维变性;囊性纤维性变病           cytokine         細胞色素           cytokine         細胞色素           cytokine storm         細胞白子风暴 <sup>m</sup> cytokine storm         細胞小刺           cytotatic         細胞毒(性)药物           Dabigaran (Pradaxa)         达比如難許; 新型口服抗凝药,由德国勃林格競 格輸公司开发           Daraprim (pyrimethamine)         乙胺嘧啶; 急疟定           Data And Safety Monitoring Board = DSMB <sup>90</sup> 数据及安全监测委员会           data mining         数据及安全监测委员会           Data And Safety Monitoring Boards (DSMBs) or Data and Safety Monitoring Boards         数据边测委员会           DBS = deep brain stimulation         脑深華电刺激技术           DBMAC = Division of Drug Marketing, Advertising, and Communications         药品销售、广告和信息处           de novo pathways; De novo synthesis <sup>93</sup> 从头会成途径           DEA (Drug Enforcement Administration )         美国缉毒局           DEA = Drug Enforcement Administration         美国缉毒局           dear hatinulation         既能股           DEA = Drug Enforcement Administration         美国缉毒局           dearnidation         既配股           dear healthcare professional letter         鼓医疗 Let人员首中           deep train stimulators         聚析 健人员信件           deep		
cystic fibrosis = CF     蒙肿性纤维化、亦称为囊性纤维化、蒙肿性纤维 变性或囊纤维变性;囊性纤维性变病       cytokine     細胞息子       cytokine storm     細胞息子       cytotoxic drugs     細胞身子       Data gatran (Pradaxa)     法比か群範;新型口服抗凝药,由德国勃林格般 格输公司开发       Data mining     乙脲嘧啶;急疟定       Data Monitoring Board = DSMB <sup>60</sup> 数据及安全监测委员会       data mining     数据总则委员会       Data Monitoring Committees <sup>91</sup> (DMCs) (also known as Data and Safety Monitoring Boards (DSMBs) or Data and Safety Monitoring Boards (DSMBs) or Data and Safety Monitoring Boards (DSMLs))     邓白氏编码       DBS = deep brain stimulation     脑深鄣电刺激技术       DBMAC = Division of Drug Marketing, Advertising, and Communications     从头含体镜颈胞白血病; 初洽急性髓性白血病       de novo Ath.c de novo acute myeloid (myelogenic, myelogenous) leukemia     从头含成途径       DEA (Drug Enforcement Administration )     美国缉毒局       DEA (Drug Enforcement Administration )     美国缉毒局       DEA apting processinal letter     致医疗原呈人员的一封信       dear healthcare professional letter     致医疗保健人员信件       deep train stimulation     K融解 运行性骨关节病       dearied adoctor letters     我居疗卫生人员的一封信       dearied adoctor letters     我居疗卫生人员的一封信       dear healthcare professional letter     女医疗像是人员信件       deep train stimulation     K融服       dear healthcare professional letter     女医疗保健人员信件       deep train stimulatorin     K配服       dear	CYP 2D6 poor metabolizer	CYP 2D6 弱代谢者
夏性或囊纤维变性;囊性纤维性变病           cytokine         細胞母素           cytokine storm         細胞母子           cytokine storm         細胞母和           cytotxic drugs         細胞毒(性) 药物           Dabigatran (Pradaxa)         法比か群酯; 新型口服抗凝药,由德国物林格段           格翰公司开发         四服寿(性) 药物           Daraprim (pyrimethamine)         乙胺嘧啶; 急疟定           Data And Safety Monitoring Board = DSMB <sup>90</sup> 数据及安全监测委员会           data mining         数据挖掘           Data Monitoring Committees <sup>91</sup> (DMCs) (also known as Data and Safety Monitoring Committees (DSMCs))         数据显测委员会           Data Universal Numbering Boards         数据           DSMBS) or Data and Safety Monitoring Committees (DSMCs))         邓白氏编码           Data Universal Numbering System <sup>92</sup> D-U-N- 52 S (DUNS)         郑白氏编码           DBA = deep brain stimulation         脑深潮电刺激技术           DDMAC = Division of Drug Marketing, Advertising, and Communications         杨信告, 广告和信息处           de novo AML; de novo acute myeloid (myelogenic, myelogenous) leukemia         从头令成途径           DEA (Drug Enforcement Administration )         美国緝毒局           DEA (Drug Enforcement Administration )         美国纬毒局           DEA = Drug Enforcement Administration         美国纬毒局           dearnidation         Rikmg           dear healthcare professional letter	CYP probe substrates	CYP 酶探针底物
变性或囊纤维变性; 囊性纤维性变病cytokine細胞色素cytokine storm細胞固子风暴 <sup>®</sup> cytokine storm細胞面子风暴 <sup>®</sup> cytokine storm細胞子风暴 <sup>®</sup> cytokine storm細胞素(性)药物Dabigatran (Pradaxa)法比か群酯; 新型口服抗凝药, 由德国勃林格殷 格翰公司不发Daraprim (pyrimethamine)乙胺零穴、息疟定Data And Safety Monitoring Board = DSMB <sup>90</sup> 数据及安全监测委员会data mining数据超振Data And Safety Monitoring Boards数据显测委员会Monitoring Committees <sup>91</sup> (DMCs) (also known as Data and Safety Monitoring Committees (DSMCs))那白氏编码Data Universal Numbering System <sup>92</sup> D-U-N- 52 S (DUNS)那白氏编码Data Universal Numbering System <sup>92</sup> D-U-N- 52 S (DUNS)苏白氏镜人Data Onitori of Drug Marketing, Advertising, and Communications从头仓成途径de novo AML; de novo acute myeloid (myelogenic, myelogenous) leukemia从头仓成途径DEA (Drug Enforcement Administration )美国維毒局DEA (Drug Enforcement Administration )美国蜂毒局DEA (Drug Enforcement Administration )美国拳动DEA = Drug Enforcement Administration )美国蜂毒局dear doctor letters食医疗保健人员信件deep brain stimulators DBS; deep brain stimulation深郁脑刺激器; 脑深部电刺激术deep frain stimulators DBS; deep brain stimulation深郁脑刺激器; 脑深部电刺激术deep frain stimulators DBS; deep brain stimulation深郁脑刺激器; 脑深部电刺激术deep frain stimulators DBS; deep brain stimulation深郁胸刺激器, 脑深部电刺激术deep frain stimulators DBS; deep brain stimulation深郁脑刺激器, 脑深部电刺激术deep frain stimulators DBS; deep brain stimulation深極刺激素, 指骨化疾病degenerative joint disea	cystic fibrosis = CF	囊肿性纤维化、亦称为囊性纤维化、囊肿性纤维
cytochrome         細胞色素           cytokine         細胞周子           cytokine storm         細胞周子(風幕)?           cytokine storm         細胞周子(風幕)?           cytoxic drugs         細胞毒(性) 药物           Dabigatran (Pradaxa)         法比か群酷; 新型口服抗凝药, 由德国物林格設 格输公司开发           Daraprim (pyrimethamine)         乙胺嘧啶; 息疟定           Data And Safety Monitoring Board = DSMB <sup>60</sup> 数据起源           Data And Safety Monitoring Board = DSMB <sup>60</sup> 数据整次           Data Monitoring Committees <sup>61</sup> (DMCs) (also known as Data and Safety Monitoring Committees (DSMCs))         数据监测委员会           Data Universal Numbering System <sup>92</sup> D-U-N- 52 S (DUNS)         双白氏编码           DBS = deep brain stimulation         脑深部电刺激技术           DDMAC = Division of Drug Marketing, Advertising, and Communications         病品销售、广告和信息处           de novo parteways; De novo synthesis <sup>03</sup> 从头冬高速径           De novo pathways; De novo synthesis <sup>03</sup> 从头令成途径           de novo process <sup>94</sup> (医疗器体量           DEA (Drug Enforcement Administration )         美国緯毒局           DEA = Drug Enforcement Administration         美国蜂毒局           dearnidation         成酰胺           dear healthcare professional letter         女医疗保健人员信件           degenerative joint disease         進行性背影           degenerative joint disease		
cytokine     細胞因子       cytokine storm     細胞因子风暴 <sup>10</sup> cytostatic     細胞肉子风暴 <sup>10</sup> cytotoxic drugs     細胞毒(性) 药物       Dabigatran (Pradaxa)     达比か鮮酯; 新型口服抗凝药,由德国物林格度 格输公司开发       Daraprim (pyrimethamine)     乙胺嘧啶;息疟定       Data Monitoring Board = DSMB <sup>50</sup> 数据及安全监测委员会       data mining     数据这撮       Data Monitoring Committees <sup>51</sup> (DMCs) (also known as Data and Safety Monitoring Boards (DSMBs) or Data and Safety Monitoring Committees (DSMCS))     邓白氏编码       Data Universal Numbering System <sup>52</sup> D-U-N- 52 S (DUNS)     邓白氏编码       DBS = deep brain stimulation     脑深鄣电刺激技术       DDMAC = Division of Drug Marketing, Advertising, and Communications     林头急性髓細胞白血病; 初治急性髓性白血病       De novo pathways; De novo synthesis <sup>93</sup> 从头含成途径       de novo process <sup>94</sup> (医疗器械) 重新分类程序       DEA (Drug Enforcement Administration )     美国维毒局       DEA = Drug Enforcement Administration     美国维毒局       dearnidation     成酰胺       dear doctor letters     发医疗卫生人员的一封信       deer parin stimulators DBS; deep brain stimulation     深郁脑刺激器; 脑深部电刺激术       degenerative joint disease     進行性骨炎节病       delayed effect     送发反应       delayed effect     送发反应       delayed effect     必須及       demographic risk factor     人口统计学风险因子	cytochrome	
cytokine storm     細胞母子风暴 <sup>®</sup> cytotxic     細胞神制       cytotxic drugs     細胞毒(性) 药物       Dabigatran (Pradaxa)     送比か距酯;新型口服抗凝药,由德国勃林格度 格输公司开发       Daraprim (pyrimethamine)     乙胺嘧啶;息疟定       Data And Safety Monitoring Board = DSMB <sup>90</sup> 数据及安全监测委员会       data mining     数据挖掘       Data And Safety Monitoring Board = DSMB <sup>90</sup> 数据应会年定       data mining     数据控漏       Data And Safety Monitoring Boards     数据监测委员会       (DSMBs) or Data and Safety Monitoring Boards     数据监测委员会       DBS = deep brain stimulation     脑深部电刺激技术       DBS = deep brain stimulation     脑深部电刺激技术       DDMAC = Division of Drug Marketing, Advertising, and Communications     药品销售、广告和信息处       de novo AML; de novo acute myeloid (myelogenic, myelogenous) leukemia     从头含成途径       DEA = Drug Enforcement Administration )     美国蜂毒局       DEA = Drug Enforcement Administration     美国蜂毒局       deamidation     脱酰胺       dear doctor letters     双医疗卫生人员的一封信       dear doctor letters     双医疗卫生人员的一封信       deare actor disease     椎间盘進雲; 脑深部电刺激术       degenerative discase     椎间盘邊雲; 椎骨退化, 長衛       degenerative disc disease     椎间盘邊雲; 椎間邊代人員信件       degenerative disc disease     七间盘邊雲; 椎間邊代人員信       delayed effect     迟发反应       delayed effect     迟发反应 </td <td>-</td> <td></td>	-	
cytotatic     細胞神制       cytotoxic drugs     細胞毒(性) 药物       Dabigatran (Pradaxa)     达比加群酯; 新型口服抗凝药,由德国物林格般 格输公司开发       Daraprim (pyrimethamine)     乙胺嘧啶,息疟定       Data And Safety Monitoring Board = DSMB <sup>90</sup> 数据及安全监测委员会       data mining     数据挖掘       Data Monitoring Committees <sup>91</sup> (DMCs) (also known as Data and Safety Monitoring Boards (DSMBs) or Data and Safety Monitoring Committees (DSMCs))     邓白氏编码       DBS = deep brain stimulation     脑深部电刺激技术       DDMAC = Division of Drug Marketing, Advertising, and Communications     从头急性髓细胞白血病; 初治急性髓性白血病 myelogenous) leukemia       De novo pathways; De novo south myeloid (myelogenic, myelogenous) leukemia     从头合成途径       DEA (Drug Enforcement Administration)     美国缉毒局       DEA (Drug Enforcement Administration)     美国缉毒局       dearnidation     成酰胺       dear doctor letters     致医疗卫生人员的一封信       dear healthcare professional letter     致医疗保健人员信枠       deep brain stimulators DBS; deep brain stimulation     深部脑刺激器; 脑深部电刺激术       degenerative disc disease     椎间盘速度; 椎骨退化疾病       dearnedutior     现眠險       dearnedutior     梁郁脑刺激器; 脑深部电刺激术       dearnedutior disease     雄间盘速度; 椎骨退化疾病       degenerative disc disease     雄间盘速度; 椎间盘速度; 椎骨退化疾病       delayed effect     迟发反应       delayed effect     远发反应       delayed effect     远发反应	-	
cytotoxic drugs細胞毒(性)药物Dabigatran (Pradaxa)达比加鲜酯; 新型口服抗凝药,由德国物林格般 格翰公司开发Daraprim (pyrimethamine)乙胺嘧啶;急疟定Data And Safety Monitoring Board = DSMB <sup>90</sup> 数据及安全监测委员会 data miningData Monitoring Committees <sup>91</sup> (DMCs) (also known as Data and Safety Monitoring Boards (DSMBs) or Data and Safety Monitoring Committees (DSMCs))邓白氏编码 为器器电台 (DSMCs)Data Universal Numbering System <sup>92</sup> D-U-N- 52 S (DUNS)邓白氏编码 方品销售、广告和信息处 Advertising, and Communicationsde novo AML; de novo acute myeloid (myelogenic, myelogenous) leukemia De novo pathways; De novo synthesis <sup>93</sup> de novo process <sup>94</sup> 从头合成途径 (医疗器械)重新分类程序DEA (Drug Enforcement Administration )美国鲜毒局 deamidation展融利激器; 脑深部电刺激术 degenerative disc disease 進行性骨关节病 degenerative joint disease 進行性骨关节病dear doctor letters致医疗卫生人员的一封信 发医疗保健人员信件 梁部脑刺激器; 脑深部电刺激术degenerative disc disease delayed effect delayed effect送发反应 达发反应 delimeats 素肉制品demographic risk factor人口统计学风险因子	-	
Dabigatran (Pradaxa)         送比加解韻;新型口服抗凝药,由德国勃林格般 格翰公司开发           Daraprim (pyrimethamine)         乙腺嘧啶;息疟定           Data And Safety Monitoring Board = DSMB <sup>90</sup> 数据及安全监测委员会           data mining         数据挖掘           Data Monitoring Committees <sup>91</sup> (DMCs) (also known as Data and Safety Monitoring Committees (DSMCs))         数据挖掘           Data Universal Numbering System <sup>92</sup> D-U-N- 52 S (DUNS)         邓白氏编码           DBAC = Division of Drug Marketing, Advertising, and Communications         病深部电刺激技术           DDMAC = Division of Drug Marketing, de novo AML; de novo acute myeloid (myelogenic, myelogenous) leukemia         从头含点途径           De novo pathways; De novo synthesis <sup>93</sup> 从头会点途径           de novo process <sup>54</sup> 美国缉毒局           DEA - Drug Enforcement Administration         美国缉毒局           dear doctor letters         致医疗足生人员的一封信           dear doctor letters         致医疗保健人员信件           deep brain stimulators DBS; deep brain stimulation         深潮脑刺激器; 脑深部电刺激术           dearedoctor letters         致医疗保健人员信种           deep rearised is disease         椎间 量速度; 椎骨递化疾病           delayed effect         送发反应           delayed effect         送欠反应           delayed effect         送欠反应           dear hoathcare professional letter         支欠反应           delayed effect         送欠反		
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DEA = Drug Enforcement Administration       美国缉毒局         deamidation       脱酰胺         dear doctor letters       致医疗卫生人员的一封信         dear healthcare professional letter       致医疗保健人员信件         deep brain stimulators DBS; deep brain stimulation       深部脑刺激器; 脑深部电刺激术         degenerative disc disease       椎间盘退变; 椎骨退化疾病         delayed effect       迟发反应         deli meats       熟肉制品         demographic risk factor       人口统计学风险因子	de novo process <sup>94</sup>	(医疗器械)重新分类程序
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deep brain stimulators DBS; deep brain stimulation深部脑刺激器; 脑深部电刺激术degenerative disc disease椎间盘退变; 椎骨退化疾病degenerative joint disease退行性骨关节病delayed effect迟发反应deli meats熟肉制品demographic risk factor人口统计学风险因子	dear healthcare professional letter	致医疗保健人员信件
degenerative disc disease椎间盘退变;椎骨退化疾病degenerative joint disease退行性骨关节病delayed effect迟发反应deli meats熟肉制品demographic risk factor人口统计学风险因子	deep brain stimulators DBS; deep brain stimulation	深部脑刺激器; 脑深部电刺激术
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delayed effect迟发反应deli meats熟肉制品demographic risk factor人口统计学风险因子	degenerative joint disease	
demographic risk factor 人口统计学风险因子	delayed effect	迟发反应
demographic risk factor 人口统计学风险因子	deli meats	熟肉制品
	demographic risk factor	人口统计学风险因子
	Dengue virus	登革病毒

denominator	分母
dental reconstruction	埋植型牙齿改建; 牙再生
denture cushions	假牙衬垫
Department of Health and Human Services	卫生与公众服务部
depression	抑郁(症)
depyrogenation	去除热原法; 去热原
dermal fibroblast	真皮成纤维细胞
DES = Drug Eluting Stent; a.k.a "drug coated	药物洗脱支架
stents" or "medicated stents"	
descriptive statistical analysis	描述性统计分析
design space <sup>95</sup>	设计空间;
design validation - customer requirements	设计验证:确认符合客户需求
design verification – internal testing	设计确认:内部检验
destructive analysis	破坏性分析
detention	海关扣留
detergent	除垢剂
development value chain	开发价值链
developmental toxicity	发育毒性
deviation	偏差
deviation/ Out of Specification (OOS) procedures	偏差/00S(不合格)程序
device listing	医疗器械产品登记
dexamethasone suppression test	地塞米松抑制试验
$DF = degree of fluctuation^{96}$	波动度
DFS = disease free survival	无病生存期
DHR = device history record	医疗器械历史记录
DIA = Drug Information Association	药品信息协会
diabetic foot ulcer	糖尿病足溃疡
diabetic neuropathy	糖尿病神经病变
diagnostic imaging	诊断影像学;
diagnostic trials	诊断性试验
diagnostics	诊断药品
dialysis fluid	透析液
diazepam; valium	地西泮(安定)
dichotomies	二分类
diclofenac ; Pennsaid	双氯芬酸
dietary supplement	膳食补充剂
Dietary Supplement Health and Education Act of 1994 (DSHEA)	膳食补充品健康与教育法
diethylene glycol = DEG	二甘醇
differentiated thyroid carcinoma,DTC	分化型甲状腺癌
Differentiation	差别化;与众不同;
Differentiation Marketing	差异化营销
Diffuse alveolar damage	弥漫性肺泡损伤
Digoxin	地高辛
DILI = drug-induced liver injury	药物性肝损伤
dioxin	二恶英
direct-to-consumer advertising = DTCA	直接面向患者作广告
5	

discretionary good	可有可无的货物 Coffee is closer to a
	staple than a discretionary good
discretionary power	裁量权
discretionary rules	任意性的规则;自由裁量的;非强制性
disinfection	消毒
dissolution	[药理学]溶出度
distributor	经销商
Division of Clinical Trial Design and Analysis	临床试验部
$DLT = dose-limiting toxicity^{97}$	剂量限制毒性
DMARD = disease-modifying antirheumatic drugs	病情缓解抗风湿药;
DMARD-naïve patients	未使用过 DMARD 的患者
DME diabetic macular edema	糖尿病黄斑水肿
DMF = drug master file	药物主文件98
DMSO = dimethyl sulfoxide	二甲亚砜
DNA modification	DNA 修饰作用
DNA sequence	DNA 序列
DOE <sup>99</sup> (design of experiments) or experimental	实验设计
design	
dolomite	白云石
dopamine	多巴胺
dosage form	剂型:包括片剂、胶囊剂、颗粒剂、干混悬剂、
	凝胶剂;
dosage regimen or dose rate	给药方案或给药速度
dose-ranging study <sup>100</sup>	剂量范围研究
dose-reaction relation	剂量-反应关系
dose-related adverse reactions	剂量相关的不良反应
double blinding	双盲
double dummy <sup>101</sup>	双模拟
double-blind study <sup>102</sup>	双盲研究
double-masked study: see double-blind study	双盲研究
double-strand DNA breaks, DSBs	DNA 双链断裂
DRGs = Diagnosis Related Group System	疾病诊断相关分组
drop out <sup>103</sup>	脱落
drop test	落震试验;跌落试验
Drug electronic supervision code (China)	药品电子监管码
drug eluting coronary stents	药物洗脱支架
drug interaction	药物相互作用
drug product	药物产品
drug response <sup>104</sup>	药物反应
drug substance	原料药
drug-drug interaction <sup>105</sup>	药物-药物相互作用
drug-food interaction	药物-食物的相互作用
drug-infusion systems	植入式药泵
DSC = Differential Scanning Calorimetry	差示扫描量热仪
DSHEA = Dietary Supplement Health and	膳食补充剂健康与教育法
Education Act of 1994	
DSI Division of Scientific Investigations	科學調查處
DSMB = Data Safety and Monitoring Board	数据安全及监控委员会

DSMICA = Division of Small Manufacturers,	小型制造商、国际及消费者协助分部106
International and Consumer Assistance DTA = differential thermal analysis	差热分析;差示热分析
Duchenne's muscular dystrophy <sup>107</sup> DMD	麦热分析; 左小热分析 炙馨氏肌营养性萎缩症;进行性肌营养不良;
Duchenne's muscular dystrophy DMD	
	杜興氏肌肉營養不良症; 假肥大型肌营养不良 
Duexis	症
	布洛芬法莫替丁片(复方药)
Dupuytren's contracture	杜普征氏掌挛缩
durable complete response	持续完全缓解
DWPE = detention without physical examination	自动扣留;不经查验即可扣留产品
dysmenorrhea	痛经
dystopia	肌肉张力障碍
E. coli	大肠杆菌;大肠埃希氏菌
EBIT = Earnings Before Interest and Tax	息税前利润
EBITDA= Earnings Before Interest, Taxes, Depreciation and Amortization	未计利息、税项、折旧及摊销前的利润
Ebola virus	
EEMEA	东欧、中东和非洲地区
EEPS = Electronic Entry Processing System	电子录入处理系统
effectiveness	· 行效
efficacy	
efficacy (Of a drug or treatment)	有效性例足 药效:药品疗效
EFPIA = European Federation of Pharmaceutical	
Industries and Associations	欧洲制约工业联合会
EFSA European Food Safety Authority	欧洲食品安全局
EIR = establishment inspection report by FDA	现场检查报告
electrical impulse	电脉冲
Electronic Batch Recording (EBR)	电子批记录
Electronic Data Capture = EDC	电子数据采集系统
Electronic Data Processing = EDP	电子数据处理
Electronic medical record (EMR)	电子医疗记录
Eli Lilly	礼来制药
eligibility criteria <sup>108</sup>	合格标准
elixir of sulfanilamide tragedy 1937 <sup>109</sup> embolic stroke	1937 年磺胺酏 (yi) 剂 (含二甘醇) 事件
	栓塞性中风
EMEA = European Medical Evaluation Agency; European Agency for the Evaluation of Medicinal	药物评价机构; 欧洲医药品管理局
Products; European Medicines Agency	
emergency envelope	应急信件
Empiric Bayesian Multiple Gamma-Poisson	经验性贝氏法(伽玛泊松分布缩检法)
Shrinker	
empirical	经验性
Enbrel, etanercept by Amgen Inc	依那西普(FDA 批准银屑病关节炎药物)□□□由 Immunex 公司研制。用于治疗类风湿性关节炎
encephalitis	脑炎
end-of-life care	临终关怀照护
endogenous system	内源性系统
endometriosis	子宫内膜异位

endotoxin	(细菌)内毒素
endpoint <sup>110</sup>	终点
endpoint criteria	终点指标
enlarged prostate	前列腺增生
enterobacter sakazakii	版峙肠杆菌
enterococci	肠球菌
entrepreneurs	创业者
enzymatic browning	酶促褐变
enzyme replacement therapy	酶替代疗法
EPA = export application	出口药申请(申请出口不被批准在美国销售的药
	品)
ephedra	麻黄
epidemiology	流行病学
epiglottis	会厌
epilepsy	癫痫
epinephrine	肾上腺素
Epipen (Epinephrine Syringe)	肾上腺素注射剂
epitope <sup>111</sup>	抗原表位;抗原决定簇
EPO = erythropoietin	促红(细胞生成)素;促红细胞生成素
equipment qualification	设备验证
equivalence	等效性
equivalence trial <sup>112</sup>	等效性试验
erectile dysfunction	勃起功能障碍
ERISA Employee Retirement Income Security Act of 1974	雇员退休收入保障法
ERK Extracellular signal-regulated kinase	细胞外信号调解蛋白激酶
erosion	糜烂
erythema multiforme	多形糜烂性红斑
erythropoietin	促血红细胞生长素
esomeprazole	埃索美拉唑
esophagus	食道
essential documentation	必须文件
Essential Medicines, WHO Model Lists of	《WHO 基本药物示范目录》
essential tremor	震颤
established name	确定的名称
establishment registration	(生产医疗器械的)厂家设施登记
Etanercept (trade name: Enbrel)	依那西普;治疗类风湿
ETASU (Elements To Assure Safe Use)	确保安全使用要素
ethanol	乙醇
ethics committee, akin to IRB Institutional Review Board	伦理委员会
ethyl alcohol, ethanol	乙醇
ethylene glycol	乙二醇;甘醇
etiology	病因学
EUA emergency use authorization <sup>113</sup>	緊急使用授權
Eudract = European Union Drug Regulating Authorities Clinical Trials = European Clinical Trial Database	欧盟临床试验数据库

EudraLex	欧盟医学产品法律法规集
Eudravigilance = European Union Drug Regulating	欧盟药物警戒
Authorities Pharmacovigilance	
excellent	显效
excessive daytime sleepiness	嗜睡
excimer laser	准分子激光
excipient <sup>114</sup>	赋形剂;药用辅料
exclusion criteria	病例排除标准
exculpatory evidence	辩护证据
exon-skipping compound	外显子跳越化合物
expanded access <sup>115</sup>	扩大使用
experimental drug	试验性药物
Expiration Date	使用有效期
explant	取出植入式医疗器械
exposure data	药品使用情况数据
express preemption	明示优先适用 (law)
external auditory canals	外耳道
external low-pressure air device	外部低压气流装置
externalities	外部性
extrapolate	推断,推知,外推
extrusion	挤出
Fab fragment <sup>116</sup> = fragment antigen-binding	Fab 片段 [免疫球蛋白上结合抗原的片段]
Fabry's disease <sup>117</sup>	酰基鞘氨醇已三糖苷脂沉积症; 法布里病
facial dysmorphia	脸部畸形
$FACP = Fellow^{118}$ of the American College of	美国内科医师学会会员
Physicians	天日门们区州于五五页
factorial design	析因设计
factorial trial	析因试验
failure	无效,失败
Fair Packaging and Labeling Act (1966)	公平包装和标签法
False Claims Act	防制不实请求法
false negative	通常指漏报,也就是说,一个东西是没有被查出
	来的,但这是错误的(false);假阴性
false positive	通常指误报,从字面上来看就是说,一个东西是
1	被查出来了,但这是错误的(false);假阳性
false therapeutic claims	错误的疗效声明
Famotidine	法莫替丁[组胺 H2 受体阻滞药]
FAS = Foreign Agricultural Service	美国农业部海外局
Fast track <sup>119</sup>	快速通道
FCA = Field Corrective Actions	产品纠正行动
FCE= Food Canning Establishment	所有罐头类食品企业都要有一个 FCE 号;和加工
	过程呈报号
FD& C Act	美国联邦食品、药品和化妆品法
FD&C Act of 1938 = Food, Drug & Cosmetic Act	食品药物及化妆品法
of 1938	A 21-10/AIU IA HE (A
FDA	美药管局;美国食品及药物管理局
FDA Adverse Event Reporting System (FAERS)	FDA 不良事件报告系统
(formerly AERS)	
FDAAA = Food and Drug Administration	食品药品管理局修正案法

Amendments Act of 2007	
FDAMA 1997	《食品和药品管理局现代化法案》
FDASIA = Food and Drug Administration Safety	FDA 安全和创新法
and Innovation Act signed into law on July 9, 2012	
Federal Import Milk Act (1927)	牛奶制品进口法
Federal Register <sup>120</sup> FR	联邦公报;联邦文件记录册(总汇)
feedback inhibition	反馈抑制
fee-for-service	按项目收费制;付费服务
FERN = Food Emergency Response Network	食品紧急反应网络
fibromyalgia syndrome	纤维肌痛综合征
fibrosis	纤维化
field correction	产品纠正行动
field notification	产品通知
final point	终点
Final Report = FR	总结报告
finfish	鳍鱼 qi yu
FIP = Federation International Pharmaceutical	国际药学联合会
first dose effect = syndrome of first dose = first dose	首剂效应;又称首剂综合征或首剂现象
phenomenon	
first line therapy	一线治疗用的药品
Fish and Fishery Products Hazards and Controls	鱼类与渔产品危害与管制准则
Guidance	
fixed-dose procedure	固定剂量法
Flector Patch (diclofenac epolamine superficial	Flector 补丁;双氯芬酸依泊胺<消炎镇痛药>
patch)	
Flex-Foot	飞毛腿碳纤储能系列假脚
flexible endoscopes	软式内镜
flocculation	絮凝
fluoroquinolones	氟喹诺酮类药物 antibiotic
flurazepam; (marketed under the brand names	氟西泮(氟安定)
Dalmane and Dalmadorm)	
$FMEA^{121} = failure modes and effects analysis$	故障模式影响分析;
FMECA = Failure Modes, Effects and Criticality	故障模式影响及危害性分析
Analysis focal glomerular sclerosis; also called Focal	焦肾小球硬化
segmental glomerulosclerosis 局灶节段性肾小球硬	
化 FSGS; focal nodular glomerulosclerosis 局灶性	
结节性肾小球硬化	
folate	叶酸盐
folding, protein	蛋白质摺叠
follow-on biologics = biosimilars	生物仿制药
follow-up	随诊; 随访; 追踪
food additives	食品添加剂
food adulteration	食品掺假
food alerts	食物警报
Food And Drug Administration = FDA	美国食品与药品管理局
food borne diseases	食源性疾病
Food Canning Establishment (FCE)	罐头类工厂; 食品罐头企业
Food Chemical Codex	食品化学法典
	N 10 J 1471

Food Code	食品法典;食品代码
Food Contact Notifications = FCN	食品接触通告
Food Contact Substances = FCS	食品接触物质
food contaminant	食品污染物质
food technology	食品工艺学
food-borne diseases	食源性疾病
force multiplier	事半功倍效应; 加力工具;倍增效应;
forced titration	强制滴定
Foreign Agricultural Service (USDA), FAS	农产品外销局
Formal Experimental Design <sup>122</sup>	
formulation, drug	药物配方
Fosamax	福善美; 骨质疏松症的药物
Francisella tularensis	土拉杆菌
fraudulent intent	欺诈意图
fresh-cut produce	鲜切果蔬
FSCA = Field Safety Corrective Action	产品安全性纠正行动
FSIS = Food Safety and Inspection Service USDA	食品安全与检查局
$FTA^{123}$ = Fault Tree Analysis	故障树分析
FTE = full time employee	专职(雇员)
full analysis set <sup>124</sup> (FAS)	全分析集
full factorial design	全因子试验法
functional (molecular) imaging	功能性(分子)成像
fungus	真菌
furan	呋喃
Fusarium moniliforme	串珠镰孢霉
fusion systems	脊椎融合系统
G-6-PD	葡萄糖-6-磷酸脱氢酶
GACC = General Administration Of Customs Of	中国海关总署
The People's Republic Of China	
gamma glutamyltransferase <sup>125</sup> = GGT	γ-谷氨酰(xian)转移酶
GAMP = Good Automated Manufacture Practice	自动化生产质量管理规范
gangrene	坏疽
GAO	美国审计总署
GAPs = Good Agricultural Practices	良好农业规范
GAqPs = Good Aquacultural Practices	良好水产养殖规范
gas chromatography-Fourier transform infrared	气相色谱-傅利叶红外联用
spectrometry = GC-FTIR	
gas chromatography-mass spectrometry = $GC-MS$	气相色谱一质谱联用
Gastro/Uro Stimulators	胃肠/泌尿刺激系统
Gastroparesis	胃轻瘫
Gaucher's Disease	戈谢病(高雪氏病)
GC-FTIR = gas chromatography Fourier transform infrared	气相色谱—傅利叶红外联用
GC-MS = gas chromatography-mass spectrometry	气相色谱—质谱联用
GCP = Good Clinical Practice	药物临床试验质量管理规范
G-CSF (granulocyte-colony stimulating factor) <sup>126</sup>	粒细胞集落刺激因子
GD = Global Development	全球开发
GDD = Global Drug Discovery	全球发掘新药

GDUFA = Generic Drug User Fee Amendments of 2012         仿制药用户费用法           gene expression <sup>127</sup> 基因的表达           gene expression <sup>127</sup> 基因的表达           gene expublic Of China = GACC         中国冷天总署           generic drug         仿制药品;非专利药品;通用名药;           generic name         非专利名称           Genetech         基因表示           genetic transcription         基因非示           genetic vulnerability         還信希性減验           genetory perform         基因型引药           genotype         「客           genotype resistance <sup>130</sup> 基因型引药           Gentamicin         虎大客素           genotype resistance <sup>130</sup> 基因型型           genotype resistance <sup>130</sup> 基因型型           genotype resistance <sup>130</sup> 基因型型           Gentamicin         虎大客素           gentamicin sulfate         katack 大客素           GFI = Good Guidance Practices         GHTF = Global Harmonization Task Force           ClassSmithKine (GSK)         莴兰素文克           glioma         股債瘤           global assessment variable         全局评价素变素文克           GLP = Good Laboratory Practice/Good non-clinical         药物非临东 研究质量で完成           glucose         血糖           glucose romitor         血糖     <	GDNF Glial Cell Line-derived Neurotrophic Factor	胶质细胞源神经营养因子
gene expression <sup>127</sup> 基因的表达           gene regulation <sup>128</sup> 基因调节           General Administration Of Customs Of The People's Republic Of China = GACC         中国诗关总署           generic drug         (分制药品: 非专利药品; 通用名药; generic toxicity tests         遺信泰克           generic transcription         基因春克         generic vulnerability           generic transcription         基因型         generic resistance <sup>130</sup> genoty cupencing         基因型利滑序         generic stance <sup>130</sup> genotypic resistance <sup>130</sup> 基因型和滑序         generic mane           GGP = Good Guidance Practices         GGP = Good Guidance Practices         GGP = Good Guidance Practices           GIDB lefunomide global integrated         未未社全球合合数据库         database           global assessment variable         全局评价变量: 全局评价变量: 全局评价指标           GLU = glucose         血糖           glucose = GLU         血糖           glucose monitor         血糖           glucose monitor         血糖/           glucose monitor         血糖/           glucose monitor         面梯           glucose monitoring         血糖/           glucose monitoring         血糖/           glucose monitoring         血糖/           glucose monitoring         血糖/           glucose	GDUFA = Generic Drug User Fee Amendments of	仿制药用户费用法
gene regulation128 $\&$ B lightGeneral Administration Of Customs Of The People's Republic Of China = GACC $\psi$ B $\beta \neq \delta$ $\Re$ generic drug(b $\delta$ b $\beta$ $\beta$ $\beta$ , $\# \in \eta$ b $\beta$ , $\beta$ generic name $\# \in f$ $\eta$ $2 $ $\beta$ generic toxicity tests(b $\delta$ $\beta$ $\beta$ $\beta$ , $\beta$ generic toxicity tests(b $\delta$ $\beta$ $\beta$ $\beta$ , $\beta$ generic toxicity tests(b $\delta$ $\beta$ $\beta$ $\beta$ , $\beta$ generic toxicity tests(b $\delta$ $\beta$ $\beta$ $\beta$ , $\beta$ generic toxicity tests(b $\delta$ $\beta$ $\beta$ $\beta$ , $\beta$ generic toxicity tests(b $\delta$ $\beta$ $\beta$ $\beta$ , $\beta$ generic toxicity tests(b $\delta$ $\beta$ $\beta$ , $\beta$ generic toxication(b $\delta$ $\beta$ $\beta$ , $\beta$ generic toxication(b $\delta$ $\beta$ $\beta$ , $\beta$ generic resistance130(b $\delta$ $\beta$ $\beta$ , $\beta$ generic resistance130(b $\delta$ $\beta$ $\beta$ , $\beta$ GGP = Good Guidance for Industry(f $2 $ $4 $ $k \beta$ , $k \beta \epsilon k \beta \delta \beta$ GID B leflunomide global integrated(c $\delta$ $\beta$ , $k \beta$ , $k \beta \epsilon k \beta \delta \beta$ diatabase(c BLP = Good Laboratory Practice/Good non-clinicalGluco Bay: Precose (acarbose tablets) by Bayer(b $k \beta$ , $k \beta \epsilon k \beta \epsilon \beta \beta$ Gluco Bay: Precose (acarbose tablets) by Bayer(b $k \beta$ , $k \beta \epsilon k \beta$ Glucose = GLU(b $k \beta$ glucose monitor(b $k \beta$ glucose monitor(b $k \beta$ glucose monitor(b $k \beta$ glucose uptake(b $k \beta$ glucose uptake(b $k \beta$ glucose uptake(b $k \beta$ glucose det or glycosylated hemoglobin(b $k \beta$ glucose det or glycosylated hemoglobin(b $k \beta$ </td <td></td> <td></td>		
General Administration Of Customs Of The People's Republic Of China = GACC         中国海关总署           generic drug         (分射药品: 非专利药品: 通用名药;           generic name         非专利名称           Genetech         基因泰克           genetic transcription         基因相聚           genetic transcription         基因相聚           genetic vulnerability         還信卷超發           genotype <sup>129</sup> 基因型           genotypic resistance <sup>130</sup> 基因型           Gentamicin         虎太家素           gentamicin sulfate         絨酸放皮、大霉素           GFI = Goidance Practices         GHTF = Global Harmonization Task Force           GIDB leftunomide global integrated         未氟米特全球含數者都各           database         GL2           GlaxoSmithKline (GSK)         萬兰素皮素之友           glioma         胶质瘤           global assessment variable         全局半榜素           GLU = glucose         血糖		基因的表达
People's Republic Of China = GACCInterviewgeneric drug(G h)\$53.; $it \neq 1$ )\$53.; $it \neq 1$ ]\$53.; $it \neq 1$ \$53.; $it \neq 1$ \$553.; $it \neq 1$ \$55		基因调节
generic drug仿制药品:非专利药品:通用名药: 運用eric nameGenetech基因奉允genetic toxicity tests還传毒性試验genetic transcription基因特录genetic transcription基因指录genetic transcription基因如genetic vulnerability還传動附性genotype <sup>129</sup> 基因型genotype <sup>129</sup> 基因型genotamicin sulfate硫酸庆大霉素GGP = Good Guidance PracticesGGTGHTF = Global Harmonization Task Force全求医疗器械法规协调组织GIDB leflunomide global integrated未氟米特全球综合数据库databaseGlaxoSmithKline (GSK)glioma販质瘤global assessment variable全局评价变量: 全局评价变量: 全局评价指标GLU = glucose血糖glucoagon高血糖素Glucobay; Precose (acarbose tablets) by Bayer阿卡波糖片,阿卡糖,阿克波什糖,拜唐苹 (原glucose e GLU血糖glucose monitor血糖沒glucose uptake葡萄糖提取glucose uptake葡萄糖提取glucose uptake葡萄糖提取glucose uptake葡萄糖提取glucose uptake葡萄糖提取glucose uptake葡萄糖提取glucose uptake葡萄糖提取glucose uptake葡萄糖提取glucose uptake葡萄糖提取glucose fertically Modified Organisms特基因生物GMD = Geod manufacturing practice药品生产质量管理规范		中国海关总署
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Genetech $\& \Box \& \Sigma$ genetic toxicity tests $@ fc # det X Be$ genetic transcription $\& \Box det X$ genetic vulnerability $@ fc # Be Be X$ genetic vulnerability $@ fc # Be Be X$ genotype <sup>129</sup> $\& \Box \Delta M P$ genotype <sup>129</sup> $\& \Box \Delta M P$ genotype <sup>129</sup> $\& \Box \Delta M P$ gentamicin sulfate $dt K K X S K$ GFI = Guidance for Industry $fT u H B_1$ ; $\sigma M H B F M M$ GGP = Good Guidance Practices $GFI = Global Harmonization Task ForceGHTF = Global Harmonization Task Force2 x K E f B K A M A M K M M M M M M M M M M M M M M$		
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genetic transcription $\underline{k}$ 因转录genetic vulnerability $\overline{a}$ (\$\ether{b}\overline{b}\ov	genetic toxicity tests	
genetic vulnerability       遺传脆弱性         genotype <sup>129</sup> 基因型         genotype <sup>129</sup> 人工         Gentamicin       床大霉素         genotype <sup>129</sup> イン         genotype <sup>129</sup> イン         Gentamicin       床大霉素         genotype <sup>129</sup> イン         Gaso       Guidance Practices         GHTF = Global Harmonization Task Force       全球医疗器械法地协调组织         GIDB leflunomide global integrated       未氟木特全球合数结库         database       GlaxoSmithKline (GSK)       葛兰素史克         glioma       胶质瘤       global assessment variable       全局评价变量; 全局评价变量; 全局评价指标         GLU = glucose       血糖       glucagon       高血糖素         Glucobay; Precose (acarbose tablets) by Bayer       阿卡波糖片,阿卡波糖片,阿卡波片,阿卡波片,香,阿克波,希糖停         glucose monitor       血糖       glucose       glucose         glucose monitoring       血糖       血糖       glucose t		-
genome sequencing $\underline{k}$ B $\underline{M}$ genotype129 $\underline{k}$ B $\underline{M}$ genotypic resistance130 $\underline{k}$ B $\underline{M}$ Gentamicin $\underline{F}_{\lambda}$ $\underline{F}_{R}$ gentamicin sulfate $(a \overline{w} \overline{w}_{L} L + \underline{F}_{R})$ GGP = Good Guidance PracticesGGTGHTF = Global Harmonization Task Force $\underline{E} x \overline{w}_{R} f^{2} \overline{w}_{R}^{2} \overline{w}_{R}^{2} \overline{w}_{R}^{2}$ GIDB leflunomide global integrated $\underline{R} a, k + 4 \leq k \cdot gc + 5 \\ \underline{K} g = 6 \\ $	•	
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genotypic resistance <sup>130</sup> 基因型耐药         Gentamicin       床大霉素         gentamicin sulfate       硫酸庆大霉素         GFI = Guidance for Industry       行业指南;研制指导原则         GGP = Good Guidace Practices          GHTF = Global Harmonization Task Force       全球医疗器械法规协调组织         GIDB leflunomide global integrated       未氟米特全球综合数据库         database          GlaxoSmithKline (GSK)       萬兰素史克         glioma       胶质瘤         global assessment variable       全局评价变量; 全局评价指标         GLU = glucose       血糖         glucagon       高血糖素         Glucobay; Precose (acarbose tablets) by Bayer       阿卡波糖片,阿卡糖,阿克波什糖, 拜唐苹 (原         glucose = GLU       血糖         glucose monitor       血糖         glucose ononitor       血糖         glucose ononitoring       血糖加減減條         glucose ononitoring       血糖加減減條         glucose uptake       葡萄萄糖摄取         glycosylated hemoglobin       糖化血红蛋白         glycerin       丙三醇; 甘油         glycosylation       病三縣 大區         GLU = Glucose       前萄糖基化         Glucose uptake       葡萄萄糖         glycosylation       病三糖	genotype <sup>129</sup>	
Gentamicin       床大霉素         gentamicin sulfate       硫酸庆大霉素         GFI = Guidance for Industry       行业指南;研制指导原则         GGP = Good Guidance Practices          GHTF = Global Harmonization Task Force       全球 医疗器械法规协调组织         GIDB leftunomide global integrated       未氟米特全球综合数据库         database          GlaxoSmithKline (GSK)       葛兰素史克         glioma       胶质瘤         global assessment variable       全局评价变量; 全局评价指标         GLU = glucose       血糖         glucagon       高血糖素         Glucobay; Precose (acarbose tablets) by Bayer       阿卡波糖片,阿卡波糖片,阿克波什糖, 拜唐苹 (原         glucose = GLU       血糖         glucose test strip       血糖別試條         glucose uptake       葡萄糖凝取         glycosylated hemoglobin       糖kc.血红蛋白         glycosylation       糖基化         GMD = Genetically Modified Organisms       特基尔会		
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GFI = Guidance for Industry       行业指南; 研制指导原则         GGP = Good Guidance Practices          GHTF = Global Harmonization Task Force       全球医疗器械法规协调组织         GIDB leflunomide global integrated       未氟米特全球综合数据库         database          GlaxoSmithKline (GSK)       葛兰素史克         glioma       胶质瘤         global assessment variable       全局评价变量; 全局评价指标         GLU = glocose       血糖         glucagon       高血糖素         Glucobay; Precose (acarbose tablets) by Bayer       阿卡波糖片,阿卡糖,阿克波什糖, 拜唐苹 (原 名: 拜糖平) 拜唐平,宝易唐,希糖停         glucose monitor       血糖         glucose test strip       血糖/         glucose uptake       葡萄糖提取         glycated or glycosylated hemoglobin       糖化血红蛋白         glycosylation       糖基化         GMO = Genetically Modified Organisms       特基出生物         GMD = Good manufacturing practice       药品生产质量管理规范		
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glucose = GLU血糖glucose monitor血糖仪glucose monitoring血糖检测glucose monitoring血糖入測glucose test strip血糖測試條glucose uptake葡萄糖摄取glycated or glycosylated hemoglobin糖化血红蛋白glycerin丙三醇; 甘油glycosylation糖基化GMO = Genetically Modified Organisms特基因生物GMP = Good manufacturing practice药品生产质量管理规范	Glucobay; Precose (acarbose tablets) by Bayer	阿卡波糖片,阿卡糖,阿克波什糖, 拜唐苹(原
glucose monitor       血糖仪         glucose monitoring       血糖位测         glucose monitoring       血糖检测         glucose test strip       血糖測試條         glucose uptake       葡萄糖摄取         glycated or glycosylated hemoglobin       糖化血红蛋白         glycerin       丙三醇; 甘油         glycosylation       糖基化         GMO = Genetically Modified Organisms       转基因生物         GMP = Good manufacturing practice       药品生产质量管理规范		名 : 拜糖平) 拜唐平, 宝易唐, 希糖停
glucose monitoring       血糖检测         glucose test strip       血糖測試條         glucose uptake       葡萄糖摄取         glycated or glycosylated hemoglobin       糖化血红蛋白         glycerin       丙三醇; 甘油         glycosylation       糖基化         GMO = Genetically Modified Organisms       转基因生物         GMP = Good manufacturing practice       药品生产质量管理规范	glucose = GLU	血糖
glucose test strip       血糖測試條         glucose uptake       葡萄糖摄取         glycated or glycosylated hemoglobin       糖化血红蛋白         glycerin       丙三醇; 甘油         glycosylation       糖基化         GMO = Genetically Modified Organisms       转基因生物         GMP = Good manufacturing practice       药品生产质量管理规范	glucose monitor	血糖仪
glucose uptake葡萄糖摄取glycated or glycosylated hemoglobin糖化血红蛋白glycerin丙三醇;甘油glycosylation糖基化GMO = Genetically Modified Organisms转基因生物GMP = Good manufacturing practice药品生产质量管理规范	glucose monitoring	血糖检测
glycated or glycosylated hemoglobin       糖化血红蛋白         glycerin       丙三醇; 甘油         glycosylation       糖基化         GMO = Genetically Modified Organisms       转基因生物         GMP = Good manufacturing practice       药品生产质量管理规范	glucose test strip	血糖測試條
glycerin     丙三醇;甘油       glycosylation     糖基化       GMO = Genetically Modified Organisms     转基因生物       GMP = Good manufacturing practice     药品生产质量管理规范	glucose uptake	葡萄糖摄取
glycerin     丙三醇;甘油       glycosylation     糖基化       GMO = Genetically Modified Organisms     转基因生物       GMP = Good manufacturing practice     药品生产质量管理规范	glycated or glycosylated hemoglobin	
glycosylation       糖基化         GMO = Genetically Modified Organisms       转基因生物         GMP = Good manufacturing practice       药品生产质量管理规范		
GMO = Genetically Modified Organisms       转基因生物         GMP = Good manufacturing practice       药品生产质量管理规范		
GMP = Good manufacturing practice 药品生产质量管理规范		
Good Clinical Practice = GCP 药物临床试验质量管理规范		
Good Laboratory Practice/Good non-clinical 药物非临床试验质量管理规范		
laboratory practice = GLP		
good manufacturing practice = GMP 药品生产质量管理规范		药品生产质量管理规范
good non-clinical laboratory practice = GLP 药物非临床研究质量管理规范	good non-clinical laboratory practice = GLP	药物非临床研究质量管理规范
Good Review Practices 审核质量管理规范	Good Review Practices	
GPF = general project frame 项目总框架	GPF = general project frame	项目总框架

GPOs = group purchasing organizations	团体采购组织
GPS = Gamma-Poisson Shrinker	伽玛泊松分布缩检法
GRA = Global Regulatory Affairs	全球监管事务
gram-negative bacilli	革兰阴性杆菌
grandfathered drugs <sup>131</sup>	法规前批准药品
granularity <sup>132</sup> of data	數據的粒度
granulation tissue <sup>133</sup>	肉芽组织
GRAS = generally recognized as safe	公认安全
group sequential design	成组序贯设计
GSP = Good Supply Practice of Pharmaceutical	药品经营质量管理规范
Products, China's	
GTP good tissue practice	良好组织规范
Guanarito virus	瓜纳瑞托病毒
Guidance for Industry Botanical Drug Products	植物药研制指导原则
guiding catheter	导引导管
GWAS <sup>134</sup> genome-wide association study	全基因组关联分析
H. pylori	幽门螺杆菌
H2RA H2-Receptor Antagonists	H2-受体拮抗剂
HACCP <sup>135</sup> = Hazard Analysis and Critical Control	危害分析关键控制点
Points	
HAI = healthcare-associated infections	医院感染
hallucinogens	致幻剂
halophiles	嗜盐生物
handling and storage	储存及转运
Hantavirus	汉坦病毒
haplotype <sup>136</sup>	单元型
hazard function	危險函數;風險函數
HAZOP Hazard and operability studies	危害和可操作性分析
$HbA1c^{137} = hemoglobin A1c$	糖化血红蛋白
HBV = Hepatitis B virus	乙型肝炎病毒
HCC = hepatic cell carcinoma	F细胞癌
HCV = hepatitis C virus	丙型肝炎病毒
HDE = humanitarian device exemption	人道主义器械豁免
health claims	健康功效宣称
health economic evaluation = HEV	健康经济学评价
health science analysts	Ⅲ
heart failure	
hemachromatosis	心衰 血色病
hematopoietic growth factors	
	造血因子
hematopoietic system <sup>138</sup>	造血系统
hemodialyzers	血液透析器
hemoglobin A	血红蛋白A
hemolytic anemia	溶血性贫血
hemophilia	血友病
hemopoietic cell	造血 or 生血细胞
hemostatic	止血
Hendra virus	亨德拉病毒
HEOR = Health Economics and Outcomes Research	卫生经济学结果研究

Heparin	肝素钠
hepatic cell carcinoma = HCC	肝细胞癌
hepatic coma	肝昏迷
hepatic necrosis	肝坏死
hepatitis C	丙型肝炎
hepatocellular injury	肝细胞损伤
hepatocellular jaundice	肝细胞性黄疸
hepatology	肝脏病学
hepatotoxicity	肝毒性
Herceptin <sup>139</sup> (Trastuzumab) by Genentech	赫赛汀(曲妥珠单抗冻干粉针剂)
hERG = human ether-à-go-go-related gene	potassium channel enhancer
Herniated discs	椎间盘突出
Herpes simiae virus (B virus)	猴疱疹病毒(B 病毒)
Herxheimers reaction	赫氏反应
Hgb = hemoglobin	血红蛋白
HHS = Department of Health and Human Services	美国卫生与公众服务部
HICPAC = Healthcare Infection Control Practices	美国医院感染控制顾问委员会
Advisory Committee	天白区优忍未任的颜门女贝云
HIF Hypoxia Inducible Factor	缺氧诱导因子
HIF Prolyl Hydroxylase Inhibitor	缺氧诱导因子(HIF)脯氨酰羟化酶(PH)抑制
	剂
High intensity focused ultrasound HIFU	高强度聚焦超声;高能超声聚焦刀
Hip Replacement	髋关节置换
HIPAA = Health Insurance Portability and	健康保险流通与责任法案
Accountability Act	
Hippocratic Oath	希波克拉底誓约
HIS, Hospital Information System	医院信息管理系统
histamine	组胺
HMO = health maintenance organizations	健康维持组织
HMPC = Committee on Herbal Medicinal Products	草药委员会
holder	DMF 持有者
homologous	同源;同源性
HOPE (Heart Outcomes Prevention Evaluation)	心脏后果预防评估
Study	
Hospice	临终关怀
Hospital Epidemiology	医院流行病学
HPAI highly pathogenic avian influenza	高致病性禽流感
HPLC = High-performance liquid chromatography	高效液相色谱; 高效液相层析;制备色谱
<sup>140</sup> ;also sometimes referred to as high-pressure	
liquid chromatography HQA Hospital Quality Alliance	医院质量联合体
HR Hazard ratio	风险比
HSA = Health Saving Account	
HSE HEALTH Saving Account	健康储蓄账户保险 健康、安全、环境
HSV = herpes simplex virus	
HTA = health technology assessment	单纯疱疹病毒 卫生技术评估
HTN = Hypertension	高血压
hub	轮毂

HUDs = humanitarian use devices人道主义使用器械human papillomavirus人类乳头瘤病毒humanized monoclonal antibody人源化的单克隆杭体Humira (adalimumab)阿达木单抗HVAC = heating, ventilating, and air conditioning暖通空调HWA486A Product code of leflunomide来氟米特产品码hydralazine肼屈嗪Hydrocephalus脑水肿,又称脑积水或水脑症hydroxyapatite <sup>141</sup> 羟基磷灰石hydroxychloroquine羟氯喹 qi ang3 l ü kui2hyperglycemia高血糖症hyperstosis; hyperosteogenesis; osteophyte骨质增生hypoglycemia低血糖	
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Humira (adalimumab)阿达木单抗HVAC = heating, ventilating, and air conditioning暖通空调HWA486A Product code of leflunomide来氟米特产品码hydralazine肼屈嗪Hydrocephalus脑水肿,又称脑积水或水脑症hydroxyapatite <sup>141</sup> 羟基磷灰石hydroxychloroquine羟氯喹 qi ang3 l ü kui2hygroscopic吸湿hyperglycemia高血糖症hyperostosis; hyperosteogenesis; osteophyte骨质增生hypoglycemia低血糖	
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hyperostosis; hyperosteogenesis; osteophyte骨质增生hypoglycemia低血糖	
hypoglycemia 低血糖	
hypokalemia 低血钾症	
hypomagnesaemia 低镁血症	
hypoproteinemia 低(白)蛋白血症	
hypothesis 假说	
hypothesis test 假设检验	
hypoxia imaging 心肌乏氧显像	
Hy's rule <sup>142</sup> Hy's 定律	
IACP International Academy of Compounding 国际复方药剂师学会	
Pharmacists	
IB = Investigator's brochure   研究者手册	
IBS = irritable bowel syndrome 过敏性肠综合症	
ibuprofen 布洛芬	
ICD implanted cardiac device 植入式心脏器械	
ICD International Classification of Diseases (of the 因际疾病分类 World Health Organization)	
ICDs = Implantable cardioverter defibrillators 植入型心律转复除颤器; 植入式心脏除颤 (ICDs)	器
ICH = International Conference of Harmonization 国际协调会议;人用药品注册技术要求国	际协调
(of Technical Requirements for Registration of Pharmaceuticals for Human Use)	
ICH Q10 药品质量体系简	
ICH Q9 质量风险管理	
IDE = Investigational Device Exemptions 研究器械豁免	
identity 真伪;鉴别;特性	
idiopathic pulmonary fibrosis, IPF 特发性肺纤维化	
idiosyncratic reaction 特异质反应	
IDMC = Independent Data Monitoring Committees 独立数据监测委员会	
IFN = interferon 千扰素	
IFPMA = International Federation of 国际制药工业协会联合会	
Pharmaceutical. Manufacturers & Associations	
IFU 使用说明书	
IHNs = Integrated Health Networks   整合医疗保健网	
IL-2 = Interleukin-2 白细胞介素 2	

imaging agents         显像剂           immute complex <sup>143</sup> 免疫复合物           immute complex <sup>143</sup> 免疫复合物           immute suppression         免疫支利           immute suppression         免疫支初           immute suppression         免疫支利           immute suppression         免疫支初           immunocity <sup>141</sup> 免疫皮力           immunogity <sup>141</sup> 免疫支利           implantable asseries the thrapy         免疫利利動液因了疗法           implantable defibrillators         益人式容別           implantable diagnostic recorders         益人式容別           implantable gastric stimulation systems         益人式容易           implantable gastric stimulation systems         益人式金利           implantable stent grafts         益人式金管内支架           implantable stent grafts         益人式金管内支架           implantable stents         拉人式金支梁           inplantable stent grafts         结人式金管内支架           indicion criteria         病例入选板公式金	ILD (Interstitial lung disease), also known as diffuse parenchymal lung disease (DPLD)	肺间质病变
immediae release drug immune complex <sup>143</sup> immune complex <sup>143</sup> immune modulation immuno-compromised 如果変積 immuno-compromised 如果変積 immuno-compromised 如果変積 immuno-compromised 如果或素者 0; mmuno-compromised 如果或素者 0; immuno-compromised 如果或素者 0; immuno-compromised 如果或素者 0; immuno-compromised 如果或素素 0; immuno-compromised 如果或素素 0; immuno-compromised 如果或書素 1, implantable ofbrillators implantable dignostic recorders implantable dignostic recorders implantable dignostic recorders implantable dignostic recorders implantable actrostimulation systems implantable neurostimulation systems implantable neurostimulation systems implantable scard stimulation systems implantable scard stimulation systems implantable stearg aftis implantable stearg aftis implantable stearg aftis implantable stearg aftis implantable stearg aftis implantable stearg implantable stearg inclusion criteria inclusion cri		民僚刻
immune complex <sup>143</sup> 免疫复合物           immune modulation         免疫與符           immune suppression         免疫抑制           immuno-compromised         免疫交預           immuno-generomised         免疫交預           immuno-generomised         免疫交預           immuno-dulatory agent (e.g. leftunomide)         免疫球分割           immuno-dulatory agent (e.g. leftunomide)         免疫球分割           implantable disgnostic recorders         植入式防衛 (A)           implantable dirg pumps         植入式防衛 (A)           implantable drug pumps         植入式防衛           implantable drug pumps         植入式防衛 (A)           implantable scaral stimulation systems         植入式太衛 (A)           implantable scaral stimulation systems         植入式太太衛 (A)           implantable stent grafts         植入式太太常           implantable stent grafts         植入式太太常           implantable stent grafts         植入式太太常           in vitro diagnostic = IVD <sup>146</sup> 体子诊断 (P-B-D)           in vitro reagent         体外诊试剂           inclusion criteria         八邊本和診           inclusion criteria         八邊本和診           inclusion vicculon criteria <sup>147</sup> 八逵/           inclusion reiteria         八邊本和診           inchorineria         八邊本和診		
immune modulation         免疫调节           immune suppression         免疫空積           immuno-compromised         免疫空積           immuno-compromised         免疫空積           immuno-compromised         免疫空積           immuno-compromised         免疫空積           immuno-compromised         免疫空積           immuno-compromised         免疫球暴白:           immuno-compromised         免疫球動動範囲子法           immuno-compromised         免疫動動動範囲子法           immuno-compromised         センス除動器           implantable defibrillators         超ン式等動刺激系分           implantable drug pumps         超ン式等動刺激系分           implantable steric stimulation systems         超ン式等加刺激系统           implantable steric stimulation systems         超ン式要和刺激系分           implantable steric stimulation systems         超ン式要和刺激系统           implantable steric grafts         超ン式要和刺激系分           implantable steric grafts         超ン式要求和影響           implantable steric grafts         超ン式支索           implantable steric grafts         超ン式支索           inclusion criteria         カイシスション           inclusion criteria         カイシスション           inclusion criteria         カイシスション           inclusion criteria         カイシュション           inclusion cr	0	
immune suppression         克痰抑制           immuno-compromised         免痰交损           immunogencity <sup>144</sup> 敌免痰力:免疫炭生;免痰原性           immunoglobulin <sup>145</sup> = Ig         免痰球蛋白;           immunosuppressive cytokine therapy         免疫球蛋白;           implantable diagnostic recorders         植入式防酸器           implantable diagnostic recorders         植入式防水           implantable drog pumps         植入式防水           implantable drog pumps         植入式防水           implantable neurostimulation systems         植入式加管和激素统           implantable neurostimulation systems         植入式血管内支架           implantable sacral stimulation systems         植入式血管内支架           implantable sacral stimulation systems         植入式血管内支架           implantable sacral stimulation systems         植入式型型           implantable sacral stimulation systems         植入式型型           implantable stents         植之式型型           implantable stents         植之式型型           inplantable stents         植心式业管内支型           in wtro diagnostic = IVD <sup>146</sup> 体外诊断(产品)           in vitro diagnostic = IVD <sup>146</sup> 体外诊断(产品)           inclusion criteria         八道体水液準           inclusion criteria         八道体大能准           inclusion criteria         八道体大能准	4	
immuno-compromised         免疫受损           immunogolicity <sup>144</sup> 最免疫力: 免疫发生: 免疫原性           immunodulatory agent (e.g. leflunomide)         免疫抑制细胞因子疗法           implantable defibrillators         植入式除颤器           implantable dignostic recorders         植入式除颤器           implantable dignostic recorders         植入式脊椎刺激系统           implantable darg pumps         植入式脊椎刺激系统           implantable darg pumps         植入式水脊椎刺激系统           implantable scaral stimulation systems         植入式支離           implantable shunts         神经外科用胞和水分流管           implantable shunts         神经外科用胞和水分流管           implantable shunts         神经外利制能水分流管           implantable shunts         神经外利用和水分流管           implantable shunts         撞人式支軟           implantable shunts         撞ん式支軟           implantable shunts         撞水分式和           inder stem cell transplantation         達血千细胞宮内移植           in vitro diagnostic = IVD <sup>146</sup> 体外诊断 (产品)           in vitro diagnostic         IV <sup>147</sup> inclusion criteria         六人進标准           inclusion criteria         六人進标准           inclusion criteria         小人進标准           inclusion criteria         人進标准           indicaterol <sup>148</sup> NDA 前中战阶段 <td></td> <td></td>		
immunogenicity <sup>141</sup> 最免疫力:免疫发生:免疫原性           immunoglobulin <sup>145</sup> = Ig         免疫球蛋白;           immunomodulatory agent (e.g. lefluomide)         免疫抑制細胞因子疗法           immunospressive cytokine therapy         免疫抑制細胞因子疗法           implantable defibrillators         植入式诊断性纪录系统           implantable dargonstic recorders         植入式诊断性纪录系统           implantable dargonstic recorders         植入式诊断性纪录系统           implantable gastric stimulation systems         植入式酸桃樹激系统           implantable scaral stimulation systems         植入式麦酸相刺激系统           implantable shunts         神经外科用版款本分流管           implantable stent grafts         植入式支案           implantable stents         植入式支案           implict preemption         販示优先运用 (Iaw)           IMPs = investigational medicinal products         临床成验研究用药           in vitro reagent         体外诊断 (产品)           inclusion criteria         八進标准           inclusion criteria         八進标准           inclusion criteria         八進标准           indcaterol <sup>148</sup> 第达特男:长炎吸入 β (2) -激动制支气管扩张           indcaterol <sup>148</sup> 第达特男:长炎吸入 β (2) -激动制支气管扩张           inclusion criteria         小進标           inclusion period/latency period         潜伏期           indecaterol <sup>148</sup> 第达特男:长炎吸入 β (2) -激动制		
immunoglobulin <sup>145</sup> = Ig     免疫球蛋白;       immunosuppressive cytokine therapy     免疫抑制细胞因子疗法       implantable defibrillators     植入式除颤器       implantable diagnostic recorders     植入式除颤器       implantable drug pumps     植入式常和刺激系统       implantable drug pumps     植入式脊柱刺激系统       implantable sacral stimulation systems     植入式脊柱刺激系统       implantable sacral stimulation systems     植入式公量作为复架       implantable sacral stimulation systems     植入式公量作为复案       implantable sacral stimulation systems     植入式如量介力集       implantable stont grafts     植入式鱼菜       implantable stont grafts     植入式鱼菜       implied preemption     联示优先适用(law)       IMPs = investigational medicinal products     临床试验研究用药       in vitro reagent     体外试剂       inclusion criteria     病例入选标准       inclusion criteria     病例入选标准       inclusion criteria     有例化选标准       inclusion criteria     人進水準       inclusion criteria     人進水       inclusion criteria     人進水       inclusion criteria     人進水       inclusion criteria     人進水		
immunomodulatory agent (e.g. leflunomide)         免疫调节剂           immunosuppressive cytokine therapy         免疫抑制细胞因子疗法           implantable defibrillators         植入式除颈器           implantable diagnostic recorders         植入式防死           implantable dug pumps         植入式防死           implantable dug pumps         植入式防水           implantable gastric stimulation systems         植入式酸橡刺激系统           implantable sucristimulation systems         植入式酸化刺激系统           implantable sucristimulation systems         植入式酸化刺激系统           implantable sucristimulation systems         植入式酸化刺激系统           implantable sucristimulation systems         植入式酸化刺激系统           implantable stent grafts         植入式支架           implantable stent grafts         植入式支架           implied preemption         販売优売金用約           IMPs = investigational medicinal products         临床状验研究           in vitro diagnostic = IVD <sup>146</sup> 体外诊断 (产品)           in vitro reagent         体外试剂           inclusion criteria         八邊休准           inclusion criteria <sup>147</sup> 入邊/排除标准           inclusion criteria <sup>147</sup> 入邊/排除标准           inclusion criteria         「           indeaterol <sup>148</sup> 節达特罗; 长效或入 β (2) -激动剂支气管扩张           IND = Investigational new drug applicatio		
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implantable neurostimulation systems         植入式脊柱刺激系统           implantable sacral stimulation systems         植入式腰椎刺激系统           implantable shunts         神经外利用脑积水分流管           implantable stent grafts         植入式鱼菜内支架           implantable stents         植入式支架           implicitable stents         植入式支架           implicitable stents         植入式支架           implicitable stents         植入式支架           implicitable stents         植太支支架           implicitable stents         塩人式東谷近月 (1aw)           IMPs = investigational medicinal products         临床试验研究用药           in vitro diagnostic = IVD <sup>146</sup> 体外诊断 (产品)           in vitro reagent         体外试剂           inclusion criteria         六遗标准           inclusion criteria         八遗标准           inclusion criteria         六遗/排除标准           incubation period/latency period         潜伏期           INDA = investigational new drug application         MDA 前中 求所致           Independent Data Monitoring = IDM         独立数据监察委员会           Independent Data Monitoring = IDM         独立数据监察           Independent Data Monitoring = IDM         独立数据监察委员会           independent Data Monitoring = IDM         独立数据监察委员会           Indomethacin         吲哚美辛           Indome		
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INDA = investigational new drug applicationNDA 前申报阶段indacaterol <sup>148</sup> 茚达特罗;长效吸入β(2)-激动剂支气管扩张 剂 bronchodilatorindemnity insurance赔偿保险Independent Data Monitoring = IDM独立数据监察 和立数据监察委员会Independent Data Monitoring Committee = IDMC独立处据监察委员会independent ethics committee = IEC独立伦理委员会indications适应症Indomethacin吲哚美辛Industrial chemicals工业化学品inert surface惰性表面Infant Formula Act of 1980婴儿配方食品法Infectious agents感染原Infectious Disease传染病		潜伏期
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Independent Data Monitoring Committee = IDMC独立数据监察委员会independent ethics committee = IEC独立伦理委员会indications适应症Indomethacin吲哚美辛Industrial chemicals工业化学品inert surface惰性表面Infant Formula Act of 1980婴儿配方食品法infectious agents感染原Infectious Disease传染病		赔偿保险
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Indomethacin吲哚美辛Industrial chemicals工业化学品inert surface惰性表面Infant Formula Act of 1980婴儿配方食品法infectious agents感染原Infectious Disease传染病	4	独立伦理委员会
Industrial chemicals       工业化学品         inert surface       惰性表面         Infant Formula Act of 1980       婴儿配方食品法         infectious agents       感染原         Infectious Disease       传染病	indications	适应症
inert surface惰性表面Infant Formula Act of 1980婴儿配方食品法infectious agents感染原Infectious Disease传染病	Indomethacin	吲哚美辛
Infant Formula Act of 1980       婴儿配方食品法         infectious agents       感染原         Infectious Disease       传染病	Industrial chemicals	工业化学品
infectious agents	inert surface	惰性表面
Infectious Disease 传染病	Infant Formula Act of 1980	婴儿配方食品法
14 /1-2/4	infectious agents	感染原
	Infectious Disease	传染病
Inflammatory pain / 炎症痛	Inflammatory pain	炎症痛
infliximab (trade name: Remicade) 英夫利昔单抗; 抗类风湿药; 是一种特异性阻断	infliximab (trade name: Remicade)	英夫利昔单抗; 抗类风湿药;是一种特异性阻断

	肿瘤坏死因子 a (TNF-a)的人鼠嵌合型单克
	所描示见因了 u (INF-u)的八瓜银石型十元 隆抗体
Influenza virus type A (subtype H2, H5 and H7)	座仉仰   甲型流行性感冒病毒(H2、H5及H7亚型)
informed consent	
informed consent form/informed consent document	知情同意
= ICF	知情同意书
INFOSAN = International Food Safety Authorities	国际食品安全当局网络
Network	
infrared = IR	红外吸收光谱
infusion pump	输液泵
infusion sets	输液器具
INH = isoniazid	异烟肼(抗结核药)
inhibitory cytokine	抑制性细胞因子
initial meeting	启动会议
in-licensing agreement	产品授权合伙协议
INN = international nonproprietary name	国际非专有名称
innovator drug	原创新药
in-process testing	过程测试
$INR^{149}$ = international normalized ratio	国际标准化比率
inspection	视察 / 检查
Institute of Medicine = IOM	医学研究所(National Academy of Sciences
	国家科学学院下设)
institution inspection	机构检查
Institutional Review Board $=$ IRB <sup>150</sup>	机构审查委员会(伦理委员会)
Insulin delivery	胰岛素注入
insulin pumps	胰岛素泵
intended population	适应人群
intended use	- 近 八 叶
intention-to-treat analysis <sup>151</sup> = ITT analysis	(治疗)意向性分析;
Interactive Voice Response System = IVRS	[石刃] 忘问任为利; 互动语音应答系统
Inter-American Institute For Co-Operation On	
Agriculture	泛美农业科学学会
interferon	
interim analysis <sup>152</sup>	期中分析
interleukin-6	白细胞介素-6
internediate	中间体
International Classification of Diseases,	国际疾病分类第9版
Ninth Revision (ICD-9)	白吹沉啊儿大型1版
International Conference of Harmonization = ICH	人用药品注册技术要求国际技术协调会,国际协
	调会议
Internet-based information technology system	基于互联网的信息交换系统
interstitial cystitis IC	间质性膀胱炎
intervention <sup>153</sup> .	干预措施
intestinal flora	
Intravenous infusion and blood transfusion	静脉输液与输血
invasive fungal infection	时 <u>你</u> 物很 つ 物 <u>w</u> 入侵性霉菌感染
inversion <sup>154</sup>	1) ()) ()) ()) ()) ()) ()) ()) (
investigational new drug = IND	個位 (週夜子) 临床研究新药
investigational new drug = IND	
mvesugational product	试验用药品;试验用药物

investigator	研究者(临床试验)
investigator's brochure = IB	研究者手册
iodophor germicidal detergent solution	碘伏消毒液
IPAB = Independent Payment Advisory Board156,	
IPC = in-process control	(生产过程)中间过程控制
IPO = Initial Public Offerings	首次公开募股
IQM = Integrated Quality Management	集成质量管理
IR	红外吸收光谱
IRB = Institutional Review Board	机构审查委员会
IRR = Internal Rate of Return	内部收益率
Irradiation	辐射
ischemic/viable myocardial tissues	缺血/存活心肌
Ishikawa Diagram; Cause and Effect Diagram	因果图
Isolator System	
Isoniazid = INH	几面闹两 <u>犯</u> 异烟肼
isopropyl alcohol	<ul> <li>7 / A///</li> <li>2-丙醇; 异丙醇</li> </ul>
isotope tracer	2 闪时,开闪时 同位素示踪物
isotype antibody	同种型抗体
ISPE = International Society for Pharmaceutical	国际制药工程协会
Engineering	
ISS (Integrated Summary of Safety)	安全性综合总结
ITT dataset, now known as FAS (full analysis set)	全分析集
IV push	静脉推注
IVD device = In vitro diagnostic device	体外诊断设备
IVDMIA = In Vitro Diagnostic Multivariate Index	体外诊断多变量索引化验
Assay	
IVIVC (In Vitro-In Vivo Correlation) <sup>157</sup>	制剂的体内外相关性
Janus kinase JAK <sup>158</sup>	JAK 激酶
Japanese encephalitis virus	日本脑炎病毒
JCAHO = Joint Commission on the Accreditation of Healthcare Organizations	保健组织认证联合委员会
JECFA = Joint FAO/WHO Expert Committee on	联合国粮农组织和世界卫生组织下的食品添加剂
Food Additives	联合专家委员会
JEMRA, the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment	微生物危险性评估专家联合会议
JIFSAN = Joint Institute of Food Safety and Applied Nutrition	食品安全和应用营养联合研究所
Johnson & Johnson	美国强生
joint tenderness (as opposed to pain)	关节压痛
JPMA = Japan Pharmaceutical Manufacturers	日本制药工业协会
Association	
Junin virus	鸠宁病毒
Ka = absorption rate constant	吸收速率常数
Ketek, also known as Telithromycin	肯立克,又称泰利霉素
ketoconazole	酮康唑
kits	器械包
Kogenate FS (Antihemophilic Factor) by Bayer	拜科奇; 重组因子VIII; 抗血友病注射剂, 重组人
	凝血Ⅲ因子
	··· ··································

KOL key opinion leaders	关键意见领袖
Konjac	魔芋
Koseisho	日本厚生省
KPI: key performance indicator	企业关键绩效指标
Kyasanur Forest disease virus	基萨诺尔森林病病毒
labeled amount	标示量
labels and labeling <sup>159</sup>	药品标签(Label、Labeling)。药品标签分为两种,一种称为"Label",是指直接接触药品的内容器、外容器或外包装上的书写物、
	印刷物、绘制物;另一种称为"Labeling", 包括所有的 Label、药品说明书和其他附加于药 品的书写物、印刷物、绘制物
LACF = low acid canned foods	低酸罐装食品
lactobacilli	乳酸菌
Laetrile, Amygdalin, Vitamin B17	杏素,苦杏仁苷
Lamictal® <sup>160</sup> (la-MIK-tal) XR <sup>TM</sup> (lamotrigine) Extended-Release Tablets	利必通24小时缓释片,成分拉莫三嗪片
laminar flow hood	层流净化罩
larynx	·····································
laser pointer	激光笔
$LASIK^{161} = laser-assisted in situ keratomileusis$	准分子激光原位角膜磨镶术;激光辅助角膜重塑 术
Lassa virus	拉沙病毒
last observation carry forward = $LOCF^{162}$	结转;最接近一次观察数据的结转;末次观测值 结转法
late stent thrombosis	药物支架晚期血栓
LCC = Low Cost Country	低成本国家
LC - MS	液相色谱-质谱联用
LD = longest diameter	(肿瘤) 最大直径
$LD10^{163} = lethal-dose 10\%$	亚致死剂量
LD50	半数致死剂量
lead arsenate	砷酸铅
lead compound	先导化合物
leak testing	检漏
Leflunomide: to treat rheumatoid arthritis	来氟米特
Lenalidomide/Revlimid <sup>164</sup>	来那度胺
lethal dose,50% = LD50	半数致死剂量
leukemia	白血病
levofloxacin hydrochloride Levaquin	盐酸左氧氟沙星
LFTs = Liver function tests	肝功能检测
librium; chlordiazepoxide	利眠宁;氯氮卓
licensed pharmacist	执业药师
licensing authorities	发证机构
life expectancy	预期寿命
ligand	配体
Limit of Quantitation <sup><math>165</math></sup> = LOQ	定量限
Line Extension	延伸性新药(新适应证、新剂型和现有药物的新
	复方)

line extensions, product	产品线扩展
lipase	<b>脂肪</b>
lipid oxydation	油脂氧化
lipid virus	亲脂病毒
lipitor	立普妥(阿托伐他汀钙)降胆固醇药物
Liquid Chromatography Mass Spectrometry = LC-	液-质联用
MS	夜 须 秋川
Listeria	李斯特菌
Listeria monocytogenes	单核细胞增多性李斯特菌; 单核细胞增生李斯特
	菌
listeriosis	李氏杆菌病
liver assist devices	肝脏辅助装置
liver biopsy	肝组织活检
liver death; hepatic death	肝性死亡
Livor mortis	尸斑 <sup>166</sup>
loading dose	负荷剂量;是指首剂增大的剂量,能使血药浓度
	迅速达到所希望的 Css
Local Quality Representative (LQR)	地方质量代表
LOCF = last observation carried forward	末次观察值结转法
log rank test	时序检验
logic check	逻辑检查
Long QT syndrome = LQTS $^{167}$	先天性长 QT 综合征
Longitudinal patient reported surveillance program	纵向患者报告监督项目
LOQ = Limit of Quantitation	定量限
loss to follow-up	失访
low molecular weight heparin = LMWH	低分子肝素
LPN = licensed practical nurse	持证职业护士
L-Tryptophan	L-色氨酸
lumbar tapered fusion device	腰椎椎间融合器
lumen	管腔
lymphocyte antigen	淋巴细胞抗原
lymphoma	淋巴瘤
M. bovis	牛分枝杆菌
M. tuberculosis	结核分枝杆菌
MAA = Marketing Authorization Application	上市许可申请;营销授权申请 (欧洲药管局术
(EMA)	语)
MAB = monoclonal antibody	单抗;单克隆抗体
MACE = major adverse cardiovascular events	主要不良心脏事件
Machupo virus	马秋波病毒
macroconstituent	常量成分
Macronutrients	常量营养元素
MAD = Multiple Ascending Dose studies	渐增型多药剂量浓度测试
MAH = Marketing Authorization Holder	销售许可持有者;药品上市许可持有人;持证
	商;
maladministration	用药不当
malignant hyperthermia = MH	恶性高热症
malpractice claims	医疗过失索赔
managed care	管理式医疗
	•

manipulated autologous structural cells (MAS cells)	经处理自体结构细胞
MAO (monoamine oxidase) inhibitor	单胺氧化酶抑制剂
Marburg virus	马尔堡病毒
market basket survey.	市场菜篮子调查
market clearance	市场准入批准件
market exclusivity <sup>168</sup> = exclusive marketing rights	市场独占;市场专卖权
granted by the FDA	
market withdrawal	撤市
marketing	营销
marketing approval/ authorization = MA	上市许可证
marketing authorization application = MAA	上市许可申请
masked	设盲
Mass Spectrometry = MS	质谱
mass-balance	质量平衡
MAST = Minimal Access Spinal Technologies	微创脊柱技术; 微创脊椎修复技术
matched pair	匹配配对
matrix protein	基质蛋白
maximum tolerated dose = MTD	最大耐受剂量
MCO = Managed Care Organization	医疗管理组织
MCyR = major cytogenetic response	细胞遗传学应答
MDFP medical device fellowship program	· · · · · · · · · · · · · · · · · · ·
MDMA = Medical Device Manufacturers	医疗器械生产商协会
Association	
MDR = Medical Device Reporting	医疗器械强制报告系统
MDUFA III = Medical Device User Fee	医疗器械用户费用法
MDUFMA = Medical Device User Fee and Modernization Act	医疗器械用户费用和现代化法
MDUFSA = Medical Device User Fee Stabilization Act	医疗器械用户费用稳定法
mean absorption time = MAT	(药物在体内的)平均吸收时间
mean disintegration time = MDIT	(药物在体内的)平均崩解时间
mean dissolution time = MDT	(药物在体内的)平均释放时间
mean residence time = MRT	(药物在体内的)平均滞留时间
measurable disease	可测量病变
measurable lesion	可测量病灶
mechanism of action	「 <u>「</u> 」「 <u>」</u> 」「 <u>」」」</u> 作用机制
MedDRA <sup>169</sup> = Medical Dictionary for Regulatory	国际医学用语词典; 药事管理的标准医学术语集
Activities Medicaid	分田医疗补偿制度,分田医促
medical device <sup>170</sup>	贫困医疗补偿制度;贫困医保;
Medical Device Amendments	医疗器械
	医疗器械修正案》1976
medical governance Medicare	医药治理
	老年医疗保险制度;联邦老年医保
medication guides (for patients)	用药指南
Medicines Control Agency = MCA	英国药品监督局
MedSun = Medical Product Surveillance Network	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Medtronic	美敦力
MedWatch <sup>171</sup>	医药警戒项目;

MEK (methyl ethyl ketone)	甲乙酮; 丁酮
Melamine	三聚氰胺
melanoma	黑色素瘤
Meloxicam	美洛昔康; (左旋)苯丙氨酸氮芥[消炎镇痛药]
MEMS = Micro Electromechanical System	微电子机械系统
Meniere's Disease	美尼尔氏病
meningitis	脑膜炎
meningitis B	乙型脑炎
meningococcal meningitis	脑膜炎球菌性脑膜炎
Merck Sharp & Dohme = MSD, part of Merck	美国默沙东(Merck)制药
mesothelin <sup>172</sup>	间皮素
messenger RNA	信使核糖核酸
meta-analysis <sup>173</sup>	荟萃分析;元分析
metabolite	代谢物
metabolizer	代谢改变剂
metabolomics	代谢组学
metastatic	转移
metformin	甲福明; 二甲双胍 gua; 抗糖尿病药
metformin hydrochloride	盐酸二甲双胍 (gua)
methadone	美沙酮[镇痛药]
Methicillin	甲氧西林
Methotrexate, MTX treatment of cancer,	甲氨喋呤;应用于白血病、淋巴瘤、头颈部肿
autoimmune diseases, ectopic pregnancy, and for	瘤、骨肉瘤以及多种自身免疫性疾病最为广泛的
the induction of medical abortions	一种抗代谢药物
methylation of DNA	DNA 的甲基化
methylmercury	甲基汞;二甲基汞
methylphenidates	哌醋甲酯
methylprednisolone	甲强龙, 甲基强的龙醋酸盐, 甲基强的松龙
metronidazole MNZ	甲硝唑 (灭滴灵)
MGPS = Multi-Item Gamma Poisson Shrinker	多项伽玛泊松分布缩检法
MHLW = Ministry of Health , Labour and Welfare	(日本)厚生劳动省
MHRA = Medicines and Healthcare products	英国药品和健康产品管理局
Regulatory Agency	
MI = myocardial infarction	心肌梗死;心肌梗塞
MIC = Minimum Inhibitory Concentration	最低抑菌浓度
microbial flora	微生物菌群
microcephaly	小头畸形
micrococci	微球菌
microneedles	微针
microphthalmia	小眼球
micropumps	微型泵
midodrine	甲氧胺福林
minimal effective dose	最小有作用剂量
minimally invasive spinal surgery	微创脊椎手术
minimum inhibitory concentration = MIC	最低抑菌浓度
Ministry of Health and Welfare = MHW	日本卫生福利部
minocycline	米诺环素

Mirena (Levonorgestrel Intrauterine System)	<b>曼月乐(左炔诺孕酮宫内节育器)</b>
MIS: minimally invasive surgery	微创外科手术
misbranding	标签误导;错误标签;冒牌
miscoding	编码错误
Misoprostol	迷索前列醇
missing value	缺失值
mixed effect model	派入值 混合效应模式
MLD = minimal lethal dose	最小致死剂量
MLD = minima reduct dose MoA = mechanism of action <sup>174</sup>	作用机制;作用机理
$MoA = memorandum of agreement^{175}$	协定备忘录
_	
modem	调制解调器
modernization	与时具进
modified atmosphere packaging (MAP)	气调包装
modified fats	改良脂肪
modified release capsule	缓释胶囊
molecular characterization	分子特征
molecular diagnostics	分子诊断学
molecular pathogenesis	致病的分子机制
molecular targeted therapy	分子靶向治疗
monitor <sup>176</sup>	监查员
monitoring plan	监查计划
monitoring report	监查报告
monkeypox virus	猴痘病毒
monoclonal antibody	单克隆抗体
movement disorders	运动障碍
MQSA = mammography quality standards act	乳房X线造影术质量标准法
MR = moderate response	好转
MRA = Agreement on Mutual Recognition	相互承认协定
MRCT Multi-Regional Clinical Trials	多中心临床试验
MRI = magnetic resonance imaging	磁共振成像
MRSA = Methicillin resistant staphylococcus	抗甲氧西林金黄色葡萄球菌
aureus	
MRT = mean residence time	平均滞留时间
$MS = multiple \ sclerosis$	多发性硬化症
MS-MS	质谱-质谱联用
MTD = maximal tolerance dose	最大耐受剂量
MTX = methotrexate	甲氨喋呤 jia an die ling
MUCOSA trial <sup>177</sup> (Misoprostol Ulcer	迷索前列醇溃疡并发症结果安全评估
Complications Outcomes Safety Assessment)	
multicenter trial	多中心试验
multi-drug resistance	多药物抗药性
multi-kinase inhibitor	多激酶抑制剂
multi-omics	多组学
multiple arm trials	多治疗组的试验
multiple sclerosis = MS	多发性硬化症
Multiple-system atrophy (MSA)	多系统萎缩
mutual recognition procedure (EU)	相互承认程序
troogination procedure (200)	-1

mycobacteria	分枝杆菌
mycobacterium tuberculosis (multidrug-resistant)	结核分枝杆菌(耐多药)
Mycophenolate mofetil (MMF) <sup>178</sup>	吗替麦考酚酯
mycotoxins	真菌毒素;霉菌毒素;
myelin	新
myocardial electrode	心肌电极
myocardial ischemia	心肌供血不足,缺血
NABP = National Association of Boards of	美国全国药房理事会协会
Pharmacy	天田生田约历生书云协云
NAI = No Action Indicated	无需采取行动
Naproxen Caps	茶普生胶囊
NARA = National Archives and Records	国家档案和记录管理局
Administration	
narcotics	麻醉药品
narrative summary	记叙体概要
National Formulary	国家处方集
National Institutes of Health = NIH	美国国家卫生研究所
Natural History Study <sup>179</sup>	自然发展研究
NCE = new chemical entity	新化合物
NCI CTEP = National Cancer Institute Cancer	国家癌症研究所的癌症治疗评价计划
Therapy Evaluation Program	
NDA new drug application <sup>180</sup>	新药申请
neoplasm	肿瘤
Neupogen(filgrastim)	优保津注射剂;非格司亭
neural interface	神经接口系统
neurodegenerative treatments	神经退行性疾病
neurogenic pain	神经源性痛
neurological stimulators	神经刺激系统
neuromodulation <sup>181</sup>	神经调控
neuromodulator	神经调质
neuron	神经元
neuropathic pain	神经病理性疼痛
neurotransmitter	神经递质
neutralizing antibody	中和抗体
neutropenia	嗜中性白血球减少症
new chemical entity = NCE	新化学实体
new drug application = $NDA^{182}$	新药申请
Nexavar = sorafenib tosylate	多吉美(索拉非尼片)用于治疗晚期肾细胞癌
NF = national formulary	美国国家处方集
NICE <sup>183</sup> National Institute for Health and Clinical	天国国家处力来 英国国家卫生与临床优化研究所
Excellence	大四四豕上土刁恒床饥化切九別
NIH = National Institute Of Health	美国全国卫生研究所
Nipah virus	尼巴病毒
nitrazepam <sup>184</sup>	硝西泮(硝基安定)
nitrite	亚硝酸盐
NLEA = Nutrition Labeling and Education Act	营养标识与教育法
NME = new molecular entity	新分子实体
NMR spectroscopy = nuclear magnetic resonance	核磁共振谱
mart speciescopy – nuclear magnetic resonance	11从124 57 712 1日

国家大洋大气管理局 / 国家海洋渔业局
未见不良反应剂量水平
伤害性疼痛
伤害性感受器
神经源性体位性(直立性)低血压;
名义显著性水平
非囊性纤维化支气管扩张
剂量不相关的不良反应
非酶褐变
非劣效性界值
非劣效性试验
亲水病毒
非参数统计方法
非显著的危险性
去甲肾上腺素
- Z - 月上/亦示 诺瓦克病毒
<u> </u>
压百夕〕 (抗反動麻疥约) 医院感染
医阮恐采 备案
认证机构
诺华制药有限公司
净现值
伤口负压治疗技术
非甾(zai)体抗炎药;非甾类消炎药
非实质等同性质的信函
核苷酸
无效假设;原假设,或称为零假设;通常将研究
者想要收集证据予以反对的假设
分子
护理医生
营养标签和教育法
骨性关节炎
需采取监管行动
OASIS 进口支援操作行政系统
最佳生物学剂量
依从性
强迫症
封闭器
犯罪调查办公室
FDA 细胞组织和基因治疗办公室
FDA 药物评估办公室
器官用药市场独占权
器官用药市场独占权 膳食补充剂办公室
膳食补充剂办公室

official compendium	法定药典(主要指 USP、 NF)
off-label use <sup>191</sup>	标示外使用;超标签使用
off-target adverse events <sup>192</sup>	脱靶效应
off-the-shelf components	成品元件; Commercial-Off-The-Shelf, 商用现 货
OH = orthostatic hypotension	体位性低血压
oligonucleotide	寡核苷酸
OLT = orthotopic liver transplant	原位肝移植
Omapro = Omacetaxine mepesuccinate	高三尖杉酯,申请用于慢性骨髓性白血病
	Chronic myeloid leukemia
ombudsman	申诉专员;
Omeprazole	奥美拉唑[抗溃疡病药]
Omsk haemorrhagic fever virus	鄂木斯克出血热病毒
oncolytic agent	溶瘤细胞剂
OND = Office of New Drugs	新药办公室
OOS = out of specification	超标;不合格
open-blinding/open-label	非盲
open-cell foam	开孔泡沫
open-chest Surgery Devices	开胸手术器材
open-heart surgery perfusion and stabilization	开胸手术灌注及稳定系统
systems	
open-label	非盲
open-label trial <sup>193</sup>	开放标记试验;开放性试验
operating margin	营业利润率
opioid	阿片样物质
opportunistic infections	机会性感染
OPQ (Office of Pharmaceutical Quality) <sup>194</sup>	藥品質量辦公室
optical sensor	光学传感器
optional titration	随意滴定;选择滴定
ORA = Office of Regulatory Affairs	监管事务办公室
oral solid dosage forms	口服固体剂型
Orange Book <sup>195</sup>	橙皮书
ORD = optical rotatory dispersion	旋光光谱
orexin	食欲素
organ replacements and assists	替代;辅助装置
organic impairment	器质性损害
organoleptic quality	感官; 口感
original medical record	原始医疗记录
orphan drugs <sup>196</sup>	罕见病用药,孤儿药
ORR ( Objective Response Rate )	客观缓解率
orthopedic implants	整形外科植入
orthopedic surgery	矫形外科学
orthopedics	骨科
orthostatic hypotensionm = OH	体位性低血压
orthotics	矫形器
OS = Overall survival	总生存率
OSA = obstructive sleep apnea	
SSII Sobracito sicop aprica	1

OSHA = Occupational Safety And Health Act	职业安全与卫生条例[管理局]
[administration]	
osmophilic yeasts	耐高渗透酵母
osteoblast	成骨细胞
osteoclast	破骨细胞
osteomyelitis	骨髓炎
OTC drug = over-the-counter drug	非处方药
OTC Switch, Rx-to-OTC Switch	处方药改列成药
ototoxicity	耳毒性
outcome	结果
outcome assessment	结果指标评价
outcome measurement	结果指标
outlier	离群值
outpatient	门诊
outreach	沟通
overactive bladder	膀胱过度活动症
oxazepam; (marketed under brand names Alepam,	奥沙西泮(去甲羟基安定,舒宁)
Murelax, Oxascand, Serax, Serepax, Seresta, Sobril)	
oxidative stress	氧化应激
oxycodone	羟可酮
P/E Ratio	市盈率
P4P = Pay for performance systems	按绩效付费制度
pacemakers	心脏起博器
package insert (for physicians) = label	药品说明书;"专业标签"("Professional
	labeling")、"处方信息"("Prescribing
	information");包装插页
package seal	包装密封
PACS = Picture Archiving Communication System	医学影像存档和通讯系统
palivizumab (Synagis)	帕利珠单抗
palliative care unit	临终照顾病房
palpitation	心悸
pancytopenia	全血细胞减少症
paracetamol	对乙酰 xian 氨基酚 (又称扑热息痛,或醋氨
1	酚)
paragraph IV certification <sup>197</sup> CFR	第四段认证;第四段专利挑战
314.94(a)(12)(i)(A)(4)	
parallel group design	平行组设计
parameter estimation	参数估计
parameter estimation parametric release <sup>198</sup>	
-	参数估计
parametric release <sup>198</sup>	参数估计 参数放行
parametric release <sup>198</sup> parametric statistics	参数估计 参数放行 参数统计方法
parametric release <sup>198</sup> parametric statistics Paraplegia parasympathetic nervous system (autonomic	参数估计 参数放行 参数统计方法 截瘫
parametric release <sup>198</sup> parametric statistics Paraplegia parasympathetic nervous system (autonomic nervous system)	参数估计 参数放行 参数统计方法 截瘫 副交感神經系統(自律神經系統)
parametric release <sup>198</sup> parametric statistics Paraplegia parasympathetic nervous system (autonomic nervous system) parathyroid hormone deficiency	参数估计 参数放行 参数统计方法 截瘫 副交感神經系統(自律神經系統) 甲状旁腺激素缺乏 震颤麻痹
parametric release <sup>198</sup> parametric statistics Paraplegia parasympathetic nervous system (autonomic nervous system) parathyroid hormone deficiency Parkinsonism partial (onset) seizure <sup>199</sup>	参数估计 参数放行 参数统计方法 截瘫 副交感神經系統(自律神經系統) 甲状旁腺激素缺乏 震颤麻痹 局部发作型癫痫症;部分发作
parametric release <sup>198</sup> parametric statistics Paraplegia parasympathetic nervous system (autonomic nervous system) parathyroid hormone deficiency Parkinsonism	参数估计 参数放行 参数统计方法 截瘫 副交感神經系統(自律神經系統) 甲状旁腺激素缺乏 震颤麻痹

Pasteurization	巴氏灭菌法
PAT = Process Analytical Technology <sup>200</sup>	过程分析技术
patent term restoration <sup>201</sup>	专利期补偿
pathogen	病原体
pathogenic cocci	病原性球菌
patient file	病人档案
patient global; pt global	病人总体评价
patient history	病历
payroll tax <sup>202</sup>	每个雇主都要支付给国税局"工资税",目前是
F	雇员总收入(就是没有扣除任何费用之前的总薪
	水)的7.65%
PBM = Pharmacy Benefits Manager	药房福利管理公司
Pbo or Pla = placebo	安慰剂
PCB = polychlorinated biphenyls	多氯联苯同类物
PCI Percutaneous coronary intervention <sup>203</sup>	经皮冠状动脉介入
PCR assays; polymerase chain reaction	PCR 检测;聚合酶链反应
$PD = pharmacodynamics^{204}$	药物效应动力学; 简称药效学
PDA = Parenteral Drug Association	注射用药物协会
PDA = Photo Diode Array	光电二极管阵列
PDCO = Pediatric Committee	小儿科委员会
PDGFR (Platelet Derived Growth Factor Receptor)	血小板衍生生长因子受体
PDP product development protocol <sup>205</sup>	产品发展协议
PDUFA = Prescription Drug User Fee Act 1992	美国处方药申报者付费法;
peer review <sup>206</sup>	专家评审
Pegasys (peginterferon alfa-2a)	派罗欣;聚乙二醇干扰素 α-2a 注射液 (to
	treat hepatitis)
pegylated enzyme	聚乙二醇修饰酶
pegylated interferon alfa-2a	聚乙二醇化干扰素 alfa-2a
PEGylation is the process of covalent attachment of	聚乙二醇化
polyethylene glycol (PEG) polymer chains to	
another molecule, normally a drug or therapeutic	
protein penicillamine	青霉胺
penicillium verrucosum	月母版 疣孢青霉
Pennsaid	元把頁每   双氯芬酸钠商品名;外用的类固醇消炎药-被
remisaid	
peptides	用于治疗膝关节骨性关节炎 肽
per protocol ( PP) analysis <sup>207</sup>	
per protocol set (PPS) <sup>208</sup>	符合方案分析 符合方案集
perchlorate	
percutaneous transluminal balloon angioplasty	高氯酸
perforated ulcer	经皮腔内气囊血管成形术
perfusion	穿孔性溃疡 灌注
perioperative antibiotic prophylaxis	
perioperative antioiotic propriyaxis	围手术期抗菌药物的使用; 用边在签库店
personalized medicine	周边血管疾病 个体化给药
pesticide residue	
PET = positron emission tomography	农药残留
r E r – postu on emission tomography	正电子发射断层显像

脉冲场凝胶电泳
辉瑞制药
卵圆孔未闭
5. 天疾病进展存活率
病人总体评价
药物遗传学;
药物遗传学;遗传药理学
预先(初步)危险(危害源)分析
药剂等效性
药剂学
法玛西亚
药物效应动力学;简称药效学
药物流行病学
药物遗传学
药物基因组学
药代动力学; 简称药动学
药理学
药物警戒
配药学
PharMetrics 索赔数据库
咽
非那根;异丙嗪
苯酚
表型
表型耐药
保泰松
有潜在危险的食品
静脉放血术
短肢畸形;海豹肢畸胎;海豹肢畸形
磷酸化
光动力疗法
美国药物研究与生产商协会
磷脂酰肌醇激酶-3
药品检查协定
药物检查合作计划
小柱软腭植入术
开发中产品
药物代谢动力学;药动学,药代动力学
安慰剂
安慰剂对照
安慰剂对照研究
安慰剂效应
植物甾醇酯
植物甾醇

$PLAS = performance-linked access systems^{221}$	动态链接系统
plasma concentrations	血药浓度
plasma protein binding <sup>222</sup>	血浆蛋白结合
Plavix (Clopidogrel bisulfate)	波立维; 氯吡格雷硫酸氢盐
pleiotropy <sup>223</sup>	基因多效性,多向性
pleural effusion	胸腔积液
Plt = platelet	血小板
PMA = pre-market application	上市前申请
PMA = premarket approval	上市前许可;销售前批准
$PMCs = post marketing commitments^{224}$	承诺药品上市后的继续研究
PMDA Pharmaceuticals and Medical Devices	医药品医疗器械综合机构; 医薬品医療機器総合
Agency, Japan	機構
PMDRA = Post Marketing Drug Risk Assessment	上市后药品风险评估(办公室)
PMHx = past medical history	既往病史
PMN = premarket notification	销售前通知
PMS = premenstrual syndrome	经前综合症
POC (proof-of-concept) Clinical Trials <sup>225</sup>	概念证明
POC = point-of-care testing	床旁分析
polio	脊髓灰质炎
polymer wafer	高分子缓释片
polymorphism	多态性
polymyxin	
polypharmacy <sup>226</sup>	之和國亦 复方用药, 混杂给药, 过多给药
polyphenol oxidase	多酚氧化酶
polytomies	多分类 多分类
pooled analysis = PA	荟萃分析
poor motor coordination	运动协调困难
pop pk, population pk	<b>群体药动学评价</b>
PoS = point-of-sales	销售点
post hoc analysis	事后分析
postmarket surveillance	上市后监督
post-marketing surveillance; postmarket safety	11·17-17-11-11 销售(上市)后监督
surveillance	· · · · · · · · · · · · · · · · · · ·
Post-translational modification, PTM	蛋白质的翻译后修饰
postural hypotension	直立性低血压
potency	效价
power <sup>227</sup>	把握度;检验效能
$Pp = Process Performance^{228}$	工序绩效
$Ppk = Process Performance Index^{229}$	工序绩效指数
PPO = preferred provider organizations	优先提供者组织
$PPS^{230} = Per-Protocol Set$	符合方案集
PQR (Product Quality Review)	产品质量审查
PR = partial response	部分缓解
practolol affair	心得宁事件
Prasterone for VV atrophy tx	普拉睾酮
Prasugrel <sup>231</sup> 商品名: Effient	普拉格雷
prazoxin	a1受体阻滞剂 哌唑嗪 pai zuo qin
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PREA = the Pediatric Research Equity Act	儿科研究公平法
Preamble <sup>232</sup> (Federal Register)	序言
precautions	慎用;注意事项
precision	精密度
preclinical (animal) data	临床前(动物实验)数据
preclinical study	临床前研究
predicate device = legally marketed device that is	和已合法在市场上销售的且不需要做 PMA"销售
not subject to premarket approval (PMA)	前批准"的
predicate rule <sup>233</sup>	已发布的 FDA 法规
prednisolone	泼尼松龙
prednisone	泼尼松, 泼尼松等皮质激素是广泛应用的免疫抑
	制剂
premarket notification (510(k)s)	上市前通知
pre-marketing surveillance	销售(上市)前监督
prescription drug	处方药
preservation	保藏
prevalence	患病率
prevention trials	预防试验
primary (coronary) event	原位病变
primary endpoint	主要终点
primary mode of action = $PMOA^{234}$	首要作用模式
primary pulmonary hypertension PPH	原发性肺动脉高血压
primary variable	主要变量
principal investigator = PI	主要研究者
Principles of Qualification	确认(验证)原则
prion	阮病毒
Prior Notice (PN) System Interface	提前通报系统界面
Priority Review designation <sup>235</sup>	优先审查
private label	贴牌生产
private label distributor	商标发行商
PRO patient-reported outcome	患者报告结局
probability	概率
probe substrate	探针底物
procedure trays	操作盘
process controls	工艺控制
pro-drug <sup>236</sup> prodrug	前体药物,也称前药、药物前体、前驅藥物等
product codes	产品的号码
product differentiation	产品差异化,产品特色化
product license = PL	产品许可证
product life cycle (PLC) <sup>237</sup>	产品生命周期
progesterone	黄体酮, 孕酮
prognosis	预后;归转
progression-free survival = PFS	无进展生存
progressive disease = PD	病情进展
proof of principle study <sup>238</sup>	原理循证研究
propensity score	倾向性评分
propionic acid	丙酸

propranolol	普萘洛尔
proprietary name	专有名称
Propulsid (Cisapride)	西沙必利;优尼比利,西沙普雷特,优尼必
	利,西沙比利,普瑞博斯,西沙比得
prostaglandin	前列腺素
prosthetics	假肢
protease inhibitor	蛋白酶抑制剂
proteasome	蛋白酶体
protein purification	蛋白纯化
proteomics	蛋白质组学
prothrombin	凝血酶原;凝血原
protocol <sup>239</sup>	临床试验方案
protocol amendment	方案补正
prototype design	原型设计
protozoa	原生动物门
proven acceptable range = $PAR^{240}$	确定可接受范围
Prozac	百忧解
PSA = prostate specific antigen	前列腺特异抗原
PsA = psoriatic arthritis	银屑病关节炎
pseudomonas	假单孢菌;假单胞杆菌
PSMA prostate specific membrane antigen	前列腺特异性膜抗原
psoriasis	银屑病;俗称牛皮癣
psoriatic arthritis PsA	银屑病关节炎
PSUR <sup>241</sup> = periodic safety update report	定期安全性更新报告
psychotropics	精神药品
psychrotrophic pathogens	嗜冷致病菌
Pt global = patient global assessment	患者总体评价
PTBA = percutaneous transluminal balloon angioplasty	经皮腔内气囊血管成形术
PTC = product technical complaints	药品技术投诉
PTCA = percutaneous transluminal coronary angioplasty	经皮冠状动脉成形术
PTM = post-translational modifications	蛋白质的翻译后修饰
PTS = probability of technical success	技术成功概率
public goods	公共产品
pulmonary arterial hypertension, PAH	肺动脉高压
pulmonary embolism	肺栓塞
Pure Food and Drug Act of 1906	1906年颁布的《纯净食品和药品法》
PVAR = preliminary variation assessment report	初步改变评估报告
pyloric sphincter	幽门括约肌
pylorus	幽门
pyrimidine synthesis inhibitor (e.g. leflunomide)	嘧啶合成抑制剂
QSIT = Quality Systems Inspection Technique	美国 FDA 质量体系检查指南
QSR = Quality Systems Regulation	质量体系规章
QT interval <sup>242</sup>	QT 间期
QTc = Corrected QT	校正QT间期
QTPP: quality target product profile <sup>243</sup>	目标药品的质量概况
qualification system for licensed pharmacist	执业药师资格准入制度

qualification, Design (DQ) <sup>345</sup> 12. 计确认           qualification, Installation (Q) <sup>256</sup> 安東南认           qualification, Operational (OQ) <sup>347</sup> 12. 扩确认           qualification, Performance (PQ) <sup>348</sup> 12. 统南认           qualification, Process <sup>2167</sup> 12. 乙南认           qualification, Process <sup>2167</sup> 12. 乙南认           qualification, Process <sup>2167</sup> 12. 乙南认           qualified person = QP <sup>2560</sup> 特易必付开发化:, 质量受权人           quality assurance = QA         质量保证           quality assurance = QA         质量依据           quality ontrol = QC         质量を記載           quality ontrol = QC         质量を認知           quality ontrol = QC         质量を記載           quality or its rules or supportive care trials         生存质量这股           quality or its rules or supportive care trials         生存质量这股           quality or its rules or supportive care trials         生存质量这股           quality or its rules or supportive care trials         生存质量之风           quality or its rules or supportive care trials         生存质量之标复           quality of its or supportive care trials         生存质量之体差           quality of its assessment         堂化风险方式           quality or its assessment         愛し人気防           quality orits assessment         愛し人気防	qualification vs validation <sup>244</sup>	确认 vs 验证
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	R & D portfolioRA = refractory anemiaRA = regulatory authoritiesRA = rheumatoid arthritisrabies or rabies-related virusradiation emitting productsradiation-emitting electronic productsradio frequency ablation RFAradioogical healthradionuclides (radioactive contaminants)radiosurgeryrandomized trialrandomized trialrange checkrating scaleraw agricultural commoditiesRBA = risk benefit assessmentRCC = renal cell carcinomaRCHSA = Radiation Control for Health and Safety	R&D 项目组合         难治性贫血         监督管理部门         类风湿关节炎         狂犬病毒或类狂犬病毒         辐射电子产品         有辐射电子产品         射频消融         放射性药品         辐射卫生         放射性核素         放射性核素         放射性核素         放射性核素         放射性核素         放射性核素         放射性核素         放射性核素         放射性核素         方射线手术         随机化         随机双盲对照研究         范围检查         量表         未加工农产品         利弊衡量         肾细胞癌

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ready-to-cat foods     與金食品       reagents     试剂       read-time continuous glucose monitoring systems     实时是续血糖检测系统       recall     召回; 强制回放       RECIST <sup>325</sup> = Response Evaluation Criteria in Solid     欠休霜約疗效评价标准       Tumors     愛起蛋白       recombinant protein     愛起蛋白       reconditioning     整式; 近物变整理; 货物变包浆       recycled plastics     可循环利用塑料制品       reference listed drug (RLD) <sup>253</sup> 原研药; 季比制剂       reference product     季比利利       reference product     季比利利       reference synolis     对混样名       regression     消退       regression     消退       regulatory methodology     廣量管力法 <sup>106</sup> regulatory methodology     廣量管理点操标准 (NDA 提供的方法       repetion     推升       Retification     廣量管理点标准 (NDA 提供的方法       repiction     推升       remision     疾病缓解       remote monitoring system     送程監測系       replication     算量       respiratory participation     資量       regulatory participation     委員       replication     算量       regulatory methodology     了愛量       regulatory system     送程       replication     算量       remote monitoring system     送程       remote monitoring system		
reagents       试剂         real-ima continuous glucose monitoring systems       实时连续血糖检测系统         recall       召中: 强制回收         RECIST <sup>252</sup> = Response Evaluation Criteria in Solid       实体瘤的疗放评价标准         recombinant protein       变如蛋白         reconditioning       差点: 貨物重整理: 貨物重色裝         reconditioning       差点: 貨物重整理: 貨物重色製         recorded drug (RLD) <sup>253</sup> 原标方: 条比药剂 as opposed to generics;         reference listed drug (RLD) <sup>253</sup> 原体方: 条比利剂         reference jisted drug (RLD) <sup>253</sup> 成体非 足, 商品名为 Stivarga         regratory methods validation       管理用分析方法的验证 (FDA 对 NDA 提供的方法 进行验证)         regulatory methods validation       管理用分析方法的验证 (FDA 对 NDA 提供的方法 进行验证)         regulatory specification       质量管理发展频系位 (NDA 提供)         rejection       #并         Remicade (trade name of infliximab)       remote monitoring system         remission       炭素结解         replicate data sets       变复分形的数据条         replicated ata sets       变复分形的数据条         respinatory paralysis       呼吸液素         respinatory paralysis       呼吸液		
real-time continuous glucose monitoring systems       笑时连续血糖检测系统         G ID:       汉银回政         RECIST <sup>252</sup> = Response Evaluation Criteria in Solid       安休癌的疗放评价标准         Tumors       重组蛋白         reconditioning       整点; 货物变整理: 货物变色表         reconditioning       整点; 管动变整理: 货物变色表         reconditioning       整点; 管动变整理: 货物变色表         reconditioning       整点; 管动变整理: 货物变色表         reconditioning       要点; 管动变整理: 货物变色表         reference samples <sup>254</sup> for analysis       对照样晶         reference samples <sup>254</sup> for analysis       对照样点         regression       消退         regulatory methodology       质量管理方法 <sup>266</sup> regulatory methodology       质量管理力分析方法的設证 (FDA 对 NDA 提供的方法         regulatory methodology       质量管理力析方法的設证 (FDA 对 NDA 提供的方法         regulatory methodology       质量管理力析方法的設证 (FDA 对 NDA 提供的方法         regulatory methodology       质量管理力析方法的設置         remission       疾病线離         remission       東病线         remission       東点线         replication       有量         replication       受量         replication       受量         replication       受量         replication       受量         replication       受量 <td></td> <td></td>		
recall     召 司; 孫朝回收       RECIST <sup>252</sup> = Response Evaluation Criteria in Solid     究体瘤的疗效评价标准       recombinant protein     复想蛋白       recombinant protein     复想蛋白       reconditioning     整次, 質物重整理; 貸物重包表       recycled plastics     可搞环利用塑料制品       reference listed drug (RLD) <sup>253</sup> 原析药; 参比药制       reference product     多比約利       reference samples <sup>254</sup> for analysis     对照样品       refractory solid tumors     現谷社突体瘤       Regorafenib <sup>355</sup> 鸡格非足, 商品名为 Stivarga       regulatory methodology     质量管理规格标准 (NDA 提供的方法 进行验证)       regulatory methods validation     管理规分析方法的验证 (FDA 对 NDA 提供的方法 进行验证)       regulatory specification     人素着髮層       remicade (trade name of infliximab)        remision     疾病殘解       remote monitoring system     這種蜜加系统; 远程监控       REMS = Risk Evaluation and Mitigation Strategies     风险 计存态加速段或       replication     可重复       rescue medication     黃檗解用       residual risk     剩合风险       reprized processed food of extended     冷藏か工食品的长期係売       respiratory distress syndrome = RDS     呼吸窘迫综合征       respiratory distress syndrome = RDS     呼吸窘心素       respiratory distress syndrome = RDS     学风意亮       respiratory distress syndrome = RDS     学风意       respinatory distress syndrome		
RECIST <sup>352</sup> = Response Evaluation Criteria in Solid         来林瀚的秀炎评价标准           recombinant protein         重组蛋白           recombinant protein         重组蛋白           recombinant protein         重组蛋白           reconditioning         整次; 货物重整理; 货物重包裹           recorded plastics         可摘取利用塑料制品           reference listed drug (RLD) <sup>253</sup> 原研約; 多比約利           reference product         条比制利           reference product         条比制利           reference product         条比制利           regorafenib <sup>255</sup> 瑞格非尼, 商品名为Stivarga           regulatory methodology         质量管理方法 <sup>266</sup> regulatory methodology         质量管理方法 <sup>266</sup> regulatory methodology         质量管理方法 <sup>266</sup> regulatory methodology         质量管理方法 <sup>266</sup> regulatory specification         质量管理方法 <sup>266</sup> regulatory specification         质量管理规系统准 (NDA 提供)           regication         水病缓解           remission         来病缓解           remission         大病缓解           replicate data sets         重复所完約           replicate data sets         重复研究的数据条           replicate data sets         重复研究的数据条           replication         資料           restidual risk         喇会成验 <td></td> <td></td>		
Tumors         重組蛋白           recombinant protein         童紅蛋白           reconditioning         整点; 貨物重整理; 貨物重包表           reconditioning         整点; 貨物重整理; 貨物重包表           reconditioning         整点; 貨物重整理; 貨物重包表           reference listed drug (RLD) <sup>253</sup> 尿研算; 参比药物 as opposed to generics;           reference samples <sup>254</sup> for analysis         对照样品           reference samples <sup>254</sup> for analysis         对照样品           regression         環過           regression         環道           regulatory methodology         质量管理方法 <sup>256</sup> regulatory methodology         质量管理方法 <sup>256</sup> regulatory methodology         质量管理方法           regulatory methods validation         管理用分析方法的验证 (FDA 对 NDA 提供的方法           regiction         推升           Remote monitoring system         送程监测系统; 远程監控           remote monitoring system         远程监测系统; 远程监测系统; 远程监控           replicate data sets         重复研究的數据集           replicate data sets         重复研究的數据集           respiratory distress syndrome = RDS         呼吸ェ飛鼎           respiratory distress syndrome = RDS         呼吸ェ飛鳥           response rate         缓解率           reterion samples <sup>257</sup> for identification         留材           retrorius         逆体ェ飛鳥 </td <td></td> <td></td>		
recombinant protein         重担蛋白           reconditioning         整点, 貨物重整理, 貨物重包装           recycled plastics         可備环利用塑料制品           reference listed drug (RLD) <sup>253</sup> 原研药; 参比勃剂           reference listed drug (RLD) <sup>253</sup> 泉小村島           reference listed drug (RLD) <sup>253</sup> 泉小村島           reference samples <sup>754</sup> for analysis         対点样品           refractory solid tumors         卑治性实体瘤           Regorafenib <sup>255</sup> 璃格非凡, 商品名为Stivarga           regulatory methodology         质量管理方法 <sup>766</sup> regulatory methodology         质量管理方法 <sup>766</sup> regulatory methodology         质量管理力法 <sup>766</sup> regulatory methods validation         常量管理力法 <sup>766</sup> regulatory methods validation         量量型力量           regulatory specification         质量管理力法 <sup>766</sup> remicade (trade name of infliximab)         ##           rememinon         東病矮解           remote monitoring system         远程整型列系统; 远程整型           REMS = Risk Evaluation and Mitigation Strategies         风险作佔和減減減           regicated ata sets         重复有力能数           replicate data sets         重复有力能数           respiratory distress syndrome = RDS         呼吸渡線           respiratory distress syndrome = RDS         呼吸渡線 <t< td=""><td></td><td>头体瘤的疗效评价标准</td></t<>		头体瘤的疗效评价标准
reconditioning整皮; 货物重整理; 货物重包装recycled plastics可循环利用塑料制品reference listed drug (RLD)253原研药; 多比药物 as opposed to generics;reference product秦比莉利reference samples <sup>554</sup> for analysis对照样品refractory solid tumors难治性实体瘤Regorafenib <sup>255</sup> 瑞洛非尼, 商品名为Stivargaregulatory methodology质量管理方法 <sup>506</sup> regulatory methodology质量管理方法 <sup>506</sup> regulatory methodo validation管理用分析方法的验证 (FDA 对 NDA 提供的方法 进行验证)regulatory methodo validation质量管理规格标准 (NDA 提供)regulatory specification质量管理规格标准 (NDA 提供)regulatory specification度素微鍵解remote monitoring system运程监测系统; 远程监控REMFED = refrigerated processed food of extended urability公赦加工食品的长期保存replicate data sets重复研究的数据集reginatory system延星報知rescue medication可重复rescue medication受量解和restidat risk剩余风险restidat risk剩余风险restidat risk剩余风险restidat risk剩余风险restidat risk剩余风险restidat risk剩余风险respiratory distress syndrome = RDS呼吸應retrovirus逆輪示病毒(-(一种致肿瘤病毒))retrovirus逆向工程; 反來工程;retrovirus逆向工程; 反來工程;retrovirus逆向素病毒retrovirus逆向工程; 反來工程;retrovirus营素和副本RF ablation surgical probes執频消融子术探針rhabdomyolysis村校法派第rinovirus, RhV暴病毒Rin Valley fever virus立大持谷热点毒rinovirus		重组蛋白
recycled plastics可循环利用塑料制品reference listed drug (RLD)253原研药: 冬比药剂reference moduct象比制剂reference samples254仿 analysisrefractory solid tumors难治性实体瘤Regorafenib255瑞絡非尼, 商品名为 Stivargaregression消退regulatory methodology质量管理力法 <sup>556</sup> regulatory methodology质量管理力法 <sup>566</sup> regulatory methods validation管理用分析方法的验证 (FDA 对 NDA 提供的方法 进行验证)regulatory specification质量管理规格标准 (NDA 提供)rejection捕爭Remicade (trade name of infliximab)近任益温测系统; 远程监控remote monitoring system远径监测系统; 远程监控REMS = Risk Evaluation and Mitigation Strategies风险评估和或缓战略REPFED = refrigerated processed food of extended冷藏加工食品的长期保存drurabilityregizejachrescue medication变解用药residual risk剩余风险respiratory distress syndrome = RDS呼吸密違综合征response rate缓解率rettorinus逆射系歸病毒(-一科或肿瘤病毒)rettorinus逆射系歸病毒(-和或肿瘤病毒)rettorinus逆射五個人RF ablation surgical probes射频消融手术探针reblation surgical probes射频消融手术探针rettorinus逆射离毒rettorinus逆射无能病毒RF ablation surgical probes射频消融手术探针rhabdionyolysis射线LNI溶解rhabdionyolysis射线LNI溶解rhabdionyolysis射频消融手术探针rhabdionyolysis力規度rinovirus, RhV鼻病毒regiser之大特公热病毒rigor mortisregiserrigor mortisregiser		
reference listed drug (RLD) <sup>233</sup> 原研药: 参比药物 as opposed to generics;reference product冬比制剂reference samples <sup>524</sup> for analysis对照样品refractory solid tumors难冶性实体瘤Regorafenib <sup>255</sup> 罵格非尼, 高品名为Stivargaregulatory methodology质量管理方法 <sup>356</sup> regulatory methods validation管理用分析方法的验证 (FDA 对 NDA 提供的方法 进行验证)regulatory specification质量管理规格标准 (NDA 提供)regiction排產remixed (trade name of infliximab)remote monitoring system远程监测系统; 远程监控REMS = Risk Evaluation and Mitigation Strategies风险评估和或缓战略REPED = refrigerated processed food of extended durabilityreplicate data sets重复研究的数据集replicate data sets重复研究的数据集respiratory gargises呼吸療力respiratory gargises呼吸療力respiratory paralysis"Fug 麻痹retion samples <sup>257</sup> for identification留材retion samples <sup>257</sup> for identification留材retorius逆传录扇病毒 (一种破肿瘤病毒)retorius逆传录扇病毒retorius旋射示和索Reface and		
reference product       泰比制剂         reference samples <sup>254</sup> for analysis       对照样品         refractory solid tumors       难治性实体瘤         Regorationib <sup>255</sup> 瑞格非尼, 商品名为Stivarga         regression       消退         regulatory methodology       质量管理方法 <sup>306</sup> regulatory methods validation       管理用分析方法的验证 (FDA 对 NDA 提供的方法         進行验证)       regulatory specification         rejection       #非异         Remicade (trade name of infliximab)       remote monitoring system         remote monitoring system       远程监监测系统; 远程监控         REMS = Risk Evaluation and Mitigation Strategies       风险评估和减缓战略         REPED = refrigerated processed food of extended       冷藏加工食品的长期保存         durability       regilcatcha sets       重复研究的数据集         replication       可重复       rescue medication         respiratory distress syndrome = RDS       呼吸廉強迫给合征         retroin samples <sup>237</sup> for identification       留样         retroins       逆槍束脑病病(一种数/m病病毒)         reterevines       炭素脑病病 <td></td> <td></td>		
reference samples254所 analysis对照样品refractory solid tumors难治性实体瘤Regoralenib255竭格非尼, 商品名为 Stivargaregression消退regulatory methodology质量管理方法700regulatory methods validation管理用分析方法的验证 (FDA 对 NDA 提供的方法 进行验证)regulatory specification原量管理规格标准 (NDA 提供)rejection#戶Remicade (trade name of infliximab)remote monitoring system远程监测系统; 远程监控REMS = Risk Evaluation and Mitigation Strategies风险评估和减缓战略REPFED = refrigerated processed food of extended durability令藏加工食品的长期保存residual risk剩余风险respiratory paralysis呼吸麻痹respiratory paralysis呼吸麻痹respiratory paralysis呼吸麻痹retention samples257for identificationretina implant视网膜移植retrovirus逆转录酶病毒(-种致肿瘤病毒)retrovirus逆转录酶病毒(-种致肿瘤病毒)retrovirus逆射不输点子术程;retrovirus逆转录酶病毒(-种致肿瘤病毒)retrovirus逆转录酶病毒(-种致肿瘤病毒)retrovirus逆转录酶病毒(-种致肿瘤病毒)retrovirus逆转录maja=/retrovirus逆转录maja=/retrovirus逆转录maja=/retrovirus逆转录maja=/retrovirus逆转录maja=/retrovirus逆转录maja=/retrovirus逆转录maja=/retrovirus逆转录maja=/retrovirus逆转录maja=/retrovirus逆转录maja=/retrovirus逆转示maja=/retrovirus逆转示maja=/retrovirus空大指令法病毒retrovirus立大指令法	-	
refractory solid tumors堆治性实体瘤Regorafenib255瑞格非尼、商品名为 Stivargaregression消退regulatory methodology质量管理方法700regulatory methods validation管理用分析方法的验证 (FDA 对 NDA 提供的方法 进行验证)regulatory specification质量管理边法700regiction椎子Remicade (trade name of infliximab)remote monitoring system远程监测系统;远程监控REMES = Risk Evaluation and Mitigation Strategies风险评估布减缓战略REPFED = refrigerated processed food of extended durabilityresicution可重复rescue medication愛魚研究的數据集replicate data sets重复研究的數据集replication可重复residual risk創令风险respiratory paralysis呼吸廉與response rate缓解平retion samples <sup>257</sup> for identification窗样retion samples <sup>257</sup> for identification這样		
Regoratenib <sup>255</sup> 瑞格非尼、育品名为 Stivargaregression消退regulatory methodology质量管理方法 <sup>766</sup> regulatory methods validation管理用分析方法的验证 (FDA 对 NDA 提供的方法 进行验证)regulatory specification质量管理规格标准 (NDA 提供)rejection排身Remicade (trade name of infliximab)remote monitoring system延程监测系统; 远程监控REMS = Risk Evaluation and Mitigation Strategies风险评估和减缓战略REPFED = refrigerated processed food of extended durabilityreplication可重复rescue medication缓解用药residual risk剩余风险respiratory distress syndrome = RDS呼吸窘迫综合征respiratory distress syndrome = RDS呼吸窘迫综合征respiratory paralysis"Fug 和小菜retention samples <sup>257</sup> for identification窗样retorius逆椅示程: 反求工程;reverse engineering逆向工程: 反求工程;reverse engineering前派融手术报针rhabdomyolysis横纹肌溶解RF ablation surgical probes射频消融手术报针rhabdomyolysis横纹肌溶解rhinovirus, RhV鼻病毒rigor mortis尸營™rigor mortis尸營™rigor mortis尸優™rigor mortis利奧馬嘶rigor mortis利奧馬嘶rigor mo		
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risk 受害		尸僵258
risk assessment (risk analysis + risk evaluation) 风险评估, 论证		受害
	risk assessment (risk analysis + risk evaluation)	风险评估,论证

risk classification	风险分类;
Risk Communications Advisory Committee	风险交流咨询委员会
risk evaluation (part of risk assessment)	风险评价
risk/ benefit analysis	风险-效益分析
risk-benefit ratio	效益/风险比
RiskMAP <sup>260</sup> = Risk Minimization Action Plan	风险最小化行动计划
Ritalin	利他林;
rituximab, Mabthera,美罗华	利妥昔单抗
RKI = Raf kinase inhibitor	Raf 激酶抑制剂
$RM = rhabdomyolysis^{261}$	横纹肌溶解
$RMS = reference member state^{262}$	参考成员国
Roche	罗氏
Rogaine	落健;生发类产品
rolling review <sup>263</sup>	滚动审查
Rosetta	罗塞塔
route of administration	给药途径
royalties	专利使用费
RPM <sup>264</sup> (FDA Regulatory Procedures Manual)	监管程序手册
$RPN = risk priority number^{265}$	风险优先指数
RR = response rate	缓解率
RSD = (intra-day and inter-day) relative standard	(日内和日间) 相对标准差
deviations	
RSV = respiratory syncytial virus <sup>266</sup>	呼吸道合胞体病毒
RTE (ready-to-eat) foods RTF (refue to file) <sup>267</sup>	即食食品
R1F (refue to file) <sup>207</sup>	拒绝受理;退审
rugged individual	自强者,个人
run-in	准备期
RVD reference vascular diameter	参考血管直径
S. aureus = Staphylococcus aureus	金黄色葡萄球菌
Sabia virus	萨比亚病毒
sacral nerve stimulation (SNS)	骶神经刺激
SAD = single ascending dose	渐增型单一药剂量浓度测试
SAE = serious adverse event	严重不良事件
safety advisory	安全建议
safety evaluation	安全性评价
safety evaluators	安全性评估人员
safety set	安全性评价的数据集
Safety Set, SS	安全集
salicylic acid	水杨酸
Salmonella	沙门氏菌
Salmonella enteritidis	肠炎沙门氏菌
salmonella typhimurium	鼠伤寒沙门氏菌
salvage treatment <sup>268</sup>	挽救性治疗
sample size (number of subjects in a clinical trial)	样本含量;样本量,样本大小
Sanofi-Aventis	赛诺菲一安万特集团
saving clause	1962年的修正案增加的保留条款(saving
	clause) 指明,州法律只有在与 FDCA 有"直接

	正面冲突"的情况下无效
SBA = serum bactericidal activities	血清杀菌活性分析;测定血清杀菌效价
SBA = summary basis of approval = approval	批准依据摘要 = 批准药品信息包
package	
scaffold	仿生支架
scale of ordered categorical ratings	有序分类指标
SCFX <sup>269</sup> = supercritical fluid extrusion	超临界流动相挤压
Schering-Plough	先灵葆雅
SCHIP State Children's Health Insurance Program	儿童医疗保险计划
SCID = severe combined immunodeficiency disease	严重联合免疫缺陷病
SCID mouse	SCID 小鼠
scleroderma	硬皮病
screening trials	筛选性试验
SD = stable disease	病情稳定
SD = standard deviation	标准(偏)差
SE = substantial equivalence	实质上的等同
seal strength test	密封强度试验
SEC = Securities and Exchange Commission	美国证券交易委员会
secondary effect	继发反应
secondary endpoint	次要终点
secondary infection	继发感染
secondary variable	次要变量
seed brachytherapy	放射性粒子组织间近距离治疗
seeding trials <sup>270</sup>	撒播试验
seizure	扣押
sensitized lymphocyte	<u>我</u> 敏淋巴细胞
Sentinel Initiative <sup>271</sup> (of the FDA)	哨点行动
sepsis	败血病;脓毒症
sequence	<u>双血病,亦毋症</u> 试验次序
serine	丝氨酸
severe	重度
severe acute respiratory syndrome—coronavirus	业反 严重急性呼吸系统综合症——冠状病毒
severely debilitating means diseases or conditions	广里心住了双示统综合症——他认病母
that cause major irreversible morbidity	
SFDA <sup>272</sup> = State Food And Drug Administration	国家食品药品监督管理局
SG & A= sales, general and administration	销售、管理和一般费用
shaft	传动轴
SHEA = Society for Healthcare Epidemiology of	美国医院流行病学学会
America	
sheaths	护套
shelf life	保存期限;保质期
shift table <sup>273</sup>	变化表
Shiga toxin	志贺毒素
shipping test	包装运输测试
SIC codes = Standard Industrial Classification	标准产业分类代码
codes	
side chain	侧链
side effects	副作用
significance level	显著性水平

significant risk (SR)	显著的危险性
Sildenafil	西地那非 drug for erectile dysfunction;
	viagra
simple randomization	简单随机
simulation model	仿真模型
Simulect = Basiliximab	舒莱 = 巴利昔单抗(诺华制药有限公司)
single blinding	单盲
single-blind study	单盲研究
single-masked study	单盲研究
sinus surgery devices	鼻窦手术器材
site assessment = SA	现场评估
site audit	试验机构稽查
Six Sigma <sup>274</sup>	六標準差, 又稱六西格玛
SMDA = Safe Medical Devices Act of 1990	1990年安全医疗器械法
SMF = Site Master File	生产场所主文件
sNDA = supplemental NDA	(疗效)补充新药(上市)申请
SNP single nucleotide polymorphism	单核甘酸多形态现象
sodium hypochlorite	次氯酸钠;
soft palate	软腭
solutions	溶液剂
SOP = standard operating procedure	标准操作规程
Sorafenib <sup>275</sup> = Nexavar	索拉非尼
sorbic acid	山梨酸
source data = SD	原始数据
source data verification = SDV	原始数据核准
$SPA^{276}$ = special protocol assessment	特殊方案评估
specific antibody	特异抗体
specification	規格;標準;
specificity	特异性
spinal deformities	脊柱畸形
spinal fusion cage	椎间融合器
spinal implants/ biologics	脊柱植入修复/生物制剂
spiral CT scan	螺旋 CT
spoilage	腐败
sponsor (of a new drug)	申办者;(指负责并着手临床研究者)
sponsor-investigator = SI	申办研究者
spontaneous reports; voluntary reports	药品不良反应自愿报告
SPS = Agreement on the Application Of Sanitary and Phytosanitary Measures	卫生与植物卫生措施实施协议;简称 SPS 协议
SSI = surgical site infection	手术部位感染
SSOPs = Sanitation Standard Operating Procedures	卫生标准操作规程
standard curve	「二王亦作來」「-元任 「标准曲线
standard deviation	标准(偏)差
standard drug	标准药物
standard operating procedure = SOP	标准操作规程
Standard Review <sup>277</sup>	标准审查
standard treatment standards of care <sup>278</sup>	<ul> <li>标准单量</li> <li>标准治疗</li> <li>医护标准</li> </ul>

staphylococcus	葡萄球菌属
startup companies	创业公司
STAT <sup>279</sup> protein (Signal Transducer and Activator	信号转导转录(信号转导子和转录激活子)蛋白
of Transcription, or Signal Transduction And	
transcription)	
State Food and Drug Administration = SFDA	国家食品药品监督管理局
statistic	统计量
statistical analysis plan = SAP	统计分析计划
statistical model	统计模型
statistical significance	统计显著性;统计学意义
statistical tables	统计分析表
Statisticians in the Pharmaceutical Industry = PSI	制药业统计学家协会
steady-state Area Under the Curve = AUCss	稳态药时曲线下面积/稳态血药浓度-时间曲线
	下面积
stenosis	狭窄
stent grafts	血管内支架血管;带膜支架
STEPS (System for Thalidomide Education and	沙利度胺处方安全教育系统
Prescribing Safety )	
sterile manufacturing facilities	无菌生产设施
sterility testing	无菌测试
sterilization	灭菌
steroid	类固醇; 甾体化合物
steroid eluting electrode	激素释放电极;激素电极起搏
steroid hormone	甾体激素;
Stevens Johnson Syndrome = SJS	Stevens-Johnson 综合征; 斯-约二氏综合征(多
	形糜烂性红斑的一型)
stratified	分层
Strattera = atomoxetine hydrochloride,	盐酸托莫西汀-多动症治疗药
strength	规格;规格含量(每一剂量单位所含有效成分的 量)
strep test	链球菌 (分泌物)试纸; 咽部病原菌抗原检查
Streptomycin	链霉素
study audit	研究稽查
study endpoint <sup>280</sup>	研究终点
Study Personnel List = SPL	研究人员名单
study site	研究中心
study type <sup>281</sup>	研究类型
subchronic toxicity studies	亚慢性毒性研究
subgroup	亚组 亚组
subgroup analysis	 亚组分析
sub-investigator	助理研究者
subject	受试者
subject diary = SD	受试者日记
subject enrollment	受试者入选
subject enrollment log = SEL	受试者入选表
Subject Identification Code List = SIC	受试者识别代码表
subject recruitment	受试者招募
subject screening $\log = SSL$	受试者筛选表
	X 14 19 24 A

专科, 内科 已合法在市场上销售的且不需要做 PMA "销售 批准"的相似产品有 <b>实质上的等同</b> 糖 脏骤停 脏唑猝死 死 系意念 胶酏 yi 剂 氮磺吡啶 bi ding 胺类药物 大生产和批准后变更 重感染 效性试验 应商资格审查 面活性剂
<ul> <li>批准"的相似产品有<b>实质上的等同</b></li> <li>糖</li> <li>脏 骤停</li> <li>脏 性 猝死</li> <li>死</li> <li>杀 意念</li> <li>胺酏 yi 剂</li> <li>氮磺吡啶 bi ding</li> <li>胺类药物</li> <li>大生产和批准后变更</li> <li>重感染</li> <li>效性试验</li> <li>应商资格审查</li> <li>面活性剂</li> </ul>
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大生产和批准后变更 重感染 效性试验 应商资格审查 面活性剂
重感染 效性试验 应商资格审查 面活性剂
效性试验 应商资格审查 面活性剂
应商资格审查 面活性剂
面活性剂
术导航系统
代终点
存分析
感人群
尼替尼;苹果酸舒尼替尼
科手术缝线
續性病毒學反應
晶X一射线衍射
交感神经药
状性子宫肌瘤
利珠单抗; 预防呼吸道感染药物 by
dImmune
射泵
统稽查
身感染
统性红斑狼疮
除半衰期
剂
动过速
望子色素
撬包装
A颁布《反篡改包装规章》
生棉條
赛瓦;特罗凯
标变量
克唑;泰素:紫杉醇制剂; anti-cancer
ug;
Jg; 西他赛;泰素帝

TBT technical barrier to trade	技术性贸易壁垒
T-CHO = total cholesterol	总胆固醇
TDI = tolerable daily intake	每日允许摄入量
TDP = torsade de pointes	尖端扭转型室性心动过速
TDS = total diet study	总膳食研究
Technical Barriers to Trade (TBT) Agreement	技术性贸易壁垒协议
tensile test	拉伸试验;材料张力试验
teratogenic	致畸
teratogenic effects	致畸性; 致畸(胎)效应
test and reference product = T&R	受试和参比试剂
test product	受试制剂;试验药
testosterone	睾丸酮
testosterone enantate	庚酸睾丸素
tetanus antitoxin	破伤风抗毒素
TG = thermogravimetry	热重分析
thalidomide	沙立度胺;反应停,酞胺哌啶酮
thalidomide incident <sup>286</sup>	"反应停(沙立度胺)事件"
therapeutic equivalence	治疗等效
therapeutic window <sup>287</sup>	治疗窗
thiamin	硫胺(维生素 B1)
threonine	苏氨酸
threshold concentration	阈浓度
thrombin	凝血酶
thrombocytopenia	血小板减少症
thrombolytic agents	溶栓药物
thrombolytic stroke	溶解血栓性中风
thrombotic diathesis	血栓素质(倾向)
thymus gland	胸腺
thyroid surgery	甲状腺手术
TIA = transient ischemic attacks	短暂性脑缺血发作
tick-borne encephalitis virus	蜱(pronounced pi2)传脑炎病毒
tilapia	罗非鱼
time to tumor progression	肿瘤进展时间
time-to-event endpoint or survival time <sup>288</sup>	存活时间
titer	浓度测定
Title 21 of the CFR is reserved for rules of the Food	美国联邦法规第21卷
and Drug Administration. Each title (or volume) of	
the CFR is revised once each calendar year	
titration	滴定
TKI = Tyrosine kinase inhibitor	酪氨酸激酶抑制物,能制止不受调控的细胞生
	长,也经常被用来治疗癌症
TLC = thin layer chromatography <sup>289</sup>	薄层色谱法;制备色谱
Tmax	峰时间
TMS = transcranial magnetic stimulation	经颅磁刺激
TNF = tumor necrosis factor s	肿瘤坏死因子
TNK = Tenecteplase	替奈普酶
tocopherols	维生素E
toluene	甲苯

TOPRA   The Organisation for Professionals in Regulatory Affairs total diet study = TDS         送居食研究           toxicant         春利           toxicity         春桂           toxicity scale/toxicity grading scale         春桂乾二           toxicity scale/toxicity grading scale         春桂乾元           toxicity scale/toxicity grading scale         春桂乾万           transer scale polypedica and grading         如素秋方           transer scale polypedica and grading         transer scale toxicity grading           transer program         大倉た長乾万           transformation         支皇皇愛美               translocation scinece <sup>921</sup> , transla	tongue depressor	压舌板,压舌器
toxi die study = TDS         急膳 会 研究           toxicant         専利           toxicity scale/toxicity grading scale         毒性标度/毒性分成标度           toxigenic moulds         卢香素霉菌           TP = total protein         总蛋白           transitional activator <sup>290</sup> 组织好溶酶原激活物; 抗栓塞药物           TPA = tissue plasminogen activator <sup>290</sup> 组织好溶酶原激活物; 抗栓塞药物           TPA = tissue polypeptide antigen         组织 多肽抗原           TPA = tissue polypeptide antigen         超叔 多肽抗原           trans fat         反式脂肪           trans fat         反式脂肪           trans fat         反式脂肪           transformation         経尿超           transformation         反正局           transformation         反正局           transformation         反量素           transformation         大量素           transformation         大量素           transforman	TOPRA   The Organisation for Professionals in	
toxicity         專利           toxicity scale/toxicity grading scale         專性标覺,專性标覺,專性分級标覺           toxics         專性新島           toxics         專性新島           toxics         專生新島           toxics         基合目の           toxics         基本目前島           DP = total protein         总蛋白           tDA = tissue polypeptide antigen         组织多版振序           TPP <sup>591</sup> = Target Product Profile         目标产高规格;           tracer         示溶剂           train-the-trainer program         培训者培训计划           transfat         反式脂肪           transdermal patch         建定版制           transformation         愛愛愛級           transformation         愛愛愛級           transformation         愛愛愛級           translational science <sup>372</sup> , translational research         特化科學           transpec         特基           transmissible spongiform encephalopathy TSE         作素性感染就廠為           transmitic pain         外伤性感激           tratamett trails         治疗性は恐怖病           transtational science         法参加           transtrail         治疗性は感染           transtational science <sup>372</sup> , translational research         特心科學           transhetiotation         分疗性、		
toxicity     毒性       toxicity scale/toxicity grading scale     毒性病人毒性分级标度       toxics     毒性前品       toxics(moulds)     戶素索窗       TP = total protein     总蛋白       tPA = tissue plasminogen activator <sup>200</sup> 组织纤溶酶原激活物;抗栓素药物       TPA = tissue ploypeptide antigen     组织多私抗原       TPA = tissue ploypeptide antigen     组织多私抗原       TPA = tissue ploypeptide antigen     長次和助       train-thc-trainer program     培训者培训计划       trans fat     反太屈助       transcranial magnetic stimulation     经质磁制激       transformation     愛愛愛換       transformation     愛愛愛換       transformation     愛愛愛換       transformation     愛愛愛換       transmissible spongiform encephalopathy TSE     传染性海绵状脑病       transmissible spongiform encephalopathy TSE     佐染性海绵状脑病       transmissible spongiform encephalopathy TSE     佐染性海绵状脑病       traument trails     治疗性试验       trial entor     武燈和       trial objective     武燈和       trial initial meeting     武燈和       trial objective     武燈和       trial entor     武燈和       trial objective     武燈和 <td></td> <td>总膳食研究</td>		总膳食研究
toxicity scale/toxicity grading scale專性格度/專性分級标度toxigenic moulds产專素霉菌TP = total protein送蛋白IPA = tissue plasminogen activator <sup>590</sup> 组织好溶酶原激活物; 机栓塞药物TPA = tissue ploypeptide antigen组织分散抗原TPP5 <sup>97</sup> = Target Product Profile目标产品规格;tracer示浆剂train-the-trainer program括闭者与训升划transfat反式脂肪transdermal patch建度服刺激transformation愛量変換transformation愛量変換transformation愛量素除不容差transformation愛量素除不容差translocation <sup>593</sup> 易信transformation支持除子管起搏器transtoration方作性水验检新药中transformation方疗性浓酸化transformation方方性水酸化transformation支量素transpene特差因transitisble spongiform encephalopathy TSE传染性海绵水脑病transmissible spongiform encephalopathy TSE传染性海泳放脑tratement group试验租treatment IND <sup>501</sup> 治疗性浓酸化trail anset file试验局trial error试验是影响trial objective试验目trial site试验局TRCARE军人医疗系统triple blinding三盲troars秦村troars素村troars素村troars大TSE = transmissible spongiform encephalopathyTTFR = Total Shareholder return炭素后病TTP = Time to progression對進長时间TTP = Time to progression對進長时間TTP = Time to progression對進泉时間TT		毒剂
toxics $\neq$ kt $\beta$ .a.toxigonic moulds $\nearrow$ $\beta$ $z$ $\beta$ $z$ $\beta$ $z$ $\beta$ TP = total protein $\&$ $\&$ $\&$ $\Delta$ TP = total protein $\&$ $\&$ $\&$ $\Delta$ TP = tissue plasminogen activator <sup>500</sup> $\exists$ kty $\forall$ $z$ $bhg$ $x$ $bhg$ TP = Target Product Profile $hfg$ $z$ $hgg$ $x$ TP = Target Product Profile $hfg$ $z$ $hgg$ Tran-the-trainer program $bill$ $af$ $dill$ $dill$ $dill$ $dill$ trans fat $\int$ $\&$ $\chi$ $x$ $hgg$ transfarmation $\xi$ $dill$ $dill$ $dill$ transformation $\xi$ $dill$ transformation $\xi$ $dill$ transformation $\xi$ $dill$ $dill$ transformation $f$ $dill$ $dill$ transformation $f$ $dill$ $dilltransformationf dill dilltransformationf dill dilltransformationf dilltransformationf dilltransformationf dilltransformationf dilltransformationf dilltransformationf dilltransformationf dilltransformation<$	toxicity	毒性
toxigenic moulds $\rho = \frac{1}{8} \frac{1}{8} \frac{1}{6} \frac{1}{6} \frac{1}{8} \frac{1}{8} \frac{1}{6} \frac{1}{6} \frac{1}{8} \frac{1}{8} \frac{1}{6} \frac{1}{8} \frac{1}{8}$	toxicity scale/toxicity grading scale	毒性标度/毒性分级标度
TP = total protein     总蛋白       tPA = tissue plasminogen activator <sup>500</sup> 组织籽溶酶原激活物;抗检素药物       TPA = tissue playeptide antigen     组织多肽抗原       TPP <sup>59</sup> = Target Product Profile     日标产思规格;       tracer     示踪剂       trans-the-trainer program     培训者培训计划       trans fat     反抗脂肪       transcranial magnetic stimulation     经颅磁刺激       transcranial magnetic stimulation     愛愛娘       transfat     反抗脂肪       transfat     麦白       transfator     養心目       transfator     麦皮酸利激       transformation     愛愛愛娘       transfator     麦白       transfator     麦伯婦利激       transfator     麦伯婦利激       transfator     麦皮酸利       transfator     麦皮酸利       transfator     麦白素       transfator     麦皮酸利       transfator     大方性染病       transfator     大方性染病       transfator     大方性染病       transternet     デロ	toxics	毒性药品
tPA = tissue plasminogen activator <sup>290</sup> 组织针溶酶原激活物:抗栓塞药物         TPP = tissue polypeptide antigen       组织多肽抗原         TPPP <sup>591</sup> = Target Product Profile       目标产品规格;         tracer       示踪剂         train-the-trainer program       培训者培训计划         transfat       反式脂肪         transfat       反式脂肪         transformation       変更強疑         transformation       変量変換         transformation       変量変換         transformation       変量変換         transformation       変量変換         transformation       変量変換         transformation       変量変換         transformation       支量変換         transformation       変量変換         transformation       支量変換         transformation       支援支援         transformation       大方能         transformation       大方能         transformation       大方能         transformatic	toxigenic moulds	产毒素霉菌
TPA = tissue polypeptide antigen         组织多肽抗原           TPP5 <sup>91</sup> = Target Product Profile         目标产品規格;           tracer         示踪剂           train-the-trainer program         培训者培训计划           trans fat         反太脂防           transcranial magnetic stimulation         经颅磁刺激           transformation         変量炎換           transformation         変量炎換           transformation         変量炎換           translational science <sup>592</sup> , translational research         特化科学           transsible spongiform encephalopathy TSE         传染性海绵状脑病           transmissible spongiform encephalopathy TSE         传染性海绵 水脑病           transmuck catheter pacemaker         经静脉导管起搏器           transmatic pain         外伤性疼痛           transent group         试验组           treatment group         试验组           treatment file         试验目的           trial initial meeting         试验局的           trial initial meeting         试验目的           trial objective         试验目的           trial objective         试验目的           trial site         试验目的           trial objective         或验目的           trial objective         或验目的           trial site         试验目的           trocar	TP = total protein	总蛋白
TPP <sup>39</sup> = Target Product Profile         目标产品规格;           tracer         示踪剂           train-the-trainer program         场训者培训计划           trans fat         反太脂防           transcranial magnetic stimulation         逐质磁刺激           transcranial magnetic stimulation         愛愛表換           transformation         愛愛愛表           transformation         愛愛愛表           translational science <sup>392</sup> , translational research         特化科学           translocation <sup>293</sup> 易位           transnew catheter pacemaker         经静脉等管起神器           traumatic pain         外伤性疼痛           treatment group         试验短           treatment IND <sup>394</sup> 治疗性试验性素           trail initial meeting         试验总检索           trial origitize         试验总检索           trial initial meeting         试验总检索           trial objective         试验目的           trial site         试验场所           TRICARE         军队医疗系统           troglizaone         曲格列酮           troglizaone         曲格列酮           Trovan (Trovafloxacin) by Pfizer         曲代浅型、           TBE = transmissible spongiform encephalopathy         可传播性海缘体脑炎: 传染性海缘水脑病           TSE = transmissible spongiform encephalopathy         Tf tage海体前	tPA = tissue plasminogen activator <sup>290</sup>	组织纤溶酶原激活物; 抗栓塞药物
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trans fat反式脂肪transcranial magnetic stimulation经颅磁刺激transdermal patch達皮貼剤transformation変量変換transgene特基transgene特基translocation <sup>293</sup> 易位transmissible spongiform encephalopathy TSE传染性海绵状脑病transmissible spongiform encephalopathy TSE传染性海绵状脑病transmissible spongiform encephalopathy TSE传染性海绵状脑病transmissible spongiform encephalopathy TSE传染性海绵状脑病traumatic pain外伤性疼痛treatment group试验组treatment TND <sup>294</sup> 治疗性试验性新药申请treatment trials治疗性试验trial error试验浸参trial error试验局trial objective试验目的trial site试验与杨所TRICARE军队医疗系统triple blinding三盲trocars左针trocars左针troglitazone曲絡列酮Trovan (Trovafloxacin) by Pfizer曲後沙星TSR = Total Shareholder return股东总咽棍TTB = Alcohol and Tobacco Tax and Trade Bureau美国湖派征视及贸易局TTP = Time to progressionJ过展时间tumor cotext of vulnerability <sup>295</sup> 肿瘤漆易基因环境tumor cotext of vulnerability <sup>295</sup> 肿瘤漆易基因环境tumor cotext (cprevent the growth of tumor cells)抑瘤作用tumor cotext (cprevent the growth of tumor cells)抑瘤作用	tracer	
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tumorstatic (prevent the growth of tumor cells) 抑瘤作用		
		靶血管重建; 靶血管再血管化治疗

two one-side test	双单侧检验
Tylenol	泰诺;止痛药
type I error <sup>296</sup>	类错误
type II diabetes	二型糖尿病
type II error <sup>297</sup>	类错误
tyrosine kinase	酪氨酸激酶
TZDs = thiazolidinediones	噻唑烷(sai zuo4 wan2)二酮类
UAE = unexpected adverse event	预料外不良事件
UC = ulcerative colitis	溃疡性结肠炎
UFI <sup>298</sup> (unique facility identifier) system for drug	药品企业注册用唯一设施识别(UFI)系统
establishment registration	
ULN = upper limits of normal	正常上限; 正常范围上限
UMC = Uppsala Monitoring Centre	乌普沙拉监测中心
unblinding	破盲;揭盲
undenatured collagen	非變性膠原蛋白
under reporting bias	少报偏差
unexplained syncope	不明原因晕厥
UNITAID <sup>299</sup>	联合援助国际药品采购机制,简称「联合援助」
unresectable	不能手术切除
Upjohn	厄普约翰
urinary retention	尿滞留
URS = user requirements specification	用户需求说明
urticaria	荨麻疹;俗称风团、风疹团、风疙瘩、风疹块
	(与风疹名称相近,但非同一疾病)
US Federal Food Drug and Cosmetic Act of 1938	1938 的美国《联邦食品、药品和化妆品法》
USDA FSIS (Food Safety and Inspection Service)	美国农业部食品安全检验部
user fees: Prescription drug provisions (PDUFA V);	
Medical device provisions (MDUFA III); Generic	
Drug User Fee Amendments of 2012 (GDUFA) Biosimilar User Fee Act (BsUFA)	
USP = United States Pharmacopeia	美国药典(现已和 NF 合并一起出版)
USP/NF = U.S. Pharmacopeia / National Formulary	《美国药典(现じ和) 合开一起山版) 《美国药典/国家处方集》
USSC = U.S Sentencing Commission	
UV-VIS Ultraviolet/Visible	美国司法部量刑委员会 紫外—可见光
VAC = vacuum-assisted closure	
VAC – vacuum-assisted closure VAI = voluntary action indicated	真空辅助闭合 应该由厂方采取志愿行动
validation	
validation master plan	验证
validation master plan validation of aseptic processing	验证主计划
Validation of aseptic processing Validation, Cleaning <sup>300</sup>	无菌工艺验证
Validation, Concurrent <sup>301</sup>	清洗验证
validation, concurrent <sup>302</sup>	同步型验证
Validation, Product <sup>303</sup>	工艺验证
Validation, Product <sup>203</sup> Validation, Prospective <sup>304</sup>	产品验证
Validation, Prospective <sup>305</sup>	预期型验证/前验证
validation, Retrospective	回顾性验证
validation: Revalidation value chain <sup>306</sup>	再验证
value chain-se vancomycin resistance	价值链
vancomychi resistance	对万古霉素的抗药性

vandetanib	凡德他尼; 是一种合成的苯胺喹唑啉化合物, 为
	口服的小分子多靶点酪酸激酶抑制剂(TKI),可同
	时作用于肿瘤细胞 EGFR、VEGFR 和 RET 酪氨酸激
	酶
variability	变异
variable	变量
variola virus	天花病毒 small pox
vascular catheter	血管内插管
vasculitis	血管炎
vasopressin receptor antagonist	血管加压素受体拮抗剂
vector sequences <sup>307</sup>	载体序列
vegetative bacteria	植物细菌
vegetative organism	活微生物
$VEGF^{308}$ = vascular endothelial growth factor	血管内皮生长因子
VEGFR = vascular endothelial growth factor	血管内皮生长因子受体
receptor	
vemurafenib <sup><math>309</math></sup> = V600E mutated BRAF inhibition	威罗菲尼
ventilator	呼吸机
ventricular fibrillation	心室纤颤
ventricular tachycardia	室性心动过速
verification <sup>310</sup>	确认
veterinary products	兽用药品
Vibrio cholerae	霍乱弧菌
Vibrio parahaemolyticus	副溶血弧菌
Vibrio vulnificus	创伤弧菌
VIGOR study (Vioxx Gastrointestinal Outcomes	万络肠胃结果研究
Research) <sup>311</sup>	
Vioxx (rofecoxib)	万络;罗非昔布; COX-2 抑制剂; 抗炎止痛药
VIPPS = Verified Internet Pharmacy Practice Site	"互联网药品营业认证"标志;互联网药店认证
viral load	病毒载量
virtual cath lab	虚拟导管室
virus inactivation	病毒灭活
visual analogy scale	直观类比打分法
visual check	人工检查
vital signs	生命体征
Voltaren gel	扶他林片凝胶
VRE vancomycin-resistant enterococci	耐万古霉素肠球菌
vulnerable subject	弱势受试者
vulvovaginal atrophy	外阴萎缩
Vytorin	为包含依折麦布(ezetimibe)和辛伐他汀
	(simvastatin)的复方药品
W/D due to adverse events	因不良反应事件而撤药
WACC = weighted average cost of capital	加权平均资本成本
Warfarin	华法林[抗凝药]
warning letter	警告信函
warranty claims	保证期索赔
wash-out; washout period	洗出期;洗脱,清洗期;洗脱期
water activity <sup>312</sup> (Aw)	水分活度,又称水活性,水活度

water binding agents	亲水试剂
water-for-injection system = WFI	注射用水系统
WBC = white blood cell	白细胞
Weber effect <sup>313</sup>	韦伯效应
Wegener's granulomatosis	韦格纳肉芽肿病
well-being	福利,健康
Wellcome	惠康
West Nile virus	
WHO International Collaborating Center for Drug	西尼罗河病毒
Monitoring	(世界卫生组织)国际药物监测合作中心
WHO International Conference of Drug Regulatory Authorities = WHO-ICDRA	WHO 国际药品管理当局会议
WHO Programme for International Drug Monitoring = PIDM	WHO 国际药物监测合作计划
WHO-ART Adverse Drug Reaction Terminology	WHO 不良反应术语集
WHO-Drug	WHO 药品词典(该词典是依据 INN 命
	名法和 ATC 分类法编辑 )
whole grains	全谷食品
withdrawal symptoms	撤药反应症状
withdrawal syndrome	撤药综合征
within-run precision	批内精密度
wound drainage	积液引流
wound dressing	创面敷料
wound management	伤口护理
WTO/SPS = Agreement on the Application of	《实施卫生与植物卫生措施的协定》
Sanitary and Phytosanitary Measures	
Xarelto®, Rivaroxaban (Bayer drug for atrial	拜瑞妥薄膜衣片;成份:利伐沙班; <sup>314</sup>
fibrillation)	
Xeljanz (tofacitinib <sup>315</sup> citrate) by Pfizer	托法替尼
xenotransplantation	异种移植
Xerophilic fungi	喜旱真菌
Ximelagatran	希美加群,抗凝药物
Xofigo by Bayer	2013 年 5 月 15 日,美国食品药品监督管理局 (FDA)批准了二氯化镭 Ra 223 (Xofigo 注射
	剂,拜耳医药保健制药公司)用于治疗去势抵抗 性前列腺癌
X-ray	X 射线
Yasmin (Ethinyl Estradiol/Drospirenone Birth Control Pills)	优思明(炔雌醇~屈螺酮避孕药)
Yellow fever virus	黄热病毒
Yersinia enterocolitica	小肠结肠炎耶尔森菌
Yersinia pestis	鼠疫耶尔森菌
Zenapax <sup>316</sup> = Daclizumab达克珠单抗	赛尼哌; 抗 Tac 单抗; 抗排异药 anti- rejection;
Zeneca	泽尼卡
Zevalin, Prep Yttrium-90/Ibritumomab	泽娃灵, 替伊莫单抗/人血白蛋白; 抗癌药物->
Tiuxetan/Albumin Human	治疗非霍奇金淋巴瘤药物
Zocor ( simvastatin )	舒降之;他汀类降胆固醇药;辛伐他汀
Zyprexa (Olanzapine)	再普乐;奥氮平;精神分裂症

α1-receptor blocker	a1受体阻滞剂
β-lactames	β-内酰氨

[Top] [Laws & Regulations] [FDA Organization] [SFDA]

## Laws & Regulations

Laws & Regulations	
Animal Drug User Fee Act 2003	《兽药用户付费法》
Anti-drug Abuse Act 1988	反毒品滥用法
Best Pharmaceuticals for Children Act <sup>317</sup> 2002	儿童最佳药品法;最佳儿童医药品法;
BPCA	
Biologics Control Act 1902	生物制品管制法
DSHEA = Dietary Supplement Health and	膳食补充品健康与教育法
Education Act of 1994	
Drug Price Competition and Patent Term	海切—维克茨曼法案
Restoration Act, more commonly known as the	
"Hatch-Waxman Act" 1984	
Fair Packaging and Labeling Act 1966	公平包装和标识法
Federal Food, Drug and Cosmetic Act 1938 <sup>318</sup>	食品、药品和化妆品法
Food and Drug Administration Modernization Act of 1997 <sup>319</sup>	美国食品和药品管理局现代化法
Kefauver-Harris Amendment to the FD&C Act <sup>320</sup> 1962	克发尔-哈里斯修正案
Medical Device Regulation Act 1976	医疗器械管制法
Medical Device User Fee and Modernization Act = MDUFMA 2002	医疗器械收费和现代化法案
Nutrition Labeling and Education Act = NLEA 1990	《营养标签及教育法》
Pediatric Research Equity Act of 2003	《2003年儿科研究公平法》
Prescription Drug Marketing Act 1987	《处方药销售法》
Prescription Drug User Fee Act $^{321}$ = PDUFA 1992	处方药收费法
Public Health Security and Bioterrorism	《2002年公共健康安全和生物恐怖预备应对
Preparedness and Response Act of 2002 (the	法》(简称《生物恐怖法》)
Bioterrorism Act)	
Public Health Service Act 1944	公共健康服务法;公共卫生服务署法
Pure Food and Drug Act 1906	纯食品和药品法
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[Top] [Laws & Regulations] [FDA Organization] [SFDA]

## **FDA Structure**

## 美国卫生与人类服务部 (HHS)美国卫生与公共服务部(HHS)部长(December 2013) 凯瑟琳·瑟比列

**斯(Kathleen Sebelius)**<a href="http://www.hhs.gov">http://www.hhs.gov</a>FDAOrganization chartDecember 2013<a href="http://www.fda.gov/">http://www.fda.gov/</a>

Office of the Commissioner	
Immediate Office of the Commissioner	
National Center for Toxicological Research	
Office of Foods and Veterinary Medicine	
Center for Food Safety and Applied Nutrition	
Center for Veterinary Medicine	
Office of Medical Products and Tobacco	

Center for Devices and Radiological Health	
Office of Special Medical Programs	
Center for Tobacco Products	
Center for Biologics Evaluation and Research	
Center for Drug Evaluation and Research	
Office of Global Regulatory Operations and Policy	
Office of International Programs	
Office of Regulatory Affairs	
Office of Operations	
Office of Management	
Office of Information Management	
Office of Finance, Budget and Acquisition	
Office of Equal Employment Opportunity	
Associate Commissioner Linda Tollefson, DVM, MPH, FDA Office of	美国食品药品管理局助理局
Foods and Veterinary Medicine	
	长琳达·托尔夫森

Acting Principal Deputy Commissioner	代理第一副局长
ATF = Bureau of Alcohol, Tobacco, Firearms and Explosives	酒精、烟草、枪支和爆炸物管理局
CBER = Center For Biologics Evaluation and Research	生物制品评价和研究中心 (职位:主任
Research	Director )
CDER = Center For Drug Evaluation and Research	药品评价和研究中心(职位:主任 Director)
CDRH = Center For Devices and Radiological Health	器械和辐射健康中心( 职位:主任 Director )
CFSAN = Center For Food Safety and Applied Nutrition	食品安全和应用营养中心 ( 职位 : 主任
	Director )
Commissioner of Food and Drugs	食品和药品局长
CVM = Center For Veterinary Medicine	兽药中心(职位:主任 Director)
Division of (Drug) Risk Evaluation	风险评估部
Division of Medication Errors and Technical Support	投药出错和技术支持部
Division of Surveillance, Research and Communication Support	监测、研究和交流支持部
Drug Safety and Risk Management Advisory Committee	药品安全和风险管理咨询委员会
NCTR = National Center for Toxicological Research	国家毒理学研究中心( 职位:主任 Director )
OAP = Office of Antimicrobial Products (under CDER)	抗菌产品办公室
OBP = Office of Biotechnology Products (under CDER)	生物技术产品办公室
OCC = Office of Chief Counsel	首席法律顾问办公室
OCI = Office of Criminal Investigations	犯罪调查办公室
OCP = Office of Clinical Pharmacology	临床药理学办公室 (under CDER); supercedes

	OCPB
ODS = Office of Drug Safety	药品安全办公室
Office For Human Research Trials	人体研究试验办公室
Office of Applied Research and Safety Assessment	应用研究和安全性评估办公室
Office of Biostatistics and Epidemiology (under CBER)	流行病学和生物统计学办公室
Office of Blood Research and Review	血液研究和审查办公室
Office of Cellular, Tissue and Gene Therapy (under CBER)	细胞组织基因治疗办公室
Office of Clinical Pharmacology and Biopharmaceutics (OCPB)	临床药理学和生物制药学办公室
Office of Communication, Education, and Radiation Programs (under CDRH)	交流、教育和放射项目办公室
Office of Communication, Training and Manufacturers Assistance	交流、培训和帮助制造商办公室
Office of Compliance	执法办公室
Office of Compliance and Biologics Quality	执法和生物制品质量办公室
Office of Constituent Operations	选民工作办公室
Office of Consumer Affairs	消费者事务办公室
Office of Cosmetics and Colors	化妆品和色素办公室
Office of Counter-Terrorism and Emergency Coordination (under CDER)	反恐紧急协调办公室
Office of Device Evaluation	器械评价办公室
Office of Drug Evaluation I	药品评价办公室I
Office of Drug Evaluation II	药品评价办公室 II
Office of Drug Evaluation III	药品评价办公室 III
Office of Drug Evaluation IV	药品评价办公室 IV
Office of Drug Evaluation V	药品评价办公室 V
Office of Enforcement	强制执法办公室
Office of Equal Opportunity	均等机会办公室(职位:主任 Director)
Office of Executive Operations	行政运行办公室
Office of Executive Programs (under CDER)	
Office of Executive Secretariat	行政秘书处办公室
Office of Facilities, Acquisitions, & Central Services	设备、办公用品和中心服务办公室
Office of Field Programs	现场项目办公室
Office of Financial Management	财务管理办公室
Office of Food Additive Safety	食品添加剂安全办公室
Office of Generic Drugs	·····································
Office of Health and Industry Programs	健康和产业项目办公室
Office of Human Resources & Management Services	人类资源和管理服务办公室

Salety (OIVD) under CDRH         IPP / Buinnam, Intrack ELD A E           Office of Information Resources Management         信息沒添管理办公室           Office of Information Technology         信息技术力公室           Office of Information Technology (under CBER)         信息技术力公室           Office of Information Technology Management         信息技术力公室           Office of Information Technology Management         信息技术力公室           Office of Internal Affairs         内部事务力公室           Office of International & Constituent Relations         国际和选民关系力公室 (职位 : 副专員 Deputy Commissioner )           Office of International Programs         国际项目力公室           Office of Management         管理和公室           Office of Management & Systems         管理和交流力公室           Office of Management & Systems         管理和交流力公室           Office of Management & Systems (under CDRH)         管理服务统力公室           Office of Management Services (under NCTR)         管理服务统力公室           Office of Management Services (under NCTR)         管理服务统力公室           Office of Management Services (under CDRH)         管理服务统力公室           Office of Management Services Animal         少使用和少数动物管药发展力公室           Office of Management Services Animal         少使用和少数动物管药公室           Office of New Drug Chemistry         新務化学力公室           Office of New Drug Products (under CDER)         新教化学力公室	Office of the Viter Discovertin D is the local state	
Office of Information Resources Management         信息资源管理办公室           Office of Information Technology (under CBER)         信息技术办公室           Office of Information Technology (under CBER)         信息技术协公室           Office of Information Technology Management         信息技术管理办公室           Office of Information Technology Management         信息技术管理办公室           Office of Information Technology Management         信息技术管理办公室           Office of Information Technology Management         国际和选民关系办公室 (职位:副专员 Deputy Commissioner )           Office of Information Affairs         内部事务か公室           Office of Information Programs         国际项目内公室           Office of Legislation         立法か公室           Office of Management & Systems         管理和系统力公室 (职位: 资深准专员 Senior Associate Commissioner )           Office of Management Operations (under CDRH)         管理服务か公室           Office of Management Systems (under CPARH)         管理服务か公室           Office of Management Systems (under CPARH)         管理服务が公室           Office of Management Systems (under CPARH)         管理服务が公室           Office of Management Systems (under CPARH)         管理服务が公室           Office of New Drug Chemistry         新药が物药が中/m公室           Office of New Drug SeoND         新药がのか公室           Office of New Drug Chemistry         新药が公室/mainAlphy           Office of Nongerscription Products (under	Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) under CDRH	体外诊断器械评估和安全性办公室
Office of Information Technology (under CBER)         信息技术均公室           Office of Information Technology Management         信息技术管理办公室           Office of Information Technology Management         信息技术管理办公室           Office of International & Constituent Relations         国际和选民关系办公室 ( 职位 : 副专員 Deputy Commissioner )           Office of International & Constituent Relations         国际和选民关系办公室 ( 职位 : 副专員 Deputy Commissioner )           Office of International Programs         国际项目办公室           Office of Management M Systems         管理和交流力公室 ( 职位 : 资深准专員 Senior Associate Commissioner )           Office of Management and Communications         管理和交流力公室           Office of Management Operations (under CDRH)         管理服务办公室           Office of Management Systems (under CDRH)         管理服务办公室           Office of Management Systems (under CPSAN)         管理服务办公室           Office of Management Systems (under CPSAN)         管理服务办公室           Office of Neadement Systems (under CDEN)         使用和少数动物兽药发展力公室           Office of New Animal Drug Evaluation         が広物物防iii がいな空           Office of New Animal Drug Evaluation         が訪物防iii がかな室           Office of New Drugs = OND         新药小公室           Office of Noprescription Products (under CDER)         非技力公室           Office of Operations         运行办公室           Office of Ophan Products (under CDER)         非技力药产品 </td <td></td> <td>信息资源管理办公室</td>		信息资源管理办公室
Office of Information Technology Management         信息技术管理办公室           Office of Internal Affairs         内部事务办公室           Office of International & Constituent Relations         国际和选民关系办公室 ( 駅位 : 副专員 Deputy Commissioner )           Office of International Programs         国际项目力公室           Office of Legislation         立法办公室           Office of Legislation         立法办公室           Office of Management         管理和系统办公室 ( 职位 : 资深准专员 Senior Associate Commissioner )           Office of Management and Communications         管理和交流办公室           Office of Management Operations (under CDRH)         管理服务办公室           Office of Management Systems (under CDRH)         空学政策办公室           Office of Management Systems (under CDRH)         少使用和少数动物兽药发展办公室           Office of Neor Use and Minor Species Animal Drug Development (under CVM)         少使用和少数动物兽药发展办公室           Office of Neor Use and Minor Species Animal Drug Development (under CVM)         影然化学办公室           Office of Neor Use and Minor Species Animal Drug Development (under CVM)         ジ使用和少数动物影动公室           Office of Neor Drug Froducts, Labeling and Dieta	Office of Information Technology	信息技术办公室
Office of Internal Affairs         内部事务办公室           Office of International & Constituent Relations         国际功选民关系办公室 (职位:副专员 Deputy Commissioner )           Office of International Programs         国际项目办公室           Office of Legislation         立法办公室           Office of Management         管理办公室           Office of Management & Systems         管理和系统办公室 (职位:资深准专员 Senior Associate Commissioner )           Office of Management and Communications         管理和交流办公室           Office of Management Ac Communications         管理運家か公室           Office of Management and Communications         管理運家か公室           Office of Management Services (under CDRH)         管理運家か公室           Office of Management Systems (under CFSAN)         管理運家施力公室           Office of Minagement Systems (under CFSAN)         管理系统力公室           Office of Neical Policy         医学政策力公室           Office of New Drug Chemistry         新药水物药评价办公室           Office of New Drug Chemistry         新药水物药评介公室           Office of New Drug Chemistry         新药力公室           Office of Oncology Drug Products (under CDER)         非验方药产品力公室           Office of Oncology Drug Products (under CDER)         pma字方品           Office of Oncology Drug Products (under CDER)         pma字方公室           Office of Oncology Drug Products (under CDER)         pmaprenans	Office of Information Technology (under CBER)	信息技术办公室
Print=学方小公室           Office of International & Constituent Relations         国际和选民关系办公室(职位:副专员 Deputy Commissioner)           Office of International Programs         国际项目办公室           Office of Legislation         立法办公室           Office of Management         管理和系统力公室(职位:资深准专员 Senior Associate Commissioner)           Office of Management & Systems         管理和交流力公室           Office of Management and Communications         管理和交流力公室           Office of Management Operations (under CDRH)         管理逐步办公室           Office of Management Services (under NCTR)         管理系统力公室           Office of Management Systems (under CFSAN)         管理系统办公室           Office of Medical Policy         医学政策办公室           Office of New Animal Drug Evaluation         新动物药评价办公室           Office of New Animal Drug Evaluation         新药力公室           Office of New Drug Chemistry         新药心室           Office of New Drug Chemistry         新药水公室           Office of Operations         运行办公室           Office of Operations         运行办公室           Office of Operations         运行办公室           Office of Nutritional Products (under CDER)         非股力方动产品か公室           Office of Operations         运行办公室           Office of Operations         运行办公室           Office of Operations         运行办公室	Office of Information Technology Management	信息技术管理办公室
ElinovituziteXxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	Office of Internal Affairs	内部事务办公室
Office of International Programs         国际项目办公室           Office of Legislation         立法办公室           Office of Management         管理办公室           Office of Management & Systems         管理和系统办公室 (职位:资深准专员 Senior Associate Commissioner )           Office of Management and Communications         管理和交流办公室           Office of Management Operations (under CDRH)         管理服务办公室           Office of Management Services (under NCTR)         管理服务办公室           Office of Management Systems (under CPSAN)         管理系统办公室           Office of Minor Use and Minor Species Animal Drug Development (under CVM)         少使用和少数动物兽药发展办公室           Office of New Drug Chemistry         新药物药评价办公室           Office of New Drug Chemistry         新药水室           Office of Nonprescription Products (under CDER)         非处方药产品办公室           Office of Ocology Drug Products (under CDER)         肿瘤学药品办公室           Office of Operations         运行办公室           Office of Operations         运行办公室           Office of Pharmaceutical Science         制药科学办公室           Office of Planning, Finance, and Information Technology         计划办公室           Office of Planning, Finance, and Information Technology         计划、财务和信息技术办公室           Office of Planning, and Resource Management (under NCTR)         计划办公室           Office of Planning, Finance, and Information Technology	Office of International & Constituent Relations	国际和选民关系办公室( 职位:副专员 Deputy
Office of Legislation         立法办公室           Office of Management         管理办公室           Office of Management & Systems         管理和系统办公室(职位:资深准专员 Senior Associate Commissioner )           Office of Management and Communications         管理和交流办公室           Office of Management Operations (under CDRH)         管理服务办公室           Office of Management Services (under NCTR)         管理服务办公室           Office of Management Services (under CPSAN)         管理系统办公室           Office of Management Systems (under CPSAN)         管理系统办公室           Office of Management Systems (under CPSAN)         管理系统办公室           Office of Management Systems (under CPSAN)         管理系统办公室           Office of Medical Policy         医学政策办公室           Office of Medical Policy         医学政策办公室           Office of New Drug Legislation         新动物药评价办公室           Office of New Drug Chemistry         新药化学办公室           Office of New Drug Chemistry         新药小公室           Office of Nonprescription Products (under CDER)         非处方药产品办公室           Office of Oncology Drug Products (under CDER)             Office of Oncology Drug Products (under CDER)             Office of Pharmaceutical Science             Office of Pharmaceutical Science             Office of Pl		Commissioner )
Office of Management         管理办公室           Office of Management & Systems         管理和系统办公室 ( 职位 : 资深准专员 Senior Associate Commissioner )           Office of Management and Communications         管理和交流办公室           Office of Management Operations (under CDRH)         管理運方办公室           Office of Management Operations (under CDRH)         管理運方办公室           Office of Management Services (under NCTR)         管理服务办公室           Office of Management Systems (under CFSAN)         管理系统办公室           Office of Medical Policy         医学政策办公室           Office of Munor Use and Minor Species Animal Drug Development (under CVM)         少使用和少数动物兽药发展办公室           Office of New Drug Chemistry         新药物药评价办公室           Office of Nonprescription Products (under CDER)         非处方药产品办公室           Office of Oncology Drug Products (under CDER)         非处方药产品开公本           Office of Operations         运行办公室           Office of Phannaceutical Science         制药科学办公室           Office of Planning, and Resource Management (under NCTR)         计划、财务和信息技术办公室           Office of Planning, and Legislation         政策办公室           Office of Policy, Planning, and Legislation         政策, 计划和立法办公室 ( 职位 : 资深准专员	Office of International Programs	国际项目办公室
Office of Management & Systems         管理和系统办公室(职位:资深准专员 Senior Associate Commissioner )           Office of Management and Communications         管理和交流办公室           Office of Management Operations (under CDRH)         管理運方办公室           Office of Management Services (under NCTR)         管理服务办公室           Office of Management Services (under CFSAN)         管理系统办公室           Office of Management Systems (under CFSAN)         管理系统办公室           Office of Medical Policy         医学政策办公室           Office of Munor Use and Minor Species Animal prug Development (under CVM)         少使用和少数动物兽药发展办公室           Office of New Animal Drug Evaluation         新动物药评价办公室           Office of New Drug Chemistry         新药力公室           Office of Nonprescription Products (under CDER)         非处方药产品力公室           Office of Oncology Drug Products (under CDER)         非处方药产品力公室           Office of Operations         运行力公室           Office of Pharmaceutical Science         制药科学办公室           Office of Planning         计划办公室           Office of Planning, and Resource Management (under NCTR)         计划、财务和信息技术办公室           Office of Planning, Finance, and Information Technology         计划、财务和信息技术办公室           Office of Planning, Finance, and Information Technology         计划、财务和信息技术办公室           Office of Planning, Finance, and Information Technology         拉利和牛幼食品及饮料办公室 <t< td=""><td>Office of Legislation</td><td>立法办公室</td></t<>	Office of Legislation	立法办公室
Associate Commissioner )Office of Management and Communications管理和交流办公室Office of Management Operations (under CDRH)管理服务办公室Office of Management Services (under NCTR)管理服务办公室Office of Management Systems (under CFSAN)管理系统办公室Office of Medical PolicyCoffice of Management Systems (under CFSAN)管理の次方公室Office of Medical PolicyCoffice of New Cluster AnimalDrug Development (under CVM)Office of New Animal Drug EvaluationSmöth%ph公室Office of New Drug ChemistrySmöth%ph公室Office of New Drugs = ONDSmöth%ph公室Office of New Drugs = ONDSmöth%ph公室Office of Oncology Drug Products (under CDER)IpupelmentsOffice of Oncology Drug Products (under CDER)Ipma?phanetsOffice of OperationsCoffice of Phanmaceutical Science制药科学为公室Office of Phaning, and Resource Managementunder KCTR)Office of Planning, Finance, and InformationTechnologyOffice of Planning, Finance, and InformationTechnologyOffice of Planning, and LegislationW\$\$\p\$p\$\DC\$\$Office of Planning, and LegislationDiffice of Planning, and LegislationDiffice of Planning, and Legislation	Office of Management	管理办公室
Office of Management and Communications管理和交流办公室Office of Management Operations (under CDRH)管理运作办公室Office of Management Services (under NCTR)管理服务办公室Office of Management Systems (under CFSAN)管理系统办公室Office of Medical Policy医学政策办公室Office of Medical Policy医学政策办公室Office of Minor Use and Minor Species Animal Drug Development (under CVM)少使用和少数动物兽药发展办公室Office of New Animal Drug Evaluation新动物药评价办公室Office of New Drug Chemistry新药化学办公室Office of New Drug S = OND新药水力学Office of Nonprescription Products (under CDER)非处方药产品办公室Office of Oncology Drug Products (under CDER)肿瘤学药品力公室Office of Operations运行办公室Office of Pharmaceutical Science制药科学办公室Office of Phanning, and Resource Management under NCTR)北划资源管理办公室Office of Planning, Finance, and Information Technology计划、财务和信息技术办公室Office of Policy政策办公室Office of Policy, Planning, and Legislation政策, 计划和立法办公室 (职位:资深准专员	Office of Management & Systems	管理和系统办公室(职位:资深准专员 Senior
Office of Management Operations (under CDRH)       管理运作办公室         Office of Management Services (under NCTR)       管理服务办公室         Office of Management Systems (under CFSAN)       管理系统办公室         Office of Medical Policy       医学政策办公室         Office of Minor Use and Minor Species Animal Drug Development (under CVM)       少使用和少数动物兽药发展办公室         Office of New Animal Drug Evaluation       新动物药评价办公室         Office of New Drug Chemistry       新药小公室         Office of New Drugs = OND       新药办公室         Office of Nutritional Products (under CDER)       非处方药产品办公室         Office of Nutritional Products, Labeling and Dietary Supplements       营养产品、标识和饮食添加剂办公室         Office of Operations       运行办公室         Office of Phanmaceutical Science       制药科学办公室         Office of Planning, and Resource Management (under NCTR)       计划办公室         Office of Planning, Finance, and Information Technology       计划、财务和信息技术办公室         Office of Planning, Finance, and Beverages       植物和牛奶食品及饮料办公室         Office of Planning, and Legislation       政策, 计划和立法办公室 (职位 : 资深准专员		Associate Commissioner)
Office of Management Services (under NCTR)管理服务办公室Office of Management Systems (under CFSAN)管理系统办公室Office of Medical Policy医学政策办公室Office of Minor Use and Minor Species Animal Drug Development (under CVM)少使用和少数动物兽药发展办公室Office of New Animal Drug Evaluation新动物药评价办公室Office of New Drug Chemistry新药化学办公室Office of Nonprescription Products (under CDER)非处方药产品办公室Office of Oncology Drug Products (under CDER)肿瘤学药品办公室Office of Operations运行办公室Office of Phanmagement (under NCTR)学见病产品开发办公室Office of Planning计划办公室Office of Planning, and Resource Management (under NCTR)抗财和公室Office of Plant and Dairy Foods and Beverages植物和牛奶食品及饮料办公室Office of Policy政策办公室Office of Policy, Planning, and Legislation政策、计划和立法办公室 (职位: 资深准专员	Office of Management and Communications	管理和交流办公室
Office of Management Systems (under CFSAN)管理系统办公室Office of Medical Policy医学政策办公室Office of Minor Use and Minor Species Animal Drug Development (under CVM)少使用和少数动物兽药发展办公室Office of New Animal Drug Evaluation新动物药评价办公室Office of New Drug Chemistry新药化学办公室Office of New Drug S = OND新药办公室Office of Nonprescription Products (under CDER)非处方药产品办公室Office of Nutritional Products, Labeling and Dietary Supplements营养产品、标识和饮食添加剂办公室Office of Operations运行办公室Office of Operations运行办公室Office of Pharmaceutical Science制药科学办公室Office of Planning, and Resource Management (under NCTR)北划资源管理办公室Office of Planning, Finance, and Information rechnology计划、财务和信息技术办公室Office of Planning, Finance, and Information rechnology计划、财务和信息技术办公室Office of Policy政策办公室Office of Policy, Planning, and Legislation政策办公室Office of Policy, Planning, and Legislation政策, 计划和立法办公室 ( 职位 : 资深准专员	Office of Management Operations (under CDRH)	管理运作办公室
Office of Medical Policy医学政策动公室Office of Minor Use and Minor Species Animal Drug Development (under CVM)少使用和少数动物兽药发展办公室Office of New Animal Drug Evaluation新动物药评价办公室Office of New Drug Chemistry新药小公室Office of New Drug Chemistry新药办公室Office of New Drugs = OND新药办公室Office of Nonprescription Products (under CDER)非处方药产品办公室Office of Nonprescription Products, Labeling and Dietary Supplements富养产品、标识和饮食添加剂办公室Office of Operations运行办公室Office of Operations运行办公室Office of Pharmaceutical Science制药科学办公室Office of Planning, and Resource Management (under NCTR)规划资源管理办公室Office of Planning, Finance, and Information Technology计划、财务和信息技术办公室Office of Policy政策办公室Office of Policy, Planning, and Legislation政策, 计划和立法办公室 (职位 : 资深准专员	Office of Management Services (under NCTR)	管理服务办公室
Office of Minor Use and Minor Species Animal Drug Development (under CVM)少使用和少数动物兽药发展办公室Office of New Animal Drug Evaluation新动物药评价办公室Office of New Drug Chemistry新药化学办公室Office of New Drugs = OND新药办公室Office of Nonprescription Products (under CDER)非处方药产品办公室Office of Oncology Drug Products (under CDER)非处方药产品办公室Office of Operations运行办公室Office of Ophan Products Development罕见病产品开发办公室Office of Planning计划办公室Office of Planning, and Resource Management (under NCTR)11划、财务和信息技术办公室Office of Plant and Dairy Foods and Beverages植物和牛奶食品及饮料办公室Office of Policy政策办公室Office of Policy, Planning, and Legislation政策、计划和立法办公室 ( 职位 : 资深准专员	Office of Management Systems (under CFSAN)	管理系统办公室
Drug Development (under CVM)Display and a subscription X ±Office of New Animal Drug Evaluation新动物药评价办公室Office of New Drug Chemistry新药小公室Office of New Drugs = OND新药办公室Office of Nonprescription Products (under CDER)非处方药产品办公室Office of Nutritional Products, Labeling and Dietary Supplements富养产品、标识和饮食添加剂办公室Office of Oncology Drug Products (under CDER)肿瘤学药品办公室Office of Oncology Drug Products (under CDER)肿瘤学药品办公室Office of Operations运行办公室Office of Operations运行办公室Office of Orphan Products Development罕见病产品开发办公室Office of Planning, and Resource Management (under NCTR)机划资源管理办公室Office of Planning, Finance, and Information Technology计划、财务和信息技术办公室Office of Policy政策办公室Office of Policy, Planning, and Legislation政策, 计划和立法办公室 (职位: 资深准专员	Office of Medical Policy	医学政策办公室
Office of New Drug Chemistry新药化学办公室Office of New Drugs = OND新药办公室Office of Nonprescription Products (under CDER)非处方药产品办公室Office of Nutritional Products, Labeling and Dietary Supplements营养产品、标识和饮食添加剂办公室Office of Oncology Drug Products (under CDER)肿瘤学药品办公室Office of Operations运行办公室Office of Operations运行办公室Office of Pharmaceutical Science制药科学办公室Office of Planning计划办公室Office of Planning, and Resource Management (under NCTR)规划资源管理办公室Office of Planning, Finance, and Information Technology计划、财务和信息技术办公室Office of Policy, Planning, and Legislation政策办公室Office of Policy, Planning, and Legislation政策、计划和立法办公室 (职位: 资深准专员		少使用和少数动物兽药发展办公室
Office of New Drugs = OND新药办公室Office of Nonprescription Products (under CDER)非处方药产品办公室Office of Nutritional Products, Labeling and Dietary Supplements营养产品、标识和饮食添加剂办公室Office of Oncology Drug Products (under CDER)肿瘤学药品办公室Office of Operations运行办公室Office of Operations运行办公室Office of Operations空见病产品开发办公室Office of Pharmaceutical Science制药科学办公室Office of Planning, and Resource Management (under NCTR)规划资源管理办公室Office of Planning, Finance, and Information Technology计划、财务和信息技术办公室Office of Policy政策办公室Office of Policy, Planning, and Legislation政策、计划和立法办公室 ( 职位 : 资深准专员	Office of New Animal Drug Evaluation	新动物药评价办公室
Office of Nonprescription Products (under CDER)非处方药产品办公室Office of Nutritional Products, Labeling and Dietary Supplements营养产品、标识和饮食添加剂办公室Office of Oncology Drug Products (under CDER)肿瘤学药品办公室Office of Operations运行办公室Office of Operations运行办公室Office of Ophan Products Development罕见病产品开发办公室Office of Pharmaceutical Science制药科学办公室Office of Planning计划办公室Office of Planning, and Resource Management (under NCTR)批划资源管理办公室Office of Planning, Finance, and Information Technology计划、财务和信息技术办公室Office of Plant and Dairy Foods and Beverages植物和牛奶食品及饮料办公室Office of Policy政策办公室Office of Policy, Planning, and Legislation政策、计划和立法办公室 (职位: 资深准专员	Office of New Drug Chemistry	新药化学办公室
Office of Nutritional Products, Labeling and Dietary Supplements请未产品、标识和饮食添加剂办公室Office of Oncology Drug Products (under CDER)肿瘤学药品办公室Office of Operations运行办公室Office of Operations运行办公室Office of Orphan Products Development罕见病产品开发办公室Office of Pharmaceutical Science制药科学办公室Office of Planning计划办公室Office of Planning, and Resource Management (under NCTR)规划资源管理办公室Office of Planning, Finance, and Information Technology计划、财务和信息技术办公室Office of Plant and Dairy Foods and Beverages植物和牛奶食品及饮料办公室Office of Policy, Planning, and Legislation政策, 计划和立法办公室 (职位:资深准专员	Office of New Drugs = OND	新药办公室
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Office of Oncology Drug Products (under CDER)肿瘤学药品办公室Office of Operations运行办公室Office of Operations运行办公室Office of Orphan Products Development罕见病产品开发办公室Office of Pharmaceutical Science制药科学办公室Office of Planning计划办公室Office of Planning, and Resource Management (under NCTR)规划资源管理办公室Office of Planning, Finance, and Information Technology计划、财务和信息技术办公室Office of Plant and Dairy Foods and Beverages植物和牛奶食品及饮料办公室Office of Policy政策办公室Office of Policy, Planning, and Legislation政策、计划和立法办公室 (职位: 资深准专员		营养产品、标识和饮食添加剂办公室
Office of Operations运行办公室Office of Orphan Products Development罕见病产品开发办公室Office of Pharmaceutical Science制药科学办公室Office of Planning计划办公室Office of Planning, and Resource Management (under NCTR)规划资源管理办公室Office of Planning, Finance, and Information Technology计划、财务和信息技术办公室Office of Plant and Dairy Foods and Beverages植物和牛奶食品及饮料办公室Office of Policy政策办公室Office of Policy, Planning, and Legislation政策、计划和立法办公室(职位:资深准专员		
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Office of Planning计划办公室Office of Planning, and Resource Management (under NCTR)规划资源管理办公室Office of Planning, Finance, and Information Technology计划、财务和信息技术办公室Office of Plant and Dairy Foods and Beverages植物和牛奶食品及饮料办公室Office of Policy政策办公室Office of Policy, Planning, and Legislation政策、计划和立法办公室(职位:资深准专员	Office of Pharmaceutical Science	
Office of Planning, and Resource Management (under NCTR)       规划资源管理办公室         Office of Planning, Finance, and Information Technology       计划、财务和信息技术办公室         Office of Plant and Dairy Foods and Beverages       植物和牛奶食品及饮料办公室         Office of Policy       政策办公室         Office of Policy, Planning, and Legislation       政策、计划和立法办公室(职位:资深准专员	Office of Planning	
(under NCTR)加站及低水目245542Office of Planning, Finance, and Information Technology计划、财务和信息技术办公室Office of Plant and Dairy Foods and Beverages植物和牛奶食品及饮料办公室Office of Policy政策办公室Office of Policy, Planning, and Legislation政策、计划和立法办公室(职位:资深准专员		
Technology     计规制 知为和自急的文书的公室       Office of Plant and Dairy Foods and Beverages     植物和牛奶食品及饮料办公室       Office of Policy     政策办公室       Office of Policy, Planning, and Legislation     政策、计划和立法办公室(职位:资深准专员	(under NCTR)	
Office of Plant and Dairy Foods and Beverages植物和牛奶食品及饮料办公室Office of Policy政策办公室Office of Policy, Planning, and Legislation政策、计划和立法办公室(职位:资深准专员)	-	计划、财务和信息技术办公室
Office of Policy, Planning, and Legislation     政策、计划和立法办公室(职位:资深准专员)		植物和牛奶食品及饮料办公室
以来、113/11·2/2/2/2/2/2/2/2/2/2/2/2/2/2/2/2/2/2/	Office of Policy	政策办公室
Senior Associate Commissioner )	Office of Policy, Planning, and Legislation	政策、计划和立法办公室(职位:资深准专员
		Senior Associate Commissioner)

Office of Post-Marketing Drug Risk Assessment	上市后药品风险评估办公室
Office of Premarket Approval	上市前审批办公室;上市前批准事宜办公室
Office of Public Affairs	公共事务办公室
Office of Regional Operations	地区性运行办公室
Office of Research	研究办公室
Office of Resource Management	资源管理办公室
Office of Review Management	审查管理办公室
Office of Science	科学办公室
Office of Science and Engineering Laboratories under CDRH	科学与工程试验室办公室
Office of Science and Technology	科学和技术办公室
Office of Science Coordination and Communication	科学协调和交流办公室(职位:主任 Director)
Office of Scientific Analysis and Support	科学分析和支持办公室
Office of Seafood	海产食品办公室
Office of Special Health Issues	特殊健康问题办公室
Office of Surveillance and Biometrics	监督和生物统计办公室
Office of Surveillance and Compliance	监督和执法办公室
Office of Surveillance and Epidemiology = OSE,	药品监测和流行病学办公室,
formerly "Office of Drug Safety"	前"药品安全办公室"
Office of Systems and Management	系统和管理办公室
Office of Testing and Research	试验和研究办公室
Office of The Administrative Law Judge	行政法官办公室(职位:行政法官
	Administrative Law Judge )
Office of the Commissioner OC	局长办公室
Office of The Ombudsman	监察专员办公室
Office of The Senior Associate Commissioner	资深准专员办公室(职位:资深准专员 Senior
	Associate Commissioner)
Office of Therapeutics Research and Review	治疗学研究和审查办公室
Office of Training and Communication	培训和交流办公室
Office of Translational Science	转化科学办公室
Office of Vaccines Research and Review	疫苗研究和审查办公室
Office of Women's Health	妇女健康办公室
OIVDDES = Office of In Vitro Diagnostic Device	体外诊断器械评价与安全办公室
Evaluation and Safety ONDQA = Office of New Drug Quality Assessment	
(under CDER)	新药质量评价办公室
OODP = Office of Oncology Drug Products (under CDER)	肿瘤学药品办公室
ORA = Office of Regulatory Affairs	监管事务办公室
<u>L</u>	<u> </u>

OSEL = Office of Science and Engineering Laboratories (under CDRH)	科学与工程试验室办公室
Regional Field Office, Central Region, Philadelphia, PA	地区性现场办公室—中部地区
Regional Field Office, Northeast Region, Jamaica, NY	地区性现场办公室—东北地区
Regional Field Office, Pacific Region, Oakland, CA	地区性现场办公室—太平洋地区
Regional Field Office, Southeast Region, Atlanta, GA	地区性现场办公室—东南地区
Regional Field Offrice, Southwest Region, Dallas, TX	地区性现场办公室—西南地区
USDA = Food Safety and Inspection Service	美国食品安全与检查局

(据董耿编译:《浙江药品监督管理》2001年第7辑第82---85页)

[Top] [Laws & Regulations] [FDA Organization] [SFDA]

## CFDA China Food and Drug Administration 国家食品药品监督管理局 <u>http://www.sda.gov.cn</u>

CFDA Structure 局长: 张勇 Organizational chart December 2013

厅		Office	
司		Department	
处		Division	
局		Bureau	
办公厅	综合处	General	Division of General Affairs
	秘书一处(值班室)	Office	Division of Secretariat I (Office of Duty)
	秘书二处	-	Division of Secretariat II
	文电处	]	Division of Documentation and Communication
	督查处(信访办公室)		Division of Superintendance (Office of Letters and Calls)
综合司(政策研究	综合协调处	Comprehensi ve Department	Division of General Coordination
室)	政策研究一处		Division of Policy Research I
	政策研究二处 (Office of Deliay	(Office of Policy	Division of Policy Research II
	督查考评处(统计办公室)	Research)	Division of Supervision and Evaluation (Office of Statistics)
法制司	综合处	Department	Division of General Affairs
	法规一处	<ul> <li>of Legal</li> <li>Affairs</li> </ul>	Division of Regulations I
	法规二处		Division of Regulations II
	执法监督处 (行政复议办公 室)		Division of Enforcement Supervision (Office of
 食品安全监管一司		Department	Administrative Reconsideration) Division of General Affairs
		of Food Safety	Division of Supervision I
	监管二处	Supervision I	Division of Supervision II

	监管三处		Division of Supervision III
			Division of Supervision IV
食品安全监管二司	综合处	Department	Division of General Affairs
	监管一处	of Food Safety	Division of Supervision I
		Supervision	Division of Supervision II
		II	Division of Supervision III
			Division of Supervision IV
食品安全监管三司	综合处	Department	Division of General Affairs
		of Food Safety	Division of Supervision I
	监管二处	Supervision	Division of Supervision II
	监管三处	- III	Division of Supervision III
	监管四处	-	Division of Supervision IV
药品化妆品注册管	综合处	Department	Division of General Affairs
理司 ( 中药民族药	中药民族药处	of Drug and Cosmetics	Division of Traditional Chinese
监管司)	 化学药品处	Registration	Medicines and Ethno-Medicines Division of Pharmaceuticals
	生物制品处	(Department of TCMs and	Division of Biological Products
		Ethno- Medicines	Division of Drug Research
	· 约彻听九面自处 	Supervision)	Supervision
	化妆品处	_	Division of Cosmetics
医疗器械注册管理	综合处	Department of Medical	Division of General Affairs
司	注册一处	Device	Division of Registration I
	注册二处	Registration	Division of Registration II
	研究监督处		Division of Research Supervision
药品化妆品监管司	综合处	Department of Drug and	Division of General Affairs
	药品生产监管处	Cosmetics	Division of Drug Manufacturing Supervision
		Supervision	Division of Drug Distribution
	——————————————————————————————————————		Supervision Division of Drug Monitoring and
	药品监测评价处	-	Re-evaluation
	特殊药品监管处		Division of Controlled Drug Supervision
	化妆品监管处	-	Division of Cosmetics Supervision
医疗器械监管司	综合处	Department	Division of General Affairs
	生产监管处	<ul> <li>of Medical</li> <li>Device</li> <li>Supervision</li> </ul>	Division of Drug Manufacturing
			Supervision Division of Distribution
			Supervision
	监测评价处		Division of Monitoring and Re- evaluation
稽查局	综合处	Bureau of	Division of General Affairs

	TH	Investigation	Division of Investigation and
	稽查一处	and	Enforcement I
	稽查二处	Enforcement	Division of Investigation and Enforcement II
	稽查三处		Division of Investigation and Enforcement III
应急管理司	综合处	Department of Emergency	Division of General Affairs
	应急监测处	Management	Division of Emergency Monitoring
	应急指导处		Division of Emergency Guidance
	应急处置处		Division of Emergency Response
科技和标准司	综合处(信息化处)	Department of Science,	Division of General Affairs (Division of Informationalization)
	科技处	Technology and Standards	Division of Science and Technology
	标准管理处		Division of Standard Management
	检验机构指导处		Division of Testing Institutes Instruction
新闻宣传司	综合处	Department of Media and	Division of General Affairs
	新闻宣传一处	Publicity	Division of Media and Publicity I
	新闻宣传二处		Division of Media and Publicity II
人事司	综合处(干部监督处)	Department of Human Resources	Division of General Affairs (Division of Personnel Supervision)
	干部处		Division of Personnel
	人才处		Division of Talents
	直属单位处(工资处)	-	Division of Affiliated Institutions (Division of Compensation)
规划财务司	综合处(规划处)	Department of Planning	Division of General Affairs (Division of General Planning)
	基建装备处	and Finance	Division of Construction and Equipment
	预算与审计处		Division of Budget and Audit
	财务资产处		Division of Finance and Assets
国际合作司(港澳	综合处	Department	Division of General Affairs
台办公室)	国际组织处	- of International - Cooperation (Office of	Division of International Organizations
	双边合作处		Division of Bilateral Cooperation
	港澳台处	Hong Kong, Macao and Taiwan Affairs)	Division of Hong Kong, Macao and Taiwan Affairs

安全监管处 医疗器械司	Div of Safety Supervision
办公室(规划财务司)	General Office = Department of Finance Planning
保健品处 药品注册司	Div of Health Food? Supplements?

标准处 医疗器械司	Div of Standards
财务处 办公室	Div of Financial Affairs
产品注册处 医疗器械司	Div of Product Registration
发展规划处 办公室	Div of Development and Planning
法规处 政策法规司	Div of Regulations
工资调配处 人事教育司	Div of Salary and Deployment
国际合作司	Dept of International Cooperation (Office for Administrative Protection of Pharmaceuticals)
合作处 国际合作司	Div of Cooperation
化学药品处 药品注册司	Div of Pharmaceuticals
监测标准与技术监督处 食品安全协调司	Div of Surveillance Standard and Technical Supervision
经营许可监督处 药品市场监督司	Div of Supervision on Distribution Licensing
考核任免处 人事教育司	Div of Personnel Assessment, Appointment and Removal
联络处 国际合作司	Div of Liaison
秘书处 办公室	Div of Secretaries
培训与技术干部管理处 人事教育司	Div of Training and Management of Technical Personnel
人事教育司	Dept of Personnel and Education
生产监督处 药品安全监管司	Div of Drug Manufacturing Supervision
生物制品处 药品注册司	Div of Biological Products
食品安全监察司	Dept of Food Safety Supervision
食品安全监督处 食品安全监察司	Div of Food Safety Supervision
食品安全协调司	Dept of Food Safety Coordination
特殊药品监管处 药品安全监管司	Div of Controlled Drugs Inspection
文档信息处 办公室	Division of Archives and Information
新闻处 政策法规司	Div of News? or Press?
信息分析处 食品安全协调司	Div of Information Analysis
信息广告监督处药品市场监督司	Div of Drug Information and Advertising Supervision
药品安全监管司	Dept of Drug Safety and Inspection
药品督察处 药品市场监督司	Div of Drug Supervision and Inspection
药品评价处 药品安全监管司	Div of Drug Re-evaluation
药品市场监督司	Dept of Drug Market Compliance
药品研究监督处药品安全监管司	Div of Drug Research Supervision
药品注册司	Dept of Drug Registration
医疗器械督察处 药品市场监督司	Div of Medical Devices Supervision and Inspection
医疗器械司	Dept of Medical Devices
预算管理处 办公室	Div of Budget Management

政策法规司	Dept of Policy and Regulations
政策研究处 政策法规司	Div of Policy Research
执法监督处 政策法规司	Div of Law Enforcement Supervision
中药处 药品注册司	Div of Traditional Chinese Medicine
专项督查处 食品安全协调司	Div of Special Supervision and Investigation
综合处 医疗器械司	Div of General Affairs
综合处 食品安全监察司	Div of General Affairs
综合处 = 应急管理办公室 办公室	Div of General Management
综合管理处 国际合作司	Div of General Management
综合管理处 药品市场监督司	Div of General Management
综合管理处 药品注册司	Div of General Management
综合协调处 食品安全协调司	Div of Comprehensive Coordination

[Top] [Laws & Regulations] [FDA Organization] [SFDA]

<sup>1</sup> allowing earlier approval of drugs to treat serious diseases, and that fill an unmet medical need based on a surrogate endpoint.

<sup>2</sup>责任制医疗组织(ACO: Accountable Care Organization)是美国奥巴马医改的核心之一, 意在解决 如何在确保医疗质量的同时降低医疗费用这个久攻不破的难题。

<sup>3</sup> of the Bureau of Customs and Border Protection (CBP)

<sup>4</sup> a biologic response modifier, is a single-chain polypeptide containing 140 amino acids

5临床适用于预防和治疗冠心病心绞痛,特别是变异型心绞痛和冠状动脉痉挛所致心绞痛

<sup>6</sup>用于缓解抗风湿性药物(DMARD)治疗无效的结构性损伤的中至重度类风湿性关节炎(RA)成年患者的体征与症状。本品可单独使用,也可与甲氨蝶呤或其他 DMARD 合用

<sup>7</sup> a new class of highly potent biopharmaceutical drugs designed as a targeted therapy for the treatment of people with cancer

<sup>8</sup> an ester of adenosine that is converted to ATP for the storage of energy

<sup>9</sup> Adventitious agents can be viruses, bacteria, mycoplasma, fungi, rickettsia, protozoa, parasites, and TSE agents. • Potential concern that adventitious. agents can be unintentionally. introduced into the manufacturing.

<sup>10</sup> An unwanted effect caused by the administration of drugs. Onset may be sudden or develop over time

<sup>11</sup> Organizations and groups that actively support participants and their families with valuable resources, including self-empowerment and survival tools.

<sup>12</sup> A negative experience encountered by an individual during the course of a clinical trial that is associated with the drug.

<sup>13</sup> 是一种重组人融合蛋白,能够结合 VEGF 的 A 亚型和 B 亚型,也能够与胎盘生长因子结合,从 而抑制肿瘤血管的生成

<sup>14</sup> The basic premise of AIP is: If FDA determines that a company's applications are not reliable, the agency will not perform substantive review of any of the company's applications until confidence in the data is restored.

<sup>15</sup> An alanine aminotransferase (ALT) test measures the amount of this enzyme in the blood. ALT is measured to see if the liver is damaged or diseased.

<sup>16</sup> to check for liver disease or damage to the liver. Symptoms of liver disease can include jaundice, belly pain, nausea, and vomiting. An ALP test may also be used to check the liver when medicines that can damage the liver are taken or to check bone problems (sometimes found on X-rays), such as rickets, osteomalacia, bone tumors, Paget's disease, or too much of the hormone that controls bone growth (parathyroid hormone).

<sup>17</sup> One of the alternative versions of a gene at a given location (locus) along a chromosome

<sup>18</sup> An allograft is a transplanted organ or tissue from a genetically non-identical member of the same species

<sup>19</sup> A test for antinuclear antibodies (ANA) test is common in people who are suspected of having an autoimmune or connective tissue disorder. The ANA test identifies autoantibodies that target substances contained in the nucleus of cells

<sup>20</sup> is a general linear model with a continuous outcome variable (quantitative) and two or more predictor variables where at least one is continuous (quantitative) and at least one is categorical (qualitative).

ANCOVA is a merger of ANOVA and regression for continuous variables. ANCOVA tests whether certain factors have an effect on the outcome variable after removing the variance for which quantitative predictors (covariates) account. The inclusion of covariates can increase statistical power because it accounts for some of the variability

<sup>21</sup> Any of the treatment groups in a randomized trial.

<sup>22</sup> Low levels of AST are normally found in the blood. When body tissue or an organ such as the heart or liver is diseased or damaged, additional AST is released into the bloodstream. The amount of AST in the blood is directly related to the extent of the tissue damage.

<sup>23</sup> A renewable permit granted by the federal government to an institution or research center to conduct clinical trials.

<sup>24</sup> in an "as treated" (or "observed data") analysis only those patients still taking the assigned treatment are analyzed; those who drop out are "censored."

<sup>25</sup> 指由不直接涉及试验的人员所进行的一种系统性检查,以评价试验的实施、数据的记录和分析是 否与试验方案、标准操作规程以及药物临床试验相关法规要求相符

26一种批准用于治疗2型糖尿病的药物

<sup>27</sup> Benzodiazepines have also been used as a "date rape" drug because they can markedly impair and even abolish functions that normally allow a person to resist or even want to resist sexual aggression or assault <sup>28</sup> 本类药物也称弱安定药,包括氯氮卓(利眠宁, chlordiazepoxide,商品名 Librium)、地西泮(安

定,diazepam,商品名valium)、硝西泮(硝基安定,nitrazepam)、氟西泮(氟安定,flurazepam)及奥沙西泮(去甲羟基安定,舒宁,oxazepam)。临床主要用于镇静、催眠及对抗癫痫

<sup>29</sup> 1993 年 7 月 23 日, Betaseron 成为美国 FDA 批准的第一个用于治疗多发性硬化的药物 <sup>30</sup> 指在设计临床试验方案、执行临床试验、分析评价临床试验结果时,有关影响因素所致的系统误

差,致使疗效或安全性评价偏离真值。

<sup>31</sup> Reports accessible from this site provide updates on the Human Subject Protection (HSP)/Bioresearch Monitoring (BIMO) Initiative. Launched in 2006 as a part of the Critical Path Initiative, the HSP/BIMO Initiative is aimed at modernizing and strengthening the agency's oversight and protection of subjects in clinical trials and the integrity of resulting data.

<sup>32</sup> expression of how much drug reaches the circulation (known to pharmacologists as the **central compartment**) after administration

<sup>33</sup> Bioburden is defined as the number of bacteria living on a surface that has not been sterilized.

<sup>34</sup> The property of being biologically compatible by not producing a toxic, injurious, or immunological response in living tissue

<sup>35</sup> Å biofilm is a structured community of microorganisms encapsulated within a self-developed polymeric matrix and adherent to a living or inert surface

<sup>36</sup> A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man. biological therapeutic agents that include blood and blood products, vaccines, allergenics, cell and tissue-based products, and gene therapy products

<sup>37</sup> Substances that stimulate the body's response to infection and disease. The body naturally produces small amounts of these substances. Scientists can produce some of them in the laboratory in large amounts for use in treating <u>cancer</u>, <u>rheumatoid arthritis</u>, and other diseases

<sup>38</sup> A biochemical feature or facet that can be used to measure the progress of disease or the effects of treatment

<sup>39</sup> The study of the physical and chemical properties of drugs and their proper dosage as related to the onset, duration, and intensity of drug action.

<sup>40</sup> Biosimilars or Follow-on biologics are terms used to describe officially-approved subsequent versions of innovator biopharmaceutical products made by a different sponsor following patent and exclusivity expiry on the innovator product. Biosimilars are also referred to as subsequent entry biologics (SEBs) in Canada <sup>41</sup> are a class of artificial bispecific monoclonal antibodies that are investigated for the use as anti-cancer drugs. They direct a host's immune system, more specifically the T cells' cytotoxic activity, against cancer cells. BiTE is a registered trademark of Micromet AG

<sup>42</sup>混合过程是固体制剂生产的重要环节,对于保证制剂活性成分分布均匀、质量长期稳定具有重要 意义。混合不充分将导致药品质量严重不均一,而混合过久则是不必要的浪费能源

<sup>43</sup> A randomized trial is "Blind" if the participant is not told which arm of the trial he is on. A clinical trial is "Blind" if participants are unaware on whether they are in the experimental or control arm of the study; also called masked

<sup>44</sup> 在最后一份病例报告表输入数据库后,第一次揭盲之前对数据保持盲态的预分析审核,以便对统 计分析计划作最后的决定。

<sup>45</sup> One of the responsibilities of the Office of Device Evaluation (ODE) is to develop and interpret regulations and guidelines regarding premarket notification submissions (510(k)s), premarket approval applications (PMAs), product development protocols (PDPs), device classifications, and investigational device exemptions (IDEs). The ODE guidance memoranda, affectionately referred to as "Blue Book Memos", clarify these guidelines

<sup>46</sup> This new designation helps FDA assist drug developers to expedite the development and review of new drugs with preliminary clinical evidence that indicates the drug may offer a substantial improvement over available therapies for patients with serious or life-threatening diseases

<sup>47</sup> a bridging study is a supplemental study on a medicine that is performed in the new region to build a bridge between the information available from the tests already done and the questions arising from the regulatory authority due to ethnic factors. Bridging studies done to assess the efficacy of new drugs could provide additional drug response data in the population of the new region. A pharmacokinetic study may be accepted as a bridging study too, if the regulatory authority in the new region requires no bridging study to provide clinical data for efficacy.

<sup>48</sup> A flat monthly fee that a health plan pays to a provider (doctor, hospital, lab, etc.) to take care of a patient's needs. Capitation is part of the provider-reimbursement mechanism

<sup>49</sup> Both the FDA and EMEA endorse the use of CCDSs to track safety data and share labeling information. The EMEA requires companies to file Periodic Safety Update Reports (PSURs) regularly and the FDA requires postmarketing reports for some drugs currently on the market and likely more in the future <sup>50</sup> occurs in the treatment of CML when cytogenetic testing is unable to detect the Philadelphia (Ph)

chromosome in bone marrow or blood cells (0% Ph+ cells)

<sup>51</sup> a medical testing protocol in which a medicine or drug is administered, withdrawn, then re-administered, while being monitored for adverse effects at each stage. The protocol is used when statistical testing is inappropriate due to an idiosyncratic reaction by a specific individual, or a lack of sufficient test subjects and unit of analysis is the individual

<sup>52</sup> (an acronym for the French "Conformite Europeenne") certifies that a product has met EU health, safety, and environmental requirements, which ensure consumer safety

<sup>53</sup> approved for colon cancer, as well as head and neck cancer

<sup>54</sup> Channeling is a form of allocation bias, where drugs with similar therapeutic indications are prescribed to groups of patients with prognostic differences. Claimed advantages of a new drug may channel it to patients with special pre-existing morbidity, with the consequence that disease states can be incorrectly attributed to use of the drug. For the study of adverse drug reactions, large databases supply information on co-medication and morbidity of patients. For diseases with a stepped-care approach, the drug history of patients, as available from some databases, can show channeling of drugs to patients with markers of relatively severe disease.

<sup>55</sup> occurs in the treatment of CML when blood cell counts return to normal, there are no immature cells visible in the blood, and the spleen returns to normal size

<sup>56</sup> a form of spectroscopy based on the differential absorption of left- and right-handed circularly polarized light. It can be used to help determine the structure of macromolecules (including the secondary structure of proteins and the handedness of DNA). 光学活性分子对左、右圆偏振光的吸收也不同, 使左、右圆偏振光透过后变成椭圆偏振光,这种现象称为圆二色性

<sup>58</sup> Class effect is usually taken to mean similar therapeutic effects and similar adverse effects, both in nature and extent. If such a class effect exists, then it makes decision-making easy: you choose the cheapest.

<sup>59</sup> Clinical equipoise is satisfied "if there is genuine uncertainty within the expert medical community — not necessarily on the part of the individual investigator — about the preferred treatment." Equipoise allows clinical investigators to continue a trial until they have enough statistical evidence to convince other experts of the validity of their results, without a loss of ethical integrity on the part of the investigators <sup>60</sup> A medical researcher in charge of carrying out a clinical trial's protocol

<sup>61</sup> A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people. Trials are in four phases: Phase I tests a new drug or treatment in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people; and Phase IV takes place after the drug or treatment has been licensed and marketed.

<sup>62</sup> also known as "CDF/cdf", or "C. diff", is a species of Gram-positive bacteria of the genus Clostridium that causes severe diarrhea and other intestinal disease when competing bacteria in the gut flora have been wiped out by antibiotics.

<sup>63</sup> In epidemiology, a group of individuals with some characteristics in common

<sup>64</sup> A clinical trial conducted primarily through primary-care physicians rather than academic research facilities

<sup>65</sup> A method of providing experimental therapeutics prior to final FDA approval for use in humans. This procedure is used with very sick individuals who have no other treatment options.

<sup>66</sup> Broad range of healing philosophies, approaches, and therapies that Western (conventional) medicine does not commonly use to promote well-being or treat health conditions. Examples include acupuncture, herbs, etc. Internet Address:

<sup>67</sup> Refers to maintaining the confidentiality of trial participants including their personal identity and all personal medical information. The trial participants' consent to the use of records for data verification purposes should be obtained prior to the trial and assurance must be given that confidentiality will be maintained.

<sup>68</sup> In developing antibody-drug conjugates, an anticancer drug (e.g. a cell toxin or cytotoxin) is coupled to an antibody that specifically targets a certain tumor marker

<sup>69</sup> the molecular and genetic alterations (context) that cause cancer cells to be particularly sensitive (vulnerable) to a drug or combination of drugs--the "context of vulnerability; the genetic configuration in a patient's **tumor** that makes it susceptible to a specific drug.

<sup>70</sup> A specific circumstance when the use of certain treatments could be harmful

<sup>71</sup> The standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo

<sup>72</sup> Control is a standard against which experimental observations may be evaluated. In clinical trials, one group of participants is given an experimental drug, while another group (i.e., the control group) is given either a standard treatment for the disease or a placebo.

<sup>73</sup> A simple and straightforward indicator of process capability

<sup>74</sup> Explain FDA policy on regulatory issues related to FDA laws or regulations and advise field inspection/compliance staff on FDA standards and procedures to be applied when determining industry compliance

<sup>75</sup> FDA uses Compliance Program Guidance Manuals (CPGM) to direct its field personnel on the conduct of inspectional and investigational activities.

<sup>76</sup> Adjustment of Cp for the effect of non-centered distribution

<sup>77</sup> A physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality

 $^{78}$  an amino acid, C<sub>4</sub>H<sub>9</sub>N<sub>3</sub>O<sub>2</sub>

<sup>&</sup>lt;sup>57</sup> randomized 8059 patients with OA or RA to celecoxib, 400 mg bid (double the recommended maximum dose for RA and 4 times the recommended maximum dose for OA), diclofenac 150 mg/d, or ibuprofen 2400 mg/d

<sup>79</sup> a crystalline end product of creatine metabolism, C<sub>4</sub>H<sub>7</sub>N<sub>3</sub>O, occurring in urine, muscle, and blood

<sup>80</sup> A third type of scientific research is urgently needed, one that is complementary to basic and translational research, but focuses on providing new tools and concepts for the medical product development process -- the steps that must be taken to get from selection of a laboratory prototype to delivery of an effective treatment to patients. We call this highly targeted and pragmatic research critical path research because it directly supports the critical path for product development success

<sup>81</sup> 辉瑞公司治疗肺癌的新药 XALKORI 胶囊获得美国食品药品管理局(FDA)批准,这是第一个对间 变性淋巴瘤激酶(ALK)进行靶向治疗的药品,可用于治疗 ALK 阳性的局部晚期或转移的非小细胞 肺癌

<sup>82</sup> one where patients are given all of the medications to be studied, or one medication and a placebo in random order. These studies are generally done on patients with chronic diseases to control their symptoms.
<sup>83</sup> a protein found in the blood, the levels of which rise in response to inflammation

<sup>84</sup> The cancer chemotherapic docetaxel has been used as treatment for CRPC with a median survival benefit of 2 to 3 months.[120][121] A second-line chemotherapy treatment is cabazitaxel.[122] A combination of bevacizumab, docetaxel, thalidomide and prednisone appears effective in the treatment of CRPC

<sup>85</sup> The 'Common Technical Document' or 'CTD' is a set of specification for application dossier for the registration of Medicines and designed to be used across Europe, Japan and the United States. It was developed by the European Medicines Agency (EMEA, Europe), the Food and Drug Administration (FDA, USA) and the Ministry of Health, Labour and Welfare (Japan).

<sup>86</sup> Cover your ass (CYA) or cover your own ass (CYOA) describes professional and organizational practices that serve to protect oneself from legal and administrative penalties, criticism, or other punitive measures. A tactic used by employees to share blame or divert blame should something go wrong.

"Covering your ass" is usually done in big projects where an employee may choose to avoid taking credit for doing a critical part of the project just in case it goes bad. C.Y.A. phrase [1950s and still in use] (originally U.S. military): A phrase meaning look after yourself before worrying about anyone else, be it colleagues, customers, the larger world, whatever; the basic admonition to anyone, at any level, working in government or a large corporation.

<sup>87</sup> blueness or lividness of the skin, as from imperfectly oxygenated blood

<sup>88</sup> is a very large and diverse superfamily of hemoproteins found in all domains of life <sup>89</sup>如果发炎太厉害,身体就会排出过量的 cvtokine

<sup>90</sup> An independent committee, composed of community representatives and clinical research experts, that reviews data while a clinical trial is in progress to ensure that participants are not exposed to undue risk. A DSMB may recommend that a trial be stopped if there are safety concerns or if the trial objectives have been achieved.

<sup>91</sup> A clinical trial DMC is a group of individuals with pertinent expertise that reviews on a regular basis accumulating data from one or more ongoing clinical trials. The DMC advises the sponsor regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial

<sup>92</sup> The Data Universal Numbering System, abbreviated as DUNS or D-U-N-S, is a proprietary system developed and regulated by Dun & Bradstreet (D&B) that assigns a unique numeric identifier, referred to as a "DUNS number" to a single business entity. It was introduced in 1963 to support D&B's credit reporting practice. It is a common standard worldwide

<sup>93</sup> the synthesis of complex molecules from simple molecules such as sugars or amino acids, as opposed to their being recycled after partial degradation

<sup>94</sup> Prior to the FDA Modernization Act of 1997 (FDAMA), all devices on the market as of May 28, 1976 were classified according to their risk. Any new type of device that was found not substantially equivalent for a reason other than performance data required a Premakert Approval (PMA) application. A device could be moved out of Class III only through a reclassification process. The De Novo process provides a possible route to market low risk device types. This process does not apply to devices that have been classified by regulation into class III, i.e., preamendment class III devices or class III devices for which a premarket approval application or a reclassification petition is appropriate.

FDAMA amended Section 513(f)(2) to provide a new mechanism for classifying new Class III devices for which there is no predicate device. The De Novo process is intended to apply to low risk products that have been classified as class III because they were found not substantially equivalent (NSE) to any identifiable

predicate device. It allows the recipient of an NSE (not substantially equivalent) letter to request a riskbased classification determination to be made for the device.

An applicant of a 510(k) who receives a Not Substantially Equivalent (NSE) determination placing the device into a Class III category can request a de novo classification of the product into Class I or II. The request must be in writing and sent within 30 days from the receipt of the NSE determination. In addition, the request should include a description of the device, labeling for the device, reasons for the recommended classification (into Class I or II), and information to support the recommendation. The de novo process has a 60 day review period. If FDA classifies the device into Class I or II, the applicant will then receive an approval order to market the device. This device type can then be used as a predicate device for other firms to submit a 510(k). However, if FDA determines that the device will remain in the Class III category, the device cannot be marketed until the applicant has obtained an approved PMA.

<sup>95</sup> The multidimensional combination and interaction of input variables (e.g., material attributes) and process parameters that have been demonstrated to provide assurance of quality. Working within the design space is not considered as a change. Movement out of the design space is considered to be a change and would normally initiate a regulatory postapproval change process. Design space is proposed by the applicant and is subject to regulatory assessment and approval

<sup>96</sup> (Cmax-Cmin)/Cave

<sup>97</sup> The dose of a drug that produces side effects severe enough to prevent larger doses being given. <sup>98</sup>持有者为谨慎起见而准备的保密资料,可以包括一个或多个人用药物在制备、加工、包装和贮存 过程中所涉及的设备、生产过程或物品。只有在 DMF 持有者或授权代表以授权书的形式授权给 FDA, FDA 在审查 IND、NDA、ANDA 时才能参考其内容

<sup>99</sup> is the design of any information-gathering exercises where variation is present, whether under the full control of the experimenter or not. However, in statistics, these terms are usually used for controlled experiments.

<sup>100</sup> A clinical trial in which two or more doses of an agent (such as a drug) are tested against each other to determine which dose works best and is least harmful.

<sup>101</sup> 在临床试验中,当两种处理(如药物的剂型、给药方法等)不能做到相同时,使试验保持双盲的一种技术。即为试验药与对照药各准备一种安慰剂,以达到试验组与对照组在用药的外观与给药 方法上的一致。

<sup>102</sup> A clinical trial design in which neither the participating individuals nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo (or another therapy). Double-blind trials are thought to produce objective results, since the expectations of the doctor and the participant about the experimental drug do not affect the outcome; also called double-masked study. See <u>Blinded Study</u>, <u>Single-Blind Study</u>, and <u>Placebo</u>.

103指由于任何原因不能继续按试验方案进行到所要求的最后一次随访的受试者。

<sup>104</sup> Drug response includes the processes of drug absorption and disposition (e.g., pharmacokinetics (PK)), and drug effects (e.g., pharmacodynamics (PD), drug efficacy, and adverse effects of drugs).

<sup>105</sup> A modification of the effect of a drug when administered with another drug. The effect may be an increase or a decrease in the action of either substance, or it may be an adverse effect that is not normally associated with either drug.

<sup>106</sup> FDA 中的一个特别办公室

<sup>107</sup> Sarepta Therapeutics Inc. (formerly AVI BioPharma Inc.) wowed clinicians and investors Tuesday with
 Phase IIb findings for its exon-skipping compound, eteplirsen, in Duchenne's muscular dystrophy (DMD).
 <sup>108</sup> Summary criteria for participant selection; includes Inclusion and Exclusion criteria. (See Inclusion/Exclusion Criteria)

<sup>109</sup> over 100 people died after using a drug formulated with a toxic, untested solvent diethylene glycol instead of ethanol.

<sup>110</sup> Overall outcome that the protocol is designed to evaluate. Common endpoints are severe toxicity, disease progression, or death.

<sup>111</sup> An epitope, also known as antigenic determinant, is the part of a macromolecule that is recognized by the immune system, specifically by antibodies, B cells, or T cells. The part of an antibody that recognizes the epitope is called a paratope 抗体结合部位, 抗体决定簇;〔抗原〕互补位

112是确认两种或多种治疗效果的差别大小在临床上并无重要意义的试验

<sup>113</sup> Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

<sup>114</sup> inert substance used as a diluent or vehicle for a drug

<sup>115</sup> any of the FDA procedures, such as compassionate use, parallel track, and treatment IND that distribute experimental drugs to participants

<sup>116</sup> The fragment antigen-binding is a region on an antibody that binds to antigens.

<sup>117</sup> Fabry disease is caused by the lack of or faulty enzyme needed to metabolize lipids, fat-like substances that include oils, waxes, and fatty acids. The disease is also called alpha-galactosidase-A deficiency. A mutation in the gene that controls this enzyme causes insufficient breakdown of lipids, which build up to harmful levels in the eyes, kidneys, autonomic nervous system, and cardiovascular system. Fabry disease is one of several lipid storage disorders and the only X-linked lipid storage disease. Since the gene that is altered is carried on a mother's X chromosome, her sons have a 50 percent chance of inheriting the disorder and her daughters have a 50 percent chance of being a carrier. A milder form is common in females, and occasionally some affected females may have severe manifestations similar to males with the disorder <sup>118</sup> Fellows are recommended by their peers, endorsed by their local chapter leadership, and reviewed by a national credentials subcommittee

<sup>119</sup> a process designed to facilitate the development, and expedite the review of drugs to treat serious diseases and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious diseases.

<sup>120</sup> Published by the Office of the Federal Register, National Archives and Records Administration (NARA), the Federal Register is the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents.

<sup>121</sup> Failure Mode and Effects Analysis (FMEA) was one of the first systematic techniques for failure analysis. It was developed by reliability engineers in the 1950s to study problems that might arise from malfunctions of military systems. A FMEA is often the first step of a system reliability study. It involves reviewing as many components, assemblies, and subsystems as possible to identify failure modes, and their causes and effects. For each component, the failure modes and their resulting effects on the rest of the system are recorded in a specific FMEA worksheet. There are numerous variations of such worksheets. A FMEA is mainly a qualitative analysis; An FMEA is an inductive reasoning (forward logic) single point of failure analysis.

<sup>122</sup> A structured, organized method for determining the relationship

between factors affecting a process and the output of that process. Also known as "Design of Experiments." DOE

<sup>123</sup> Fault tree analysis (FTA) is a top down, deductive failure analysis in which an undesired state of a system is analyzed using Boolean logic to combine a series of lower-level events

<sup>124</sup> 指尽可能接近符合意向性治疗原则的理想的受试者集。该数据集是从所有随机化的受试者中以 最少的和合理的方法剔除受试者后得出的。

<sup>125</sup> It is produced by the liver cell microsomes and is widely distributed in cells that are involved in the secretion and absorption of bile. It is a useful laboratory marker as an indicator of early liver cell damage or cholestatic disease

<sup>126</sup> stimulates the bone marrow to produce more white blood cells

<sup>127</sup> The phenotypic manifestation of a gene or <u>genes</u> by the processes of genetic transcription and genetic translation

<sup>128</sup> Gene regulation is the process of turning genes on and off. During early development, cells begin to take on specific functions. Gene regulation ensures that the appropriate genes are expressed at the proper times. Gene regulation can also help an organism respond to its environment. Gene regulation is accomplished by a variety of mechanisms including chemically modifying genes and using regulatory proteins to turn genes on or off.

<sup>129</sup> The genetic constitution (the genome) of a cell, an individual or an organism. The genotype is distinct from its expressed features, or phenotype

<sup>130</sup> 指在 HBV 聚合酶基因区检测出与耐药相关的基因突变,并发生相关的氨基酸被替换

<sup>131</sup> unapproved drugs whose makers claim the drugs are "grandfathered" under older standards and therefore don't require approval under the current regulatory framework

<sup>134</sup> In genetic epidemiology, a genome-wide association study (GWA study, or GWAS), also known as whole genome association study (WGA study, or WGAS) or common-variant association study (CVAS), is an examination of many common genetic variants in different individuals to see if any variant is associated with a trait.

<sup>135</sup>危害分析关键控制点(HACCP)是一个保证食品安全的预防性技术管理体系.它运用食品工艺学、 微生物学、化学和物理学、质量控制和危险性评估等方面的原理和方法,对整个食品链,即食品原料 的种植/饲养、收获、加工、流通和消费过程中实际存在和潜在的危害进行危险性评估,找出对最终 产品质量影响的关键控制点

<sup>136</sup> A haplotype is a set of DNA variations, or polymorphisms, that tend to be inherited together. A haplotype can refer to a combination of alleles or to a set of single nucleotide polymorphisms (SNPs) found on the same chromosome.

<sup>137</sup> 糖尿病患者最容易被检测的生物标志物之一; a test that measures the amount of glycated hemoglobin in your blood

<sup>138</sup> The bodily system of organs and tissues, primarily the bone marrow, spleen, tonsils, and lymph nodes, involved in the production of blood.

<sup>139</sup> 赫赛汀是一种重组 DNA 衍生的人源化单克隆抗体,选择性地作用于人表皮生长因子受体-2(HER2)的细胞外部位。在原发性乳腺癌患者中观察到有 25%-30%的患者 HER2 过度表达。研究表明,HER2 过度表达的肿瘤患者较无过度表达的无病生存期短。赫赛汀?在体外及动物实验中均显示可抑制 HER2 过度表达的肿瘤细胞的增殖。另外,赫赛汀是抗体依赖的细胞介导的细胞毒反应(ADCC)的潜在介质。在体外研究中,赫赛汀介导的 ADCC 被证明在 HER2 过度表达的癌细胞中比 HER2 非过度表达的癌细胞中更优先产生。

<sup>140</sup> a form of column chromatography used frequently in biochemistry and analytical chemistry. It is also sometimes referred to as high-pressure liquid chromatography. HPLC is used to separate components of a mixture by using a variety of chemical interactions between the substance being analyzed (analyte) and the chromatography column

<sup>141</sup> an inorganic mineral primarily consisting of calcium and phosphate, is the principal inorganic component of bone

<sup>142</sup> Hy Zimmerman, a legendary pioneer in DILI research, observed that the combination of severe acute hepatocellular injury with clinical jaundice (i.e., total bilirubin > 2.5 mg/dL) was associated with a poor prognosis (i.e., a case-fatality rate of ~10%) for many drugs. This observation has been called Hy's rule and is often used by the U.S. Food and Drug Administration and other regulatory agencies in the evaluation of investigational drugs to show potential hepatotoxic signals during clinical trials.

<sup>143</sup> An immune complex is formed from the integral binding of an antibody to a soluble antigen. The bound antigen acting as a specific epitope, bound to an antibody is referred to as a singular immune complex <sup>144</sup> ability of a substance to provoke an immune response

<sup>145</sup> An antibody (Ab), also known as an immunoglobulin (Ig), is a large Y-shaped protein produced by Bcells that is used by the immune system to identify and neutralize foreign objects such as bacteria and viruses.

<sup>146</sup> In vitro diagnostic products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body

<sup>147</sup> The medical or social standards determining whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate participants and keep them safe.

<sup>&</sup>lt;sup>132</sup> Granularity is the level of depth represented by the data in a fact or dimension table in a data warehouse.
High granularity means a minute, sometimes atomic grade of detail, often at the level of the transaction.
<sup>133</sup>乃由旺盛增生的毛细血管及纤维结缔组织和各种炎性细胞组成,肉眼表现为鲜红色,颗粒状,柔软湿润,形似鲜嫩的肉芽故名

<sup>148</sup> an ultra-long-acting beta-adrenoceptor agonist developed by by Novartis.It was approved by the European Medicines Agency (EMA) under the trade name Onbrez on November 30, 2009, and by the United States Food and Drug Administration (FDA), under the trade name Arcapta Neohaler, on July 1, 2011. It needs to be taken only once a day, unlike the currently available formoterol and salmeterol. It is licensed only for the treatment of chronic obstructive pulmonary disease (COPD) (long-term data in patients with asthma are thus far lacking). It is delivered as an aerosol formulation through a dry powder inhaler

<sup>149</sup> the prothrombin time ratio that would have been obtained if a standard reagent had been used in a prothrombin time determination; the prothrombin time ratio is expressed as the patient prothrombin time divided by the mean of the prothrombin time reference interval

<sup>150</sup> A committee of physicians, statisticians, researchers, community advocates, and others that ensures that a clinical trial is ethical and that the rights of study participants are protected.

<sup>151</sup> In epidemiology, an intention to treat (ITT) analysis (sometimes also called Intent to Treat) is an analysis based on the initial treatment intent, not on the treatment eventually administered. ITT analysis is intended to avoid various misleading artifacts that can arise in intervention research. For example, if people who have a more refractory or serious problem tend to drop out at a higher rate, even a completely ineffective treatment may appear to be providing benefits if one merely compares those who finish the treatment with those who were never enrolled in it.

152 指正式完成临床试验前,按事先制订的分析计划,比较处理组间的有效性和安全性所作的分析 <sup>153</sup> Primary interventions being studied: types of interventions are Drug, Gene Transfer, Vaccine, Behavior, Device, or Procedure

<sup>154</sup> a chromosome rearrangement in which a segment of a chromosome is reversed end to end. An inversion occurs when a single chromosome undergoes breakage and rearrangement within itself. 155 用于临床试验中的试验药物、对照药品或安慰剂

<sup>156</sup> a fifteen-member United States Government agency created in 2010 by sections 3403 and 10320 of the Patient Protection and Affordable Care Act which has the explicit task of achieving specified savings in Medicare without affecting coverage or quality. Under previous and current law, changes to Medicare payment rates and program rules are recommended by MedPAC but require an act of Congress to take effect. The new system grants IPAB the authority to make changes to the Medicare program with the Congress being given the power to overrule the agency's decisions through supermajority vote.

<sup>157</sup> An In-vitro in-vivo correlation (IVIVC) has been defined by the U.S. Food and Drug Administration (FDA) as "a predictive mathematical model describing the relationship between an in-vitro property of a dosage form and an in-vivo response".

<sup>158</sup> JAK(ianus kinase)是一类非受体酪氨酸激酶家族, JAK 的底物为 STAT, 即信号转导子和转录 激活子,STAT 被 JAK 磷酸化后发生二聚化,然后穿过核膜进入核内调节相关基因的表达,这条信 号通路称为 JAK-STAT 途径。

<sup>159</sup> Section 201 of the FD&C Act distinguishes between label and labeling Certain provisions in Chapter V of the FD&C Act apply specifically to the "label" of the device, others are related to its "labeling," These terms are related, but not interchangeable. Of the two, the term "label" is more restricted. Generally, it consists of that part of the display confined to the device itself. On the other hand, "labeling" deals with the label on the device, and descriptive and informational literature that accompanies the device.

<sup>160</sup> prescription medicine used together with other medicines to treat partial onset seizures in people 13 years of age and older

<sup>161</sup> LASIK stands for Laser-Assisted *In Situ* Keratomileusis and is a procedure that permanently changes the shape of the cornea, the clear covering of the front of the eye, using an excimer laser. A mechanical microkeratome (a blade device) or a laser keratome (a laser device) is used to cut a flap in the cornea. 162 对临床试验中有效性指标缺失值的一种估计方法,即采用缺失值之前最接近一次的观察数据来 代替缺失值。

<sup>163</sup> the dosage (in milligrams per surface area) at which 10% of the mouse population died <sup>164</sup> fda 批准 revlimid 用于治疗骨髓增生异常综合征:美国食品药品管理局(fda)批准了美国细胞基因 公司的来那度胺(lenalidomide/revlimid)。 revlimid 为口服制剂 evlimid (lenalidomide) 是由 celgene 公司研发的用于治疗致死性血液疾病以及癌症的药物。该品是用于治疗孕吐曾引起数以千

计的婴儿出生缺陷沙利度胺(thalidomide)的加强版,具有抗癌潜力。与沙利度胺相比,其不良反应更少,研究证明其不会引起婴儿出生缺陷。2005年9月,fda肿瘤药物顾问委员会建议以revlimid用于治疗输液依赖型贫血症。输液依赖型贫血症是由于5q染色体异常相关的骨髓增生异常综合征所引起的。10月,欧洲药品管理局接受了revlimid的上市申请。同时,该品在欧洲获得了治疗骨髓增生异常综合征的罕用药物和治疗多发性骨髓瘤的罕用药物的地位。

<sup>165</sup> the lowest amount of analyte in a sample that can be quantitatively determined with suitable precision and accuracy; Suppose you are at an airport with lots of noise from jets taking off. If the person next to you speaks softly, you will probably not hear them. Their voice is less than the LOD. If they speak a bit louder, you may hear them but it is not possible to be certain of what they are saying and there is still a good chance you may not hear them. Their voice is >LOD but <LOQ. If they speak even louder, then you can understand them and take action on what they are saying and there is little chance you will not hear them. Their voice is then >LOD and >LOQ.

<sup>166</sup>是指动物死亡后,血液循环停止,血液停留在尸体的低处,红血球从血清中进一步分离沉积,在 表皮下形成可见的紫红色淤斑现象

<sup>167</sup> a heart rhythm disorder that can potentially cause fast, chaotic heartbeats

<sup>168</sup>Patents are granted by the patent and trademark office anywhere along the development lifeline of a drug and can encompass a wide range of claims. Exclusivity is exclusive marketing rights granted by the FDA upon approval of a drug and can run concurrently with a patent or not. Exclusivity was designed to promote a balance between new drug innovation and generic drug competition.

<sup>169</sup> used to report adverse event data from clinical trials, as well as post-marketing and pharmacovigilance <sup>170</sup> products from the simple toothbrush to complex devices such as implantable brain pacemakers. The CDRH also oversees the safety performance of non-medical devices which emit certain types of electromagnetic radiation. Examples of CDRH-regulated devices include cellular phones, airport baggage screening equipment, television receivers, microwave ovens, tanning booths, and laser products

<sup>171</sup> The MedWatch program provides important safety information associated with FDA-regulated products. Under MedWatch, health care professionals and consumers submit reports to FDA when they find a problem with a drug, medical device, biologic, or other FDA-regulated products.

<sup>172</sup> 是一种分子量为 40 kDa 的细胞表面糖蛋白, 高表达于多种 肿瘤组织中, 也可表达于正常 胸膜、 心包和腹膜的间皮细胞中

<sup>173</sup> In statistics, a meta-analysis combines the results of several studies that address a set of related research hypotheses. In its simplest form, this is normally by identification of a common measure of effect size, for which a weighted average might be the output of a meta-analyses. Here the weighting might be related to sample sizes within the individual studies. More generally there are other differences between the studies that need to be allowed for, but the general aim of a meta-analysis is to more powerfully estimate the true "effect size" as opposed to a smaller "effect size" derived in a single study under a given single set of assumptions and conditions.

<sup>174</sup> For example, the mechanism of action of aspirin involves irreversible inhibition of the enzyme cyclooxygenase, which suppresses the production of prostaglandins and thromboxanes, thereby reducing pain and inflammation.

<sup>175</sup> On Dec. 11, 2007, the U.S. Department of Health and Human Services (HHS) and the State Food and Drug Administration (SFDA) of the People's Republic of China signed a Memorandum of Agreement (MOA) to enhance the safety of drugs, excipients and medical devices exported to the U.S. from China. gentamicin sulfate (an antibiotic), atorvastatin (a cholesterol-lowering drug), sildenafil (a drug for erectile dysfunction), dietary supplements intended for erectile dysfunction, human growth hormone,

oseltamivir (an antiviral product), cephalosporins (a class of antibiotics) manufactured in facilities that also manufacture non-cephalosporin drugs, glycerin, glucose test strips, and condoms

<sup>176</sup> 由申办者任命并对申办者负责的具备相关知识的人员,其任务是监查和报告试验的进行情况和 核实数据

<sup>177</sup> a 6 month, randomized, double blind, placebo controlled study to investigate whether concurrent administration of misoprostol would significantly reduce the occurrence of serious upper GI complications in patients with rheumatoid arthritis (RA) who were receiving NSAID

<sup>178</sup> an immunosuppressant used extensively in transplant medicine

<sup>179</sup> Study of the natural development of something (such as an organism or a disease) over a period of time.

<sup>180</sup> An application submitted by the manufacturer of a drug to the FDA - after clinical trials have been completed - for a license to market the drug for a specified indication.

<sup>182</sup> An application submitted by the manufacturer of a drug to the FDA - after clinical trials have been completed - for a license to market the drug for a specified indication.

<sup>183</sup> The United Kingdom's National Institute for Health and Clinical Excellence (NICE) is often cited as a model in discussions of potential uses of comparative effectiveness research in the United States. NICE makes recommendations to the British National Health Service (NHS) on coverage for certain technologies or treatments based on cost–effectiveness analysis

<sup>184</sup> (marketed under the trade names Mogadon, Alodorm, Hypnotex, Remnos, Pacisyn, Eunoctin and Pelson) <sup>185</sup> In toxicology it is specifically the highest tested dose or concentration of a substance (i.e. a drug or chemical) or agent (e.g. radiation), at which no such adverse effect is found in exposed test organisms where higher doses or concentrations resulted in an adverse effect

<sup>186</sup> a noninferiority trial aims to demonstrate that the test product is not worse than the comparator by more than a pre-specified, small amount. This amount is known as the non-inferiority margin, or delta ( $\Delta$ ).

<sup>187</sup> The objective of a non-inferiority trial is sometimes stated as being to demonstrate that the test product is not inferior to the comparator

<sup>188</sup> comes from the Greek word *nosokomeion* (νοσοκομείον) meaning hospital (*nosos* = disease, *komeo* = to take care of

<sup>189</sup> a statistical hypothesis to be tested and accepted or rejected in favor of an alternative; *specifically* : the hypothesis that an observed difference (as between the means of two samples) is due to chance alone and not due to a systematic cause; A hypothesis that says that there is no difference, or that asserts the existing knowledge, and is tested for refutation by the study.

<sup>190</sup> the quantity of a radiological or pharmacological treatment that will produce the desired effect with acceptable toxicity

<sup>191</sup> A drug prescribed for conditions other than those approved by the FDA.

<sup>192</sup> Adverse toxicologic effects are categorized as chemical-based, on-target, or off-target effects. Chemicalbased toxicity is defined as toxicity that is related to the physicochemical characteristics of a compound and its effects on cellular organelles, membranes, and/or metabolic pathways. On-target refers to exaggerated and adverse pharmacologic effects at the target of interest in the test system. Off-target refers to adverse effects as a result of modulation of other targets; these may be related biologically or totally unrelated to the target of interest.

<sup>193</sup> A clinical trial in which doctors and participants know which drug or vaccine is being administered. <sup>194</sup> is a new office within CDER that creates a single unit dedicated to product quality. The new structure, to be stood-up in January 2015, is expected to provide better alignment among all drug quality functions at CDER, including review, inspection, and research, but not enforcement.

<sup>195</sup> The publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the List, commonly known as the Orange Book), identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act). Drugs on the market approved only on the basis of safety (covered by the ongoing Drug Efficacy Study Implementation [DESI] review [e.g., Donnatal® Tablets and Librax® Capsules] or pre-1938 drugs [e.g., Phenobarbital Tablets]) are not included in this publication. The main criterion for the inclusion of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons. Inclusion of products on the List is independent of any current regulatory action through administrative or judicial means against a drug product. In addition, the List contains therapeutic equivalence evaluations for approved multisource prescription drug products <sup>196</sup> An FDA category that refers to medications used to treat diseases and conditions that occur rarely.

question is invalid or is not infringed by the generic product (known as "paragraph IV certification") <sup>198</sup> Parametric release is defined as a sterility release procedure based upon effective control, monitoring, and documentation of a validated sterilization process cycle in lieu of release based upon end-product sterility testing (21 CFR 211.167). All parameters within the procedure must be met before the lot is released

<sup>&</sup>lt;sup>181</sup> 2008 年 3 月 21 日,美国 FDA 和美敦力公司(Medtronic, Inc)发布通告,对美敦力公司的 Neuromodulation 植入式输液泵进行 I 级召回

<sup>199</sup> In partial seizures the seizure is generated in and affects just one part of the brain - the whole hemisphere or part of a lobe

<sup>200</sup> defined by the United States Food and Drug Administration (FDA) as a mechanism to design, analyze, and control pharmaceutical manufacturing processes through the measurement of Critical Process Parameters (CPP) which affect Critical Quality Attributes (CQA).

<sup>201</sup> in order to stimulate product development and innovation, Congress in 1984 enacted Title II of the Drug Price Competition and Patent Term Restoration Act (Public Law 98-417) to extend patent life to compensate patent holders for marketing time lost while developing the product and awaiting government approval

<sup>202</sup> In the <u>United States</u>, employers are required to withhold <u>federal income tax</u>, plus one-half of the <u>Social</u> <u>Security</u> tax, and one-half of the <u>Medicare</u> tax. Together, the employer's and employee's shares of the Social Security and Medicare taxes are known as the <u>FICA tax</u>

<sup>203</sup> commonly known as coronary angioplasty or simply angioplasty, is a non-surgical procedure used to treat the stenotic (narrowed) coronary arteries of the heart found in coronary heart disease.
 <sup>204</sup> 研究药物对机体的作用及其规律,阐明药物防治疾病的机制

<sup>205</sup> The PDP is essentially a contract that describes the agreed upon details of design and development activities, the outputs of these activites, and acceptance criteria for these outputs. It establishes reporting milestones that convey important information to the FDA as it is generated, where they can be reviewed and responded to in a timely manner. The sponsor would be able to execute their PDP at their own pace, keeping FDA informed of its progress with these milestone reports. A PDP that has been declared completed by FDA is considered to have an approved PMA

<sup>206</sup> Review of a clinical trial by experts chosen by the study sponsor. These experts review the trials for scientific merit, participant safety, and ethical considerations.

<sup>207</sup> Analysis based only on those patients who complete the entire treatment protocol

<sup>208</sup>又称有效病例、有效样本、可评价病例样本。是由充分依从于试验方案的病例子集所产生的数据 集,是全分析集的一个子集。依从性包括以下一些考虑,如:所接受的治疗、主要指标测量的可行 性以及未对试验方案有大的违反等。

<sup>209</sup> In 1993, a large outbreak of foodborne illness caused by the bacterium Escherichia coli O157:H7 occurred in the western United States. In this outbreak, scientists at CDC performed DNA "fingerprinting" by pulsed-field gel electrophoresis (PFGE) and determined that the strain of E. coli O157:H7 found in patients had the same PFGE pattern as the strain found in hamburger patties served at a large chain of regional fast food restaurants. Prompt recognition of this outbreak and its cause may have prevented an estimated 800 illnesses.

210 研究药物对机体的作用及其规律,阐明药物防治疾病的机制

<sup>211</sup> Pharmacogenetics (PGt) is a subset of pharmacogenomics (PGx) and is defined as: the study of variations in DNA sequence as related to drug response

<sup>212</sup> broadly refers to the study of variations of DNA and RNA characteristics as related to drug response <sup>213</sup> The processes (in a living organism) of absorption, distribution, metabolism, and excretion of a drug or vaccine.

<sup>214</sup> pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines

<sup>215</sup> The PharMetrics Integrated Database is the largest non-Payer owned integrated claims database of commercial insurers in the U.S. This de-identified, Integrated Database includes medical and pharmacy claims for more than 70 million members from more than 100 health plans across the U.S. The Integrated Database includes inpatient and outpatient claims, diagnoses and procedures based on ICD-9 and CPT-4 codes, as well as retail and mail order pharmacy claims. The records in the PharMetrics Integrated Database are representative of the national commercially insured population, and include a variety of demographic measures such as age, gender and plan type. This longitudinal data has an average member enrollment period of two years.

<sup>216</sup> The appearance of an individual, which results from the interaction of the person's genetic makeup and his or her environment. By contrast, the genotype is merely the genetic constitution (genome) of an individual. For example, if a child's genotype includes the gene for osteogenesis imperfecta (brittle bone disease), minimal trauma can cause fractures. The gene is the genotype, and the brittle bones themselves are the phenotype

<sup>217</sup> 指经体外药物敏感实验证实,发生 HBV 聚合酶基因突变的病毒对某种药物的敏感性下降<sup>218</sup> An individual exhibiting phocomelia

<sup>219</sup>光动力疗法(Photodynamic Therapy , PDT )原称光辐射疗法(Photoradiation Therapy , PRT )、光化学疗法(Photochemical Therapy , PCT ),它是利用光动力反应进行疾病诊断和治疗的一种新技术。在临床上,光动力疗法通常仅指光动力治疗,而将光动力诊断称为荧光诊断

(Photodynamic Diagnosis, PDD) 。

光动力反应的基本过程: 生物组织中的内源性或外源性光敏物质受到相应波长(可见光、近红外光 或紫外光)光照时,吸收光子能量,由基态变成激发态,处于激发态的光敏物质很不稳定,迅速经 过物理退激或化学退激过程释放出能量而返回基态,其物理退激过程可以产生荧光,通过分析荧光 光谱能进行疾病的诊断: 其化学退激过程可以生成大量活性氧,其中最主要的是单线态氧,活性氧 能与多种生物大分子相互作用,损伤细胞结构或影响细胞功能,因而产生治疗作用。

<sup>220</sup> The processes (in a living organism) of absorption, distribution, metabolism, and excretion of a drug or vaccine

<sup>221</sup>对少数有特别价值的高风险药品,实行使用、检验相关信息链接,以保证医药学工作者正确处 方、正确调剂、合理用药,发挥药品最大效益,实现风险最小化

<sup>222</sup> A drug's efficiency may be affected by the degree to which it binds to the proteins within blood plasma. The less bound a drug is, the more efficiently it can traverse cell membranes or diffuse. Common blood proteins that drugs bind to are human serum albumin, lipoprotein, glycoprotein, and  $\alpha$ ,  $\beta$ , and  $\gamma$  globulins

<sup>223</sup> Pleiotropy occurs when one gene influences two or more seemingly unrelated phenotypic traits, an example being phenylketonuria, which is a human disease that affects multiple systems but is caused by one gene defect. Consequently, a mutation in a pleiotropic gene may have an effect on some or all traits simultaneously.

<sup>224</sup> As a requirement for approval or continued marketing of some medicines, FDA may require additional information in the form of post marketing commitments. These commitments are agreed to by a company with the FDA, and are used to gather additional information about a medicine's safety, efficacy, or optimal use. These agreements can be reached either before or after FDA has granted approval to a company to market a medicine

<sup>225</sup> In PoC trials, the drug is for the first time given to humans

<sup>226</sup> administration of many drugs together

<sup>227</sup> The number of patients enrolled in a study has a large bearing on the ability of the study to reliably detect the size of the effect of the study intervention. This is described as the "power" of the trial. The larger the sample size or number of participants in the trial, the greater the statistical power <sup>228</sup> A simple and straightforward indicator of process performance

<sup>229</sup> Adjustment of Pp for the effect of non-centered distribution

<sup>230</sup> PPS 包括除中止治疗或对试验方案至少有一次大的违反的受试者之外的所有随机化的受试者。 方案违反的确切定义将在数据审核时最终确定,一般包括以下几种情况:不符合入选标准、入选后 存在干扰性治疗、依从性差、随访超出窗口期等。PPS 是本次研究疗效评价的次要数据集。

<sup>231</sup>新型血栓预防药物 Effient(prasugrel, 普拉格雷)用于预防接受经皮冠状动脉介入(PCI)治疗后的冠脉综合症患者的血栓形成。Effient 帮助预防血小板凝聚成块,在接受 PCI 手术后使用阿司匹林与 Effient 已证明可降低冠脉综合症患者发生心血管事件的风险。

<sup>232</sup> Each agency publishing a proposed or final rule in the Federal Register is required by 1 CFR 18.12 to include a preamble that informs readers of the basis and purpose for the rule. The preamble must include the following information: Name of issuing agency, Action being taken by agency, Brief statements of the action being taken, the circumstances which created the need for action, and the intended effect of the action, Pertinent dates, Any relevant addresses, Agency contact information, Other information, as applicable

 $^{233}$  A predicate rule is any requirement set forth in the Federal Food, Drug and Cosmetic Act, the Public Health Service Act, or any FDA regulation other than Part 11

<sup>234</sup> The Food and Drug Administration (FDA) is amending its combination product regulations to define "mode of action" (MOA) and "primary mode of action" (PMOA). Along with these definitions, the final rule sets forth an algorithm the agency will use to assign combination products to an agency component for regulatory oversight when the agency cannot determine with reasonable certainty which mode of action provides the most important therapeutic action of the combination product

<sup>235</sup> is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A Priority Review means that the time it takes FDA to review a new drug application is reduced. The goal for completing a Priority Review is six months

<sup>236</sup> A precursor (forerunner) of a drug. A prodrug must undergo chemical conversion by metabolic processes before becoming an active pharmacological agent. For example, sulfasalazine is a prodrug. It is not active in its ingested form. It has to be broken down by bacteria in the colon into two products -- 5- aminosalicylic acid (5ASA) and sulfapyridine -- before becoming active as a drug.

<sup>237</sup> After a period of development it is introduced or launched into the market; it gains more and more customers as it grows; eventually the market stabilises and the product becomes mature; then after a period of time the product is overtaken by development and the introduction of superior competitors, it goes into decline and is eventually withdrawn.

<sup>238</sup> A study that demonstrates an agent to have the desired biological effect on its target

<sup>239</sup> A study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study.

<sup>240</sup> A characterised range of a process parameter for which operation within this range, while keeping other parameters constant, will result in producing a material meeting relevant quality criteria

<sup>241</sup> The Periodic Safety Update Report (PSUR) is required as part of the FDA Post Marketing Drug Risk Assessment (PMDRA) program

 $^{242}$  a measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle

<sup>243</sup> A prospective summary of the quality characteristics of a drug product that ideally will be achieved to ensure the desired quality, taking into account safety and efficacy of the drug product.

<sup>244</sup> Qualification is a process of assurance that the specific system, premises or equipment are able to achieve the predetermined acceptance criteria to confirm the attributes what it purports to do. Validation is establishing a documented evidence to provide a high degree of assurance that a specific

system, process or facility will consistently produce a product meeting its predetermined specifications and quality attributes. Qualification is documented evidence that a specific equipment, facility or system is fit/ready for intended use. Validation is documenting that the way equipment, facility or system used will result in product meeting its predetermined specifications and quality attributes. Things are qualified: equipments, systems etc. Process/Procedures (the way we use things) are validated. Before you do validation on a process, you have to be sure that the equipment has passed qualification.<sup>245</sup> The documented verification that the proposed design of the facilities, systems and

equipment is suitable for the intended purpose

<sup>246</sup> The documented verification that the facilities, systems and equipment, as installed or modified, comply with the approved design and the manufacturer's recommendations.
<sup>247</sup> The documented verification that the facilities, systems and equipment, as installed or modified, perform as intended throughout the anticipated operating ranges.

<sup>248</sup> The documented verification that the facilities, systems and equipment, as connected together, can perform effectively and reproducibly, based on the approved process method and product specification

<sup>249</sup> Confirming that the manufacturing process as designed is capable of reproducible commercial manufacturing.

<sup>250</sup> no batch of medicinal product can be released for sale or supply prior to certification by a QP that the batch is in accordance with the relevant requirements

<sup>251</sup> 美国联邦《防制不实请求法》规定的公益代位诉讼制度是为了防制政府合同的承包商通过提交 虚假的请求谋取不当利益而设计的,所规范的对象涉及到以联邦政府资金支付的各种采购活动。这 一制度允许知情人直接对有不实请求的法人或个人进行告发起诉,成功后将获得一定的酬金,并可 以获得相应的权益保障。这一程序为美国国库挽回了大量损失,也取得了良好的社会效益

<sup>252</sup> Since the year 2000, an international committee promulgated these unified, easily applicable criteria for measuring tumor response using X-ray, CT and MRI

<sup>255</sup> 2012 年 9 月 27 日,美国品药品管理局(FDA)批准拜耳公司研发的新药 Regorafenib(瑞格非尼,商品名为 Stivarga)上市。Regorafenib 是一种新型的多激酶抑制剂,阻断促进肿瘤生长的多种酶,是多个肿瘤通路为作用靶点的多激酶阻滞剂,也是第一个在晚期结直肠癌中被证实有效的口服 多激酶阻滞剂

<sup>256</sup> FDA 用于考核原料药或药物产品是否符合批准了的质量管理规格标准的整套步骤

<sup>257</sup> Retention sample: a sample of a fully packaged unit from a batch of finished product. It is stored for identification purposes. For example, presentation, packaging, labelling, patient information leaflet, batch number, expiry date should the need arise during the shelf life of the batch concerned.
<sup>258</sup>是指动物死亡后, 肌肉僵硬挛缩的现象

<sup>259</sup> FDA Approves Bayer's New Class of Drug Adempas® (riociguat) tablets to Treat Adults with PAH and Persistent, Recurrent or Inoperable CTEPH

<sup>260</sup> The FDA defines a *RiskMAP* as the "strategic safety program designed to meet specific goals and objectives in minimizing known risks of a medication while preserving its benefits"

<sup>261</sup> Syndrome characterized by muscle breakdown and necrosis, resulting in elevated. serum concentrations of creatine kinase (CK) 肌酸激酶

<sup>262</sup> Under the mutual recognition procedure, where the applicant seeks approval in additional member states (concerned member states) for a product already approved in an initial member state (the reference member state), the reference member state prepares an assessment report, which the concerned member states must approve or reject within 90 days.

<sup>263</sup> means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed.

<sup>264</sup> Reference manual for FDA personnel

<sup>265</sup> is a measure used when assessing risk to help identify critical failure modes associated with your design or process

<sup>266</sup> Its name comes from the fact that F proteins on the surface of the virus cause the cell membranes on nearby cells to merge, forming syncytia

<sup>267</sup> an important regulatory tool to help CDER avoid unnecessary review of

incomplete applications or certain applications that are submitted as an NDA but should have been submitted as an abbreviated new drug application (ANDA).

<sup>268</sup> Salvage chemotherapy is a somewhat morbid term and little used by medical professionals interacting with patients. The phrase is used in medical journals written in cold dispassionate language where it refers to chemotherapy given to a patient when other options are exhausted. The attempt is to "salvage" the person's life with last ditch measures.

<sup>269</sup> Protein, calcium and heat-sensitive vitamins can be added directly to products with supercritical fluid extrusion

<sup>270</sup> A seeding trial or marketing trial is a form of marketing, conducted in the name of research, designed to target product sampling towards selected consumers. In medicine, seeding trials are clinical trials or research studies where the primary objective is to introduce the concept of a particular medical intervention—such as a pharmaceutical drug or medical device—to physicians, rather than to test a scientific hypothesis. In software, seeding trials are commonly termed beta-testing

<sup>271</sup> In response to the FDA Amendments Act (FDAAA) of 2007, in May 2008 the FDA launched the Sentinel Initiative. Sentinel enhances the FDA's ability to proactively monitor the safety of medical products after they have reached the market and complements the Agency's existing Adverse Event Reporting System.

<sup>272</sup> http://www.sda.gov.cn/

<sup>273</sup> shows the number of patients who are low, normal, or high at baseline and at selected time intervals.

<sup>274</sup> seeks to improve the quality of process outputs by identifying and removing the causes of defects (errors) and minimizing variability in manufacturing and business processes. It uses a set of quality management

<sup>&</sup>lt;sup>253</sup> An approved drug product to which new generic versions are compared to show bioequivalence. <sup>254</sup> Reference sample: a sample of a batch of starting material, packaging material or finished product which is stored for the purpose of being analysed should the need arise during the shelf life of the batch concerned.

methods, including statistical methods 是一套商业管理战略,最初于 1986年由摩托罗拉创立。后来由于杰克•韦尔奇(Jack Welch,時任 GE 執行長)的推广让六西格玛于 1995年成为通用電氣的核心管理思想,今天广泛应用于很多行业中

<sup>275</sup>拜耳药业开发的多靶点新药 Sorafenib (索拉非尼,商品名 Nexavar)2005 年 12 月经美国 FDA 批准 作为治疗晚期肾癌的一线药物上市

<sup>276</sup> Upon request, FDA will evaluate within 45 days certain protocols and issues relating to the protocols to assess whether they are adequate to meet scientific and regulatory requirements identified by the sponsor. Three types of protocols related to PDUFA

products are eligible for this special protocol assessment under the PDUFA goals: (1)

animal carcinogenicity protocols, (2) final product stability protocols, and (3) clinical

protocols for phase 3 trials whose data will form the primary basis for an efficacy claim if

the trials had been the subject of discussion at an end-of-phase 2/pre-phase 3 meeting with the review division

<sup>277</sup> is applied to a drug that offers at most, only minor improvement over existing marketed therapies. The 2002 amendments to PDUFA set a goal that a Standard Review of a new drug application be accomplished within a ten-month time frame.

<sup>278</sup>Treatment regimen or medical management based on state of the art participant care.

<sup>279</sup> regulates many aspects of growth, survival and differentiation in cells. The transcription factors of this family are activated by Janus kinase (or 'Just Another Kinase', JAK) and dysregulation of this pathway is frequently observed in primary tumours and leads to increased angiogenesis, enhanced survival of tumours and immunosuppression. Gene knockout studies have provided evidence that STAT proteins are involved in the development and function of the immune system and play a role in maintaining immune tolerance and tumour surveillance

<sup>280</sup> A primary or secondary outcome used to judge the effectiveness of a treatment.

<sup>281</sup> The primary investigative techniques used in an observational protocol; types are Purpose, Duration, Selection, and Timing.

<sup>282</sup> Surrogate markers are used when the primary endpoint is undesired (e.g., death), or when the number of events is very small, thus making it impractical to conduct a clinical trial to gather a statistically significant number of endpoints. "Death from heart disease" is the endpoint of interest, but "cholesterol" is the surrogate marker.

<sup>283</sup> first-line therapy for metastatic Renal Cell Carcinoma

<sup>284</sup> Sustained virologic response (SVR) is defined as aviremia 24 weeks after completion of antiviral therapy for chronic hepatitis C virus (HCV) infection.

<sup>285</sup> Synagis 是一种人源化的单克隆抗体,于 1998 年获 FDA 批准用于防止呼吸道合胞病毒(RSV) 感染高危婴幼儿因 RSV 而引起的严重下呼吸道疾病。Synagis 是首个获准用于防止此类感染的单克 隆抗体,也是该类药物中首个可以安全用于儿科患者的药物

286 60年代初,在联邦德国等国家,孕妇因服用反应停而引致成千上万例海豹肢畸胎

<sup>287</sup> 1 : the range of dosage of a drug or of its concentration in a bodily system that provides safe effective therapy <the narrow therapeutic window...the effect may go from therapeutic to toxic with an increase of just 10 micrograms per milliliter [in] blood concentration—Lisa Davis>

2 : a usually short time interval (as after a precipitating event) during which a particular therapy can be given safely and effectively <has a narrow therapeutic window: the drug must be given within three hours of a stroke in order to be effective—Genesis Report-RX>

<sup>288</sup> is the most important type of endpoint that is widely used in clinical cancer research

<sup>289</sup> Chromatography may be preparative or analytical. Preparative chromatography seeks to separate the components of a mixture for further use (and is thus a form of purification).

<sup>290</sup> tPA is used in clinical medicine to treat only embolic 栓塞性中风 or thrombolytic stroke 溶解血栓性中风. Use is contraindicated in hemorrhagic stroke and head trauma

<sup>291</sup> A TPP is a format for a summary of a drug development program described in terms of labeling concepts. A TPP can be prepared by a sponsor and then shared with the appropriate FDA review staff to facilitate communication regarding a particular drug development program. Submission of a TPP is voluntary. The ideal version of what the sponsor would like to claim in labeling guides the design, conduct, and analysis of clinical trials to maximize the efficiency of the development program. Ideally, the final

version of the TPP will be similar to the annotated draft labeling submitted with a new drug application (NDA) or biologics license application (BLA)

<sup>292</sup> It is the responsibility of those of us involved in today's biomedical research enterprise to translate the remarkable scientific innovations we are witnessing into health gains for the nation

<sup>293</sup> A chromosome alteration in which a whole chromosome or segment of a chromosome becomes attached to or interchanged with another whole chromosome or segment, the resulting hybrid segregating together at meiosis; balanced translocations (in which there is no net loss or gain of chromosome material) are usually not associated with phenotypic abnormalities, although gene disruptions at the breakpoints of the translocation can, in some cases, cause adverse effects, including some known genetic disorders; unbalanced translocations (in which there is loss or gain of chromosome material) nearly always yield an abnormal phenotype

<sup>294</sup> Final regulations were issued in May of 1987 establishing conditions under which promising new drugs and biologics that have not yet been approved or licensed for sale may be made available to persons with serious and life threatening illnesses, for whom no comparable or satisfactory alternative drug or therapy is available. The regulation was revised and expanded in 2009, effective October 12, 2009. Treatment IND regulations allow the treatment use of an investigational drug for treatment under a treatment protocol, or treatment investigational new drug application (IND), outside of the clinical trial

<sup>295</sup> the clinical or genomic configuration in a patient's tumor that makes it susceptible to a specific drug <sup>296</sup>The error of rejecting a true null hypothesis, i.e., concluding that there is a difference when actually there is none. The sample or data might be such that this lead to such a wrong conclusion. This error leads to false positive result 错误的拒绝无效假设,常用  $\alpha$ 表示。

<sup>297</sup>The error of wrongly concluding that there is no difference when actually some difference is present. This error leads to false negative result.错误的不拒绝无效假设,常用β表示。安全性数据集:安全性 与耐受性评价时,用于汇总的受试者集称为安全性数据集。安全性数据集应包括所有随机化后至少 接受一次治疗的受试者。

<sup>298</sup> FDA's preferred UFI for a drug establishment is the Data Universal Numbering System D-U-N-52 S (DUNS) number, assigned and managed by Dun and Bradstreet. The FDA has been using the 53 DUNS number as a registration number for drug establishments since the implementation of 54 electronic drug registration and listing

<sup>299</sup> UNITAID is a global health initiative in great part financed by a solidarity levy on airline tickets. Established in 2006 by the governments of Brazil, Chile, France, Norway and the United Kingdom, it provides sustainable funding in order to tackle inefficiencies in markets for medicines, diagnostics and prevention for HIV/AIDS, Malaria and Tuberculosis in developing countries.

<sup>300</sup> Cleaning validation is documented evidence that an approved cleaning procedure will provide equipment which is suitable for processing medicinal products

<sup>301</sup> Validation carried out during routine production of products intended for sale

<sup>302</sup> The documented evidence that the process, operated within established parameters, can perform effectively and reproducibly to produce a medicinal product meeting its predetermined specifications and quality attributes.

303指按生产工艺规程进行的试生产,确认生产工艺及质量保证体系的可靠性

<sup>304</sup> Validation carried out before routine production of products intended for sale

<sup>305</sup> Validation of a process for a product which has been marketed based upon accumulated manufacturing, testing and control batch data.

<sup>306</sup> Porter 认为企业经营的每一活动,均对最终产品有所贡献,而企业赖以生存的便是端赖这些活动 所创造的价值

<sup>307</sup> Refers to specific sequences of nucleotides, either DNA or RNA, that have been introduced into a gene therapy vector. The sequence includes all components of the gene therapy vector, the vector backbone, transgene(s), and regulatory elements.

<sup>308</sup> Vascular endothelial growth factor (VEGF) is an important signaling protein involved in both vasculogenesis (the formation of the embryonic circulatory system) and angiogenesis (the growth of blood vessels from pre-existing vasculature).

<sup>309</sup> a B-Raf enzyme inhibitor developed by Plexxikon (now part of Daiichi-Sankyo) and Genentech for the treatment of late-stage melanoma

<sup>310</sup> Verification is a Quality control process that is used to evaluate whether or not a product, service, or system complies with regulations, specifications, or conditions imposed at the start of a development phase. Verification can be in development, scale-up, or production. This is often an internal process.

Validation is a Quality assurance process of establishing evidence that provides a high degree of assurance that a product, service, or system accomplishes its intended requirements. This often involves acceptance of fitness for purpose with end users and other product stakeholders.

It is sometimes said that validation can be expressed by the query "Are you building the right thing?" and verification by "Are you building it right?" "Building the right thing" refers back to the user's needs, while "building it right" checks that the specifications be correctly implemented by the system.

<sup>311</sup> 9 8076 patients with RA were randomized to receive rofecoxib (Vioxx) 50 mg/d or naproxen 500 mg bid. Median duration of follow-up was 9 months, and ASA use was not permitted

<sup>312</sup> the quotient of the water vapor pressure of the substance, divided by the vapor pressure of pure water at the same temperature. Generally speaking, it is the amount of water available in the product to allow bacteria to live and grow.

<sup>313</sup> a phenomenon which states that the number of reported adverse reactions for a drug increases until the middle to end of the second year of marketing

<sup>314</sup>适应症用于择期髋关节或膝关节置换手术成年患者,以预防静脉血栓形成(VTE);获准用于房 颤患者预防卒中:溶栓抗凝药物

<sup>315</sup> In November 2012, the US Food and Drug Administration approved Xeljanz (tofacitinib) for patients with rheumatoid arthritis who have an insufficient or allergic response to methotrexate, as treatment for fiercely active rheumatoid arthritis. Tofacitinib, the active ingredient of Xeljanz, is an immunosuppressant that blocks the action of Janus kinases, enzymes that play a crucial role in the process of inflammation and damage of the joints. It is being studied for treatment of psoriasis, inflammatory bowel disease, and other immunological diseases, as well as for the prevention of organ transplant rejection. Tofacitinib was not approved by the European regulatory agencies because of concerns over efficacy and safety.

<sup>316</sup> Daclizumab (trade name Zenapax) is a therapeutic humanized monoclonal antibody to the alpha subunit of the IL-2 receptor of T cells. It is used to prevent rejection in organ transplantation, especially in kidney transplants

<sup>317</sup> allowed the FDA to request NIH-sponsored testing for pediatric drug testing

<sup>318</sup> also called Title 21, Chapter 9 of the United States Code (21 USC 9).

<sup>319</sup> passes incentives which gave pharmaceutical manufacturers a six-month patent term extension on new drugs submitted with pediatric trial data

<sup>320</sup> represented a "revolution" in FDA regulatory authority. The most important change was the requirement that all new drug applications demonstrate "substantial evidence" of the drug's efficacy for a marketed indication, in addition to the existing requirement for pre-marketing demonstration of safety <sup>321</sup> in which the industry pays a fee for the review of the new product

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