药品注册管理办法

第一章　总　则

第一条　为保证药品的安全、有效和质量可控，规范药品注册行为，根据《中华人民共和国药品管理法》（以下简称《药品管理法》）、《中华人民共和国行政许可法》（以下简称《行政许可法》）、《中华人民共和国药品管理法实施条例》（以下简称《药品管理法实施条例》），制定本办法。

第二条　在中华人民共和国境内申请药物临床试验、药品生产和药品进口，以及进行药品审批、注册检验和监督管理，适用本办法。

第三条　药品注册，是指国家食品药品监督管理局根据药品注册申请人的申请，依照法定程序，对拟上市销售药品的安全性、有效性、质量可控性等进行审查，并决定是否同意其申请的审批过程。

第四条　国家鼓励研究创制新药，对创制的新药、治疗疑难危重疾病的新药实行特殊审批。

第五条　国家食品药品监督管理局主管全国药品注册工作，负责对药物临床试验、药品生产和进口进行审批。

第六条 药品注册工作应当遵循公开、公平、公正的原则。

国家食品药品监督管理局对药品注册实行主审集体负责制、相关人员公示制和回避制、责任追究制，受理、检验、审评、审批、送达等环节接受社会监督。

第七条 在药品注册过程中，药品监督管理部门认为涉及公共利益的重大许可事项，应当向社会公告，并举行听证。

行政许可直接涉及申请人与他人之间重大利益关系的，药品监督管理部门在作出行政许可决定前，应当告知申请人、利害关系人享有要求听证、陈述和申辩的权利。

第八条 药品监督管理部门应当向申请人提供可查询的药品注册受理、检查、检验、审评、审批的进度和结论等信息。

药品监督管理部门应当在行政机关网站或者注册申请受理场所公开下列信息：

（一）药品注册申请事项、程序、收费标准和依据、时限，需要提交的全部材料目录和申请书示范文本；

（二）药品注册受理、检查、检验、审评、审批各环节人员名单和相关信息；

（三）已批准的药品目录等综合信息。

第九条 药品监督管理部门、相关单位以及参与药品注册工作的人员，对申请人提交的技术秘密和实验数据负有保密的义务。

第二章　基本要求

第十条　药品注册申请人（以下简称申请人），是指提出药品注册申请并承担相应法律责任的机构。

境内申请人应当是在中国境内合法登记并能独立承担民事责任的机构，境外申请人应当是境外合法制药厂商。境外申请人办理进口药品注册，应当由其驻中国境内的办事机构或者由其委托的中国境内代理机构办理。

办理药品注册申请事务的人员应当具有相应的专业知识，熟悉药品注册的法律、法规及技术要求。

第十一条　药品注册申请包括新药申请、仿制药申请、进口药品申请及其补充申请和再注册申请。

境内申请人申请药品注册按照新药申请、仿制药申请的程序和要求办理，境外申请人申请进口药品注册按照进口药品申请的程序和要求办理。

第十二条　新药申请，是指未曾在中国境内上市销售的药品的注册申请。

对已上市药品改变剂型、改变给药途径、增加新适应症的药品注册按照新药申请的程序申报。

仿制药申请，是指生产国家食品药品监督管理局已批准上市的已有国家标准的药品的注册申请；但是生物制品按照新药申请的程序申报。

进口药品申请，是指境外生产的药品在中国境内上市销售的注册申请。

补充申请，是指新药申请、仿制药申请或者进口药品申请经批准后，改变、增加或者取消原批准事项或者内容的注册申请。

再注册申请，是指药品批准证明文件有效期满后申请人拟继续生产或者进口该药品的注册申请。

第十三条 申请人应当提供充分可靠的研究数据，证明药品的安全性、有效性和质量可控性，并对全部资料的真实性负责。

第十四条 药品注册所报送的资料引用文献应当注明著作名称、刊物名称及卷、期、页等；未公开发表的文献资料应当提供资料所有者许可使用的证明文件。外文资料应当按照要求提供中文译本。

第十五条 国家食品药品监督管理局应当执行国家制定的药品行业发展规划和产业政策，可以组织对药品的上市价值进行评估。

第十六条 药品注册过程中，药品监督管理部门应当对非临床研究、临床试验进行现场核查、有因核查，以及批准上市前的生产现场检查，以确认申报资料的真实性、准确性和完整性。

第十七条 两个以上单位共同作为申请人的，应当向其中药品生产企业所在地省、自治区、直辖市药品监督管理部门提出申请；申请人均为药品生产企业的，应当向申请生产制剂的药品生产企业所在地省、自治区、直辖市药品监督管理部门

提出申请；申请人均不是药品生产企业的，应当向样品试制现场所在地省、自治区、直辖市药品监督管理部门提出申请。

第十八条 申请人应当对其申请注册的药物或者使用的处方、工艺、用途等，提供申请人或者他人在中国的专利及其权属状态的说明；他人在中国存在专利的，申请人应当提交对他人的专利不构成侵权的声明。对申请人提交的说明或者声明，药品监督管理部门应当在行政机关网站予以公示。

药品注册过程中发生专利权纠纷的，按照有关专利的法律法规解决。

第十九条 对他人已获得中国专利权的药品，申请人可以在该药品专利期届满前2年内提出注册申请。国家食品药品监督管理局按照本办法予以审查，符合规定的，在专利期满后核发药品批准文号、《进口药品注册证》或者《医药产品注册证》。

第二十条 按照《药品管理法实施条例》第三十五条的规定，对获得生产或者销售含有新型化学成份药品许可的生产者或者销售者提交的自行取得且未披露的试验数据和其他数据，国家食品药品监督管理局自批准该许可之日起6年内，对未经已获得许可的申请人同意，使用其未披露数据的申请不予批准；但是申请人提交自行取得数据的除外。

第二十一条 为申请药品注册而进行的药物临床前研究，包括药物的合成工艺、提取方法、理化性质及纯度、剂型选择、处方筛选、制备工艺、检验方法、质

量指标、稳定性、药理、毒理、动物药代动力学研究等。中药制剂还包括原药材的来源、加工及炮制等的研究；生物制品还包括菌毒种、细胞株、生物组织等起始原材料的来源、质量标准、保存条件、生物学特征、遗传稳定性及免疫学的研究等。

第二十二条 药物临床前研究应当执行有关管理规定，其中安全性评价研究必须执行《药物非临床研究质量管理规范》。

第二十三条 药物研究机构应当具有与试验研究项目相适应的人员、场地、设备、仪器和管理制度，并保证所有试验数据和资料的真实性；所用实验动物、试剂和原材料应当符合国家有关规定和要求。

第二十四条 申请人委托其他机构进行药物研究或者进行单项试验、检测、样品的试制等的，应当与被委托方签订合同，并在申请注册时予以说明。申请人对申报资料中的药物研究数据的真实性负责。

第二十五条 单独申请注册药物制剂的，研究用原料药必须具有药品批准文号、《进口药品注册证》或者《医药产品注册证》，且必须通过合法的途径获得。研究用原料药不具有药品批准文号、《进口药品注册证》或者《医药产品注册证》的，必须经国家食品药品监督管理局批准。

第二十六条 药品注册申报资料中有境外药物研究机构提供的药物试验研究资料的，必须附有境外药物研究机构出具的其所提供资料的项目、页码的情况说明

和证明该机构已在境外合法登记的经公证的证明文件。国家食品药品监督管理局根据审查需要组织进行现场核查。

第二十七条 药品监督管理部门可以要求申请人或者承担试验的药物研究机构按照其申报资料的项目、方法和数据进行重复试验，也可以委托药品检验所或者其他药物研究机构进行重复试验或方法学验证。

第二十八条 药物研究参照国家食品药品监督管理局发布的有关技术指导原则进行，申请人采用其他评价方法和技术的，应当提交证明其科学性的资料。

第二十九条 申请人获得药品批准文号后，应当按照国家食品药品监督管理局批准的生产工艺生产。

药品监督管理部门根据批准的生产工艺和质量标准对申请人的生产情况进行监督检查。

第三章 药物的临床试验

第三十条 药物的临床试验（包括生物等效性试验），必须经过国家食品药品监督管理局批准，且必须执行《药物临床试验质量管理规范》。

药品监督管理部门应当对批准的临床试验进行监督检查。

第三十一条 申请新药注册，应当进行临床试验。仿制药申请和补充申请，根据本办法附件规定进行临床试验。

临床试验分为Ⅰ、II、III、IV期。

I期临床试验：初步的临床药理学及人体安全性评价试验。观察人体对于新药的耐受程度和药代动力学，为制定给药方案提供依据。

II期临床试验：治疗作用初步评价阶段。其目的是初步评价药物对目标适应症患者的治疗作用和安全性，也包括为III期临床试验研究设计和给药剂量方案的确定提供依据。此阶段的研究设计可以根据具体的研究目的，采用多种形式，包括随机盲法对照临床试验。

III期临床试验：治疗作用确证阶段。其目的是进一步验证药物对目标适应症患者的治疗作用和安全性，评价利益与风险关系，最终为药物注册申请的审查提供充分的依据。试验一般应为具有足够样本量的随机盲法对照试验。

IV期临床试验：新药上市后应用研究阶段。其目的是考察在广泛使用条件下的药物的疗效和不良反应，评价在普通或者特殊人群中使用的利益与风险关系以及改进给药剂量等。

生物等效性试验，是指用生物利用度研究的方法，以药代动力学参数为指标，比较同一种药物的相同或者不同剂型的制剂，在相同的试验条件下，其活性成份吸收程度和速度有无统计学差异的人体试验。

第三十二条 药物临床试验的受试例数应当符合临床试验的目的和相关统计学的要求，并且不得少于本办法附件规定的最低临床试验病例数。罕见病、特殊病

种等情况，要求减少临床试验病例数或者免做临床试验的，应当在申请临床试验时提出，并经国家食品药品监督管理局审查批准。

第三十三条 在菌毒种选种阶段制备的疫苗或者其他特殊药物，确无合适的动物模型且实验室无法评价其疗效的，在保证受试者安全的前提下，可以向国家食品药品监督管理局申请进行临床试验。

第三十四条 药物临床试验批准后，申请人应当从具有药物临床试验资格的机构中选择承担药物临床试验的机构。

第三十五条 临床试验用药物应当在符合《药品生产质量管理规范》的车间制备。制备过程应当严格执行《药品生产质量管理规范》的要求。

申请人对临床试验用药物的质量负责。

第三十六条 申请人可以按照其拟定的临床试验用样品标准自行检验临床试验用药物，也可以委托本办法确定的药品检验所进行检验；疫苗类制品、血液制品、国家食品药品监督管理局规定的其他生物制品，应当由国家食品药品监督管理局指定的药品检验所进行检验。

临床试验用药物检验合格后方可用于临床试验。

药品监督管理部门可以对临床试验用药物抽查检验。

第三十七条 申请人在药物临床试验实施前，应当将已确定的临床试验方案和临床试验负责单位的主要研究者姓名、参加研究单位及其研究者名单、伦理委员会审核同意书、知情同意书样本等报送国家食品药品监督管理局备案，并抄送临床试验单位所在地和受理该申请的省、自治区、直辖市药品监督管理部门。

第三十八条 申请人发现药物临床试验机构违反有关规定或者未按照临床试验方案执行的，应当督促其改正；情节严重的，可以要求暂停或者终止临床试验，并将情况报告国家食品药品监督管理局和有关省、自治区、直辖市药品监督管理部门。

第三十九条 申请人完成临床试验后，应当向国家食品药品监督管理局提交临床试验总结报告、统计分析报告以及数据库。

第四十条 药物临床试验应当在批准后 3 年内实施。逾期未实施的，原批准证明文件自行废止；仍需进行临床试验的，应当重新申请。

第四十一条 临床试验过程中发生严重不良事件的，研究者应当在 24 小时内报告有关省、自治区、直辖市药品监督管理部门和国家食品药品监督管理局，通知申请人，并及时向伦理委员会报告。

第四十二条 临床试验有下列情形之一的，国家食品药品监督管理局可以责令申请人修改试验方案、暂停或者终止临床试验：

（一）伦理委员会未履行职责的；

（二）不能有效保证受试者安全的；

（三）未按照规定时限报告严重不良事件的；

（四）有证据证明临床试验用药物无效的；

（五）临床试验用药物出现质量问题的；

（六）临床试验中弄虚作假的；

（七）其他违反《药物临床试验质量管理规范》的情形。

第四十三条 临床试验中出现大范围、非预期的不良反应或者严重不良事件，或者有证据证明临床试验用药物存在严重质量问题时，国家食品药品监督管理局或者省、自治区、直辖市药品监督管理部门可以采取紧急控制措施，责令暂停或者终止临床试验，申请人和临床试验单位必须立即停止临床试验。

第四十四条 境外申请人在中国进行国际多中心药物临床试验的，应当按照本办法向国家食品药品监督管理局提出申请，并按下列要求办理：

（一）临床试验用药物应当是已在境外注册的药品或者已进入II期或者III期临床试验的药物；国家食品药品监督管理局不受理境外申请人提出的尚未在境外注册的预防用疫苗类药物的国际多中心药物临床试验申请；

（二）国家食品药品监督管理局在批准进行国际多中心药物临床试验的同时，可以要求申请人在中国首先进行I期临床试验；

（三）在中国进行国际多中心药物临床试验时，在任何国家发现与该药物有关的严重不良反应和非预期不良反应，申请人应当按照有关规定及时报告国家食品药品监督管理局；

（四）临床试验结束后，申请人应当将完整的临床试验报告报送国家食品药品监督管理局；

（五）国际多中心药物临床试验取得的数据用于在中国进行药品注册申请的，应当符合本办法有关临床试验的规定并提交国际多中心临床试验的全部研究资料。

第四章　新药申请的申报与审批

第四十五条　国家食品药品监督管理局对下列申请可以实行特殊审批：

（一）未在国内上市销售的从植物、动物、矿物等物质中提取的有效成份及其制剂，新发现的药材及其制剂；

（二）未在国内外获准上市的化学原料药及其制剂、生物制品；

（三）治疗艾滋病、恶性肿瘤、罕见病等疾病且具有明显临床治疗优势的新药；

（四）治疗尚无有效治疗手段的疾病的新药。

符合前款规定的药品，申请人在药品注册过程中可以提出特殊审批的申请，由国家食品药品监督管理局药品审评中心组织专家会议讨论确定是否实行特殊审批。

特殊审批的具体办法另行制定。

第四十六条 多个单位联合研制的新药，应当由其中的一个单位申请注册，其他单位不得重复申请；需要联合申请的，应当共同署名作为该新药的申请人。新药申请获得批准后每个品种，包括同一品种的不同规格，只能由一个单位生产。

第四十七条 对已上市药品改变剂型但不改变给药途径的注册申请，应当采用新技术以提高药品的质量和安全性，且与原剂型比较有明显的临床应用优势。

改变剂型但不改变给药途径，以及增加新适应症的注册申请，应当由具备生产条件的企业提出；靶向制剂、缓释、控释制剂等特殊剂型除外。

第四十八条 在新药审批期间，新药的注册分类和技术要求不因相同活性成份的制剂在国外获准上市而发生变化。

在新药审批期间，其注册分类和技术要求不因国内药品生产企业申报的相同活性成份的制剂在我国获准上市而发生变化。

第四十九条 药品注册申报资料应当一次性提交，药品注册申请受理后不得自行补充新的技术资料；进入特殊审批程序的注册申请或者涉及药品安全性的新发现，以及按要求补充资料的除外。申请人认为必须补充新的技术资料的，应当撤回其药品注册申请。申请人重新申报的，应当符合本办法有关规定且尚无同品种进入新药监测期。

第一节　新药临床试验

第五十条　申请人完成临床前研究后，应当填写《药品注册申请表》，向所在地省、自治区、直辖市药品监督管理部门如实报送有关资料。

第五十一条　省、自治区、直辖市药品监督管理部门应当对申报资料进行形式审查，符合要求的，出具药品注册申请受理通知书；不符合要求的，出具药品注册申请不予受理通知书，并说明理由。

第五十二条　省、自治区、直辖市药品监督管理部门应当自受理申请之日起5日内组织对药物研制情况及原始资料进行现场核查，对申报资料进行初步审查，提出审查意见。申请注册的药品属于生物制品的，还需抽取3个生产批号的检验用样品，并向药品检验所发出注册检验通知。

第五十三条　省、自治区、直辖市药品监督管理部门应当在规定的时限内将审查意见、核查报告以及申报资料送交国家食品药品监督管理局药品审评中心，并通知申请人。

第五十四条　接到注册检验通知的药品检验所应当按申请人申报的药品标准对样品进行检验，对申报的药品标准进行复核，并在规定的时间内将药品注册检验报告送交国家食品药品监督管理局药品审评中心，并抄送申请人。

第五十五条 国家食品药品监督管理局药品审评中心收到申报资料后，应在规定的时间内组织药学、医学及其他技术人员对申报资料进行技术审评，必要时可以要求申请人补充资料，并说明理由。完成技术审评后，提出技术审评意见，连同有关资料报送国家食品药品监督管理局。

国家食品药品监督管理局依据技术审评意见作出审批决定。符合规定的，发给《药物临床试验批件》；不符合规定的，发给《审批意见通知件》，并说明理由。

第二节 新药生产

第五十六条 申请人完成药物临床试验后，应当填写《药品注册申请表》，向所在地省、自治区、直辖市药品监督管理部门报送申请生产的申报资料，并同时向中国药品生物制品检定所报送制备标准品的原材料及有关标准物质的研究资料。

第五十七条 省、自治区、直辖市药品监督管理部门应当对申报资料进行形式审查，符合要求的，出具药品注册申请受理通知书；不符合要求的，出具药品注册申请不予受理通知书，并说明理由。

第五十八条 省、自治区、直辖市药品监督管理部门应当自受理申请之日起5日内组织对临床试验情况及有关原始资料进行现场核查，对申报资料进行初步审查，提出审查意见。除生物制品外的其他药品，还需抽取3批样品，向药品检验所发出标准复核的通知。

省、自治区、直辖市药品监督管理部门应当在规定的时限内将审查意见、核查报告及申报资料送交国家食品药品监督管理局药品审评中心，并通知申请人。

第五十九条 药品检验所应对申报的药品标准进行复核，并在规定的时间内将复核意见送交国家食品药品监督管理局药品审评中心，同时抄送通知其复核的省、自治区、直辖市药品监督管理部门和申请人。

第六十条 国家食品药品监督管理局药品审评中心收到申报资料后，应当在规定的时间内组织药学、医学及其他技术人员对申报资料进行审评，必要时可以要求申请人补充资料，并说明理由。

经审评符合规定的，国家食品药品监督管理局药品审评中心通知申请人申请生产现场检查，并告知国家食品药品监督管理局药品认证管理中心；经审评不符合规定的，国家食品药品监督管理局药品审评中心将审评意见和有关资料报送国家食品药品监督管理局，国家食品药品监督管理局依据技术审评意见，作出不予批准的决定，发给《审批意见通知件》，并说明理由。

第六十一条 申请人应当自收到生产现场检查通知之日起6个月内向国家食品药品监督管理局药品认证管理中心提出现场检查的申请。

第六十二条 国家食品药品监督管理局药品认证管理中心在收到生产现场检查的申请后，应当在30日内组织对样品批量生产过程等进行现场检查，确认核定的生产工艺的可行性，同时抽取1批样品（生物制品抽取3批样品），送进行该药

品标准复核的药品检验所检验，并在完成现场检查后10日内将生产现场检查报告送交国家食品药品监督管理局药品审评中心。

第六十三条 样品应当在取得《药品生产质量管理规范》认证证书的车间生产；新开办药品生产企业、药品生产企业新建药品生产车间或者新增生产剂型的，其样品生产过程应当符合《药品生产质量管理规范》的要求。

第六十四条 药品检验所应当依据核定的药品标准对抽取的样品进行检验，并在规定的时间内将药品注册检验报告送交国家食品药品监督管理局药品审评中心，同时抄送相关省、自治区、直辖市药品监督管理部门和申请人。

第六十五条 国家食品药品监督管理局药品审评中心依据技术审评意见、样品生产现场检查报告和样品检验结果，形成综合意见，连同有关资料报送国家食品药品监督管理局。国家食品药品监督管理局依据综合意见，作出审批决定。符合规定的，发给新药证书，申请人已持有《药品生产许可证》并具备生产条件的，同时发给药品批准文号；不符合规定的，发给《审批意见通知件》，并说明理由。

改变剂型但不改变给药途径，以及增加新适应症的注册申请获得批准后不发给新药证书；靶向制剂、缓释、控释制剂等特殊剂型除外。

第三节　新药监测期

第六十六条　国家食品药品监督管理局根据保护公众健康的要求，可以对批准生产的新药品种设立监测期。监测期自新药批准生产之日起计算，最长不得超过5年。

监测期内的新药，国家食品药品监督管理局不批准其他企业生产、改变剂型和进口。

第六十七条　药品生产企业应当考察处于监测期内的新药的生产工艺、质量、稳定性、疗效及不良反应等情况，并每年向所在地省、自治区、直辖市药品监督管理部门报告。药品生产企业未履行监测期责任的，省、自治区、直辖市药品监督管理部门应当责令其改正。

第六十八条　药品生产、经营、使用及检验、监督单位发现新药存在严重质量问题、严重或者非预期的不良反应时，应当及时向省、自治区、直辖市药品监督管理部门报告。省、自治区、直辖市药品监督管理部门收到报告后应当立即组织调查，并报告国家食品药品监督管理局。

第六十九条　药品生产企业对设立监测期的新药从获准生产之日起2年内未组织生产的，国家食品药品监督管理局可以批准其他药品生产企业提出的生产该新药的申请，并重新对该新药进行监测。

第七十条 新药进入监测期之日起，国家食品药品监督管理局已经批准其他申请人进行药物临床试验的，可以按照药品注册申报与审批程序继续办理该申请，符合规定的，国家食品药品监督管理局批准该新药的生产或者进口，并对境内药品生产企业生产的该新药一并进行监测。

第七十一条 新药进入监测期之日起，不再受理其他申请人的同品种注册申请。已经受理但尚未批准进行药物临床试验的其他申请人同品种申请予以退回；新药监测期满后，申请人可以提出仿制药申请或者进口药品申请。

第七十二条 进口药品注册申请首先获得批准后，已经批准境内申请人进行临床试验的，可以按照药品注册申报与审批程序继续办理其申请，符合规定的，国家食品药品监督管理局批准其进行生产；申请人也可以撤回该项申请，重新提出仿制药申请。对已经受理但尚未批准进行药物临床试验的其他同品种申请予以退回，申请人可以提出仿制药申请。

第五章 仿制药的申报与审批

第七十三条 仿制药申请人应当是药品生产企业，其申请的药品应当与《药品生产许可证》载明的生产范围一致。

第七十四条 仿制药应当与被仿制药具有同样的活性成份、给药途径、剂型、规格和相同的治疗作用。已有多家企业生产的品种，应当参照有关技术指导原则选择被仿制药进行对照研究。

第七十五条 申请仿制药注册，应当填写《药品注册申请表》，向所在地省、自治区、直辖市药品监督管理部门报送有关资料和生产现场检查申请。

第七十六条 省、自治区、直辖市药品监督管理部门对申报资料进行形式审查，符合要求的，出具药品注册申请受理通知书；不符合要求的，出具药品注册申请不予受理通知书，并说明理由。

已申请中药品种保护的，自中药品种保护申请受理之日起至作出行政决定期间，暂停受理同品种的仿制药申请。

第七十七条 省、自治区、直辖市药品监督管理部门应当自受理申请之日起5日内组织对研制情况和原始资料进行现场核查，并应当根据申请人提供的生产工艺和质量标准组织进行生产现场检查，现场抽取连续生产的3批样品，送药品检验所检验。

样品的生产应当符合本办法第六十三条的规定。

第七十八条 省、自治区、直辖市药品监督管理部门应当在规定的时限内对申报资料进行审查，提出审查意见。符合规定的，将审查意见、核查报告、生产现场检查报告及申报资料送交国家食品药品监督管理局药品审评中心，同时通知申请

人；不符合规定的，发给《审批意见通知件》，并说明理由，同时通知药品检验所停止该药品的注册检验。

第七十九条 药品检验所应当对抽取的样品进行检验，并在规定的时间内将药品注册检验报告送交国家食品药品监督管理局药品审评中心，同时抄送通知其检验的省、自治区、直辖市药品监督管理部门和申请人。

第八十条 国家食品药品监督管理局药品审评中心应当在规定的时间内组织药学、医学及其他技术人员对审查意见和申报资料进行审核，必要时可以要求申请人补充资料，并说明理由。

第八十一条 国家食品药品监督管理局药品审评中心依据技术审评意见、样品生产现场检查报告和样品检验结果，形成综合意见，连同相关资料报送国家食品药品监督管理局，国家食品药品监督管理局依据综合意见，做出审批决定。符合规定的，发给药品批准文号或者《药物临床试验批件》；不符合规定的，发给《审批意见通知件》，并说明理由。

第八十二条 申请人完成临床试验后，应当向国家食品药品监督管理局药品审评中心报送临床试验资料。国家食品药品监督管理局依据技术意见，发给药品批准文号或者《审批意见通知件》。

第八十三条 已确认存在安全性问题的上市药品，国家食品药品监督管理局可以决定暂停受理和审批其仿制药申请。

第六章 进口药品的申报与审批

第一节 进口药品的注册

第八十四条 申请进口的药品，应当获得境外制药厂商所在生产国家或者地区的上市许可；未在生产国家或者地区获得上市许可，但经国家食品药品监督管理局确认该药品安全、有效而且临床需要的，可以批准进口。

申请进口的药品，其生产应当符合所在国家或者地区药品生产质量管理规范及中国《药品生产质量管理规范》的要求。

第八十五条 申请进口药品注册，应当填写《药品注册申请表》，报送有关资料和样品，提供相关证明文件，向国家食品药品监督管理局提出申请。

第八十六条 国家食品药品监督管理局对申报资料进行形式审查，符合要求的,出具药品注册申请受理通知书，并通知中国药品生物制品检定所组织对 3 个生产批号的样品进行注册检验；不符合要求的,出具药品注册申请不予受理通知书，并说明理由。

国家食品药品监督管理局可以组织对其研制和生产情况进行现场检查，并抽取样品。

第八十七条 中国药品生物制品检定所收到资料和样品后，应当在5日内组织进行注册检验。

第八十八条 承担进口药品注册检验的药品检验所在收到资料、样品和有关标准物质后，应当在60日内完成注册检验并将药品注册检验报告报送中国药品生物制品检定所。

特殊药品和疫苗类制品的样品检验和药品标准复核应当在90日内完成。

第八十九条 中国药品生物制品检定所接到药品注册检验报告和已经复核的进口药品标准后，应当在20日内组织专家进行技术审查，必要时可以根据审查意见进行再复核。

第九十条 中国药品生物制品检定所完成进口药品注册检验后，应当将复核的药品标准、药品注册检验报告和复核意见送交国家食品药品监督管理局药品审评中心，并抄送申请人。

第九十一条 国家食品药品监督管理局药品审评中心应当在规定的时间内组织药学、医学及其他技术人员对申报资料进行审评，必要时可以要求申请人补充资料，并说明理由。

第九十二条 国家食品药品监督管理局药品审评中心依据技术审评意见和样品检验结果等，形成综合意见，连同相关资料报送国家食品药品监督管理局，国家

食品药品监督管理局依据综合意见，做出审批决定。符合规定的，发给《药物临床试验批件》；不符合规定的，发给《审批意见通知件》，并说明理由。

第九十三条 临床试验获得批准后，申请人应当按照本办法第三章及有关要求进行试验。

临床试验结束后，申请人应当填写《药品注册申请表》，按照规定报送临床试验资料及其他变更和补充的资料，并详细说明依据和理由，提供相关证明文件。

第九十四条 国家食品药品监督管理局药品审评中心应当在规定的时间内组织药学、医学及其他技术人员对报送的临床试验等资料进行全面审评，必要时可以要求申请人补充资料，并说明理由。

国家食品药品监督管理局依据综合意见，做出审批决定。符合规定的，发给《进口药品注册证》。中国香港、澳门和台湾地区的制药厂商申请注册的药品，参照进口药品注册申请的程序办理，符合要求的，发给《医药产品注册证》；不符合要求的，发给《审批意见通知件》，并说明理由。

第九十五条 申请进口药品制剂，必须提供直接接触药品的包装材料和容器合法来源的证明文件、用于生产该制剂的原料药和辅料合法来源的证明文件。原料药和辅料尚未取得国家食品药品监督管理局批准的，应当报送有关生产工艺、质量指标和检验方法等规范的研究资料。

第二节　进口药品分包装的注册

第九十六条　进口药品分包装，是指药品已在境外完成最终制剂生产过程，在境内由大包装规格改为小包装规格，或者对已完成内包装的药品进行外包装、放置说明书、粘贴标签等。

第九十七条　申请进口药品分包装，应当符合下列要求：

（一）该药品已经取得《进口药品注册证》或者《医药产品注册证》；

（二）该药品应当是中国境内尚未生产的品种，或者虽有生产但是不能满足临床需要的品种；

（三）同一制药厂商的同一品种应当由一个药品生产企业分包装，分包装的期限不得超过《进口药品注册证》或者《医药产品注册证》的有效期；

（四）除片剂、胶囊外，分包装的其他剂型应当已在境外完成内包装；

（五）接受分包装的药品生产企业，应当持有《药品生产许可证》。进口裸片、胶囊申请在国内分包装的，接受分包装的药品生产企业还应当持有与分包装的剂型相一致的《药品生产质量管理规范》认证证书；

（六）申请进口药品分包装，应当在该药品《进口药品注册证》或者《医药产品注册证》的有效期届满1年前提出。

第九十八条　境外制药厂商应当与境内药品生产企业签订进口药品分包装合同，并填写《药品补充申请表》。

第九十九条 申请进口药品分包装的，应当由接受分包装的药品生产企业向所在地省、自治区、直辖市药品监督管理部门提出申请，提交由委托方填写的《药品补充申请表》，报送有关资料和样品。省、自治区、直辖市药品监督管理部门对申报资料进行形式审查后，符合要求的，出具药品注册申请受理通知书；不符合要求的，出具药品注册申请不予受理通知书，并说明理由。

省、自治区、直辖市药品监督管理部门提出审核意见后，将申报资料和审核意见报送国家食品药品监督管理局审批，同时通知申请人。

第一百条 国家食品药品监督管理局对报送的资料进行审查，符合规定的，发给《药品补充申请批件》和药品批准文号；不符合规定的，发给《审批意见通知件》，并说明理由。

第一百零一条 进口分包装的药品应当执行进口药品注册标准。

第一百零二条 进口分包装药品的说明书和标签必须与进口药品的说明书和标签一致，并且应当标注分包装药品的批准文号和分包装药品生产企业的名称。

第一百零三条 境外大包装制剂的进口检验按照国家食品药品监督管理局的有关规定执行。包装后产品的检验与进口检验执行同一药品标准。

第一百零四条 提供药品的境外制药厂商应当对分包装后药品的质量负责。分包装后的药品出现质量问题的，国家食品药品监督管理局可以撤销分包装药品的

批准文号，必要时可以依照《药品管理法》第四十二条的规定，撤销该药品的《进口药品注册证》或者《医药产品注册证》。

第七章　非处方药的申报

第一百零五条　申请仿制的药品属于按非处方药管理的，申请人应当在《药品注册申请表》的“附加申请事项”中标注非处方药项。

第一百零六条　申请仿制的药品属于同时按处方药和非处方药管理的，申请人可以选择按照处方药或者非处方药的要求提出申请。

第一百零七条　属于以下情况的，申请人可以在《药品注册申请表》的“附加申请事项”中标注非处方药项，符合非处方药有关规定的，按照非处方药审批和管理；不符合非处方药有关规定的，按照处方药审批和管理。

（一）经国家食品药品监督管理局确定的非处方药改变剂型，但不改变适应症或者功能主治、给药剂量以及给药途径的药品；

（二）使用国家食品药品监督管理局确定的非处方药活性成份组成的新的复方制剂。

第一百零八条　非处方药的注册申请，其药品说明书和包装标签应当符合非处方药的有关规定。

第一百零九条 进口的药品属于非处方药的，适用进口药品的申报和审批程序，其技术要求与境内生产的非处方药相同。

第八章 补充申请的申报与审批

第一百一十条 变更研制新药、生产药品和进口药品已获批准证明文件及其附件中载明事项的，应当提出补充申请。

申请人应当参照相关技术指导原则，评估其变更对药品安全性、有效性和质量可控性的影响，并进行相应的技术研究工作。

第一百一十一条 申请人应当填写《药品补充申请表》，向所在地省、自治区、直辖市药品监督管理部门报送有关资料和说明。省、自治区、直辖市药品监督管理部门对申报资料进行形式审查，符合要求的，出具药品注册申请受理通知书；不符合要求的，出具药品注册申请不予受理通知书，并说明理由。

第一百一十二条 进口药品的补充申请，申请人应当向国家食品药品监督管理局报送有关资料和说明，提交生产国家或者地区药品管理机构批准变更的文件。国家食品药品监督管理局对申报资料进行形式审查，符合要求的，出具药品注册申请受理通知书；不符合要求的，出具药品注册申请不予受理通知书，并说明理由。

第一百一十三条 修改药品注册标准、变更药品处方中已有药用要求的辅料、改变影响药品质量的生产工艺等的补充申请，由省、自治区、直辖市药品监督

管理部门提出审核意见后，报送国家食品药品监督管理局审批，同时通知申请人。

修改药品注册标准的补充申请，必要时由药品检验所进行标准复核。

第一百一十四条 改变国内药品生产企业名称、改变国内生产药品的有效期、国内药品生产企业内部改变药品生产场地等的补充申请，由省、自治区、直辖市药品监督管理部门受理并审批，符合规定的，发给《药品补充申请批件》，并报送国家食品药品监督管理局备案；不符合规定的，发给《审批意见通知件》，并说明理由。

第一百一十五条 按规定变更药品包装标签、根据国家食品药品监督管理局的要求修改说明书等的补充申请，报省、自治区、直辖市药品监督管理部门备案。

第一百一十六条 进口药品的补充申请，由国家食品药品监督管理局审批。其中改变进口药品制剂所用原料药的产地、变更进口药品外观但不改变药品标准、根据国家药品标准或国家食品药品监督管理局的要求修改进口药说明书、补充完善进口药说明书的安全性内容、按规定变更进口药品包装标签、改变注册代理机构的补充申请，由国家食品药品监督管理局备案。

第一百一十七条 对药品生产技术转让、变更处方和生产工艺可能影响产品质量等的补充申请，省、自治区、直辖市药品监督管理部门应当根据其《药品注册批件》附件或者核定的生产工艺，组织进行生产现场检查，药品检验所应当对抽取的 3 批样品进行检验。

第一百一十八条 国家食品药品监督管理局对药品补充申请进行审查，必要时可以要求申请人补充资料，并说明理由。符合规定的，发给《药品补充申请批件》；不符合规定的，发给《审批意见通知件》，并说明理由。

第一百一十九条 补充申请获得批准后，换发药品批准证明文件的，原药品批准证明文件由国家食品药品监督管理局予以注销；增发药品批准证明文件的，原批准证明文件继续有效。

第九章 药品再注册

第一百二十条 国家食品药品监督管理局核发的药品批准文号、《进口药品注册证》或者《医药产品注册证》的有效期为 5 年。有效期届满，需要继续生产或者进口的，申请人应当在有效期届满前 6 个月申请再注册。

第一百二十一条 在药品批准文号、《进口药品注册证》或者《医药产品注册证》有效期内，申请人应当对药品的安全性、有效性和质量控制情况，如监测期内的相关研究结果、不良反应的监测、生产控制和产品质量的均一性等进行系统评价。

第一百二十二条 药品再注册申请由药品批准文号的持有者向省、自治区、直辖市药品监督管理部门提出，按照规定填写《药品再注册申请表》，并提供有关

申报资料。

进口药品的再注册申请由申请人向国家食品药品监督管理局提出。

第一百二十三条 省、自治区、直辖市药品监督管理部门对申报资料进行审查，符合要求的，出具药品再注册申请受理通知书；不符合要求的，出具药品再注册申请不予受理通知书，并说明理由。

第一百二十四条 省、自治区、直辖市药品监督管理部门应当自受理申请之日起6个月内对药品再注册申请进行审查，符合规定的，予以再注册；不符合规定的，报国家食品药品监督管理局。

第一百二十五条 进口药品的再注册申请由国家食品药品监督管理局受理，并在6个月内完成审查，符合规定的，予以再注册；不符合规定的，发出不予再注册的通知，并说明理由。

第一百二十六条 有下列情形之一的药品不予再注册：

（一）有效期届满前未提出再注册申请的；

（二）未达到国家食品药品监督管理局批准上市时提出的有关要求的；

（三）未按照要求完成IV期临床试验的；

（四）未按照规定进行药品不良反应监测的；

（五）经国家食品药品监督管理局再评价属于疗效不确、不良反应大或者其他原因危害人体健康的；

（六）按照《药品管理法》的规定应当撤销药品批准证明文件的；

（七）不具备《药品管理法》规定的生产条件的；

（八）未按规定履行监测期责任的；

（九）其他不符合有关规定的情形。

第一百二十七条 国家食品药品监督管理局收到省、自治区、直辖市药品监督管理部门意见后，经审查不符合药品再注册规定的，发出不予再注册的通知，并说明理由。

对不予再注册的品种，除因法定事由被撤销药品批准证明文件的外，在有效期届满时，注销其药品批准文号、《进口药品注册证》或者《医药产品注册证》。

第十章 药品注册检验

第一百二十八条 药品注册检验，包括样品检验和药品标准复核。

样品检验，是指药品检验所按照申请人申报或者国家食品药品监督管理局核定的药品标准对样品进行的检验。

药品标准复核，是指药品检验所对申报的药品标准中检验方法的可行性、科学性、设定的项目和指标能否控制药品质量等进行的实验室检验和审核工作。

第一百二十九条 药品注册检验由中国药品生物制品检定所或者省、自治区、直辖市药品检验所承担。进口药品的注册检验由中国药品生物制品检定所组织实施。

第一百三十条 下列药品的注册检验由中国药品生物制品检定所或者国家食品药品监督管理局指定的药品检验所承担：

（一）本办法第四十五条（一）、（二）规定的药品；

（二）生物制品、放射性药品；

（三）国家食品药品监督管理局规定的其他药品。

第一百三十一条 获准进入特殊审批程序的药品，药品检验所应当优先安排样品检验和药品标准复核。

第一百三十二条 从事药品注册检验的药品检验所，应当按照药品检验所实验室质量管理规范和国家计量认证的要求，配备与药品注册检验任务相适应的人员和设备，符合药品注册检验的质量保证体系和技术要求。

第一百三十三条 申请人应当提供药品注册检验所需要的有关资料、报送样品或者配合抽取检验用样品、提供检验用标准物质。报送或者抽取的样品量应当为检验用量的 3 倍；生物制品的注册检验还应当提供相应批次的制造检定记录。

第一百三十四条 药品检验所进行新药标准复核时，除进行样品检验外，还应当根据药物的研究数据、国内外同类产品的药品标准和国家有关要求，对药物的药品标准、检验项目等提出复核意见。

第一百三十五条 要求申请人重新制订药品标准的，申请人不得委托提出原复核意见的药品检验所进行该项药品标准的研究工作；该药品检验所不得接受此项委托。

第十一章 药品注册标准和说明书

第一节 药品注册标准

第一百三十六条 国家药品标准，是指国家食品药品监督管理局颁布的《中华人民共和国药典》、药品注册标准和其他药品标准，其内容包括质量指标、检验方法以及生产工艺等技术要求。

药品注册标准，是指国家食品药品监督管理局批准给申请人特定药品的标准，生产该药品的药品生产企业必须执行该注册标准。

药品注册标准不得低于中国药典的规定。

第一百三十七条 药品注册标准的项目及其检验方法的设定，应当符合中国药典的基本要求、国家食品药品监督管理局发布的技术指导原则及国家药品标准编写原则。

第一百三十八条 申请人应当选取有代表性的样品进行标准的研究工作。

第二节　药品标准物质

第一百三十九条　药品标准物质，是指供药品标准中物理和化学测试及生物方法试验用，具有确定特性量值，用于校准设备、评价测量方法或者给供试药品赋值的物质，包括标准品、对照品、对照药材、参考品。

第一百四十条　中国药品生物制品检定所负责标定国家药品标准物质。

中国药品生物制品检定所可以组织有关的省、自治区、直辖市药品检验所、药品研究机构或者药品生产企业协作标定国家药品标准物质。

第一百四十一条　中国药品生物制品检定所负责对标定的标准物质从原材料选择、制备方法、标定方法、标定结果、定值准确性、量值溯源、稳定性及分装与包装条件等资料进行全面技术审核，并作出可否作为国家药品标准物质的结论。

第三节　药品名称、说明书和标签

第一百四十二条　申请注册药品的名称、说明书和标签应当符合国家食品药品监督管理局的规定。

第一百四十三条　药品说明书和标签由申请人提出，国家食品药品监督管理局药品审评中心根据申报资料对其中除企业信息外的内容进行审核，在批准药品生产时由国家食品药品监督管理局予以核准。

申请人应当对药品说明书和标签的科学性、规范性与准确性负责。

第一百四十四条 申请人应当跟踪药品上市后的安全性和有效性情况，及时提出修改药品说明书的补充申请。

第一百四十五条 申请人应当按照国家食品药品监督管理局规定的格式和要求、根据核准的内容印制说明书和标签。

第十二章 时 限

第一百四十六条 药品监督管理部门应当遵守《药品管理法》、《行政许可法》及《药品管理法实施条例》规定的药品注册时限要求。本办法所称药品注册时限，是药品注册的受理、审查、审批等工作的最长时间，根据法律法规的规定中止审批或者申请人补充资料等所用时间不计算在内。

药品注册检验、审评工作时间应当按照本办法的规定执行。有特殊原因需要延长时间的，应当说明理由，报国家食品药品监督管理局批准并告知申请人。

第一百四十七条 药品监督管理部门收到申请后进行形式审查，并根据下列情况分别作出处理：

（一）申请事项依法不需要取得行政许可的，应当即时告知申请人不受理；

（二）申请事项依法不属于本部门职权范围的，应当即时作出不予受理的决定，并告知申请人向有关行政机关申请；

（三）申报资料存在可以当场更正的错误的，应当允许申请人当场更正；

（四）申报资料不齐全或者不符合法定形式的，应当当场或者在5日内一次告

知申请人需要补正的全部内容，逾期不告知的，自收到申报资料之日起即为受理；

（五）申请事项属于本部门职权范围，申报资料齐全、符合法定形式，或者申请人按照要求提交全部补正资料的，应当受理药品注册申请。

药品监督管理部门受理或者不予受理药品注册申请，应当出具加盖药品注册专用印章和注明日期的书面凭证。

第一百四十八条 省、自治区、直辖市药品监督管理部门应当在受理申请后30日内完成对研制情况及原始资料的核查、对申报资料的审查、抽取样品、通知药品检验所进行注册检验、将审查意见和核查报告连同申请人的申报资料一并报送国家食品药品监督管理局等工作，同时将审查意见通知申请人。

第一百四十九条 药品注册检验的时间按照以下规定执行：

（一）样品检验：30日；同时进行样品检验和标准复核：60日；

（二）特殊药品和疫苗类制品的样品检验：60日；同时进行样品检验和标准复核：90日。

按照本办法第三十六条的规定由药品检验所进行临床试验用样品检验的，应当按照前款样品检验的时间完成。

第一百五十条 技术审评工作时间按照下列规定执行：

（一）新药临床试验：90日；获准进入特殊审批程序的品种：80日；

（二）新药生产：150日；获准进入特殊审批程序的品种：120日；

（三）对已上市药品改变剂型和仿制药的申请：160 日；

（四）需要进行技术审评的补充申请：40 日。

进口药品注册申请的技术审评时间参照前款执行。

第一百五十一条 在技术审评过程中需要申请人补充资料的，应当一次性发出补充资料通知，申请人对补充资料通知内容提出异议的，可以当面听取申请人的陈述意见。申请人应当在 4 个月内按照通知要求一次性完成补充资料，进入特殊审批程序的，按照特殊审批程序的要求办理。

收到补充资料后，技术审评时间应当不超过原规定时间的 1/3；进入特殊审批程序的，不得超过原规定时间的 1/4。

药品注册过程中申请人自行提出撤回申请的，其审批程序自行终止。

第一百五十二条 国家食品药品监督管理局应当在 20 日内作出审批决定；20 日内不能作出决定的，经主管局领导批准，可以延长 10 日，并应当将延长时限的理由告知申请人。

第一百五十三条 国家食品药品监督管理局应当自作出药品注册审批决定之日起 10 日内颁发、送达有关行政许可证件。

第十三章　复　审

第一百五十四条　有下列情形之一的，国家食品药品监督管理局不予批准：

（一）不同申请人提交的研究资料、数据相同或者雷同，且无正当理由的；

（二）在注册过程中发现申报资料不真实，申请人不能证明其申报资料真实的；

（三）研究项目设计和实施不能支持对其申请药品的安全性、有效性、质量可控性进行评价的；

（四）申报资料显示其申请药品安全性、有效性、质量可控性等存在较大缺陷的；

（五）未能在规定的时限内补充资料的；

（六）原料药来源不符合规定的；

（七）生产现场检查或者样品检验结果不符合规定的；

（八）法律法规规定的不应当批准的其他情形。

第一百五十五条　药品监督管理部门依法作出不予受理或者不予批准的书面决定，应当说明理由，并告知申请人享有依法提请行政复议或者提起行政诉讼的权利。

第一百五十六条　申请人对国家食品药品监督管理局作出的不予批准决定有异议的，可以在收到不予批准的通知之日起60日内填写《药品注册复审申请

表》，向国家食品药品监督管理局提出复审申请并说明复审理由。

复审的内容仅限于原申请事项及原申报资料。

第一百五十七条 国家食品药品监督管理局接到复审申请后，应当在50日内作出复审决定，并通知申请人。维持原决定的，国家食品药品监督管理局不再受理再次的复审申请。

第一百五十八条 复审需要进行技术审查的，国家食品药品监督管理局应当组织有关专业技术人员按照原申请时限进行。

第十四章 法律责任

第一百五十九条 有《行政许可法》第六十九条规定情形的，国家食品药品监督管理局根据利害关系人的请求或者依据职权，可以撤销有关的药品批准证明文件。

第一百六十条 药品监督管理部门及其工作人员违反本法的规定，有下列情形之一的，由其上级行政机关或者监察机关责令改正；情节严重的，对直接负责的主管人员和其他直接责任人员依法给予行政处分：

（一）对符合法定条件的药品注册申请不予受理的；

（二）不在受理场所公示依法应当公示的材料的；

（三）在受理、审评、审批过程中，未向申请人、利害关系人履行法定告知义

务的；

（四）申请人提交的申报资料不齐全、不符合法定形式，不一次告知申请人必须补正的全部内容的；

（五）未依法说明不受理或者不批准药品注册申请理由的；

（六）依法应当举行听证而不举行听证的。

第一百六十一条 药品监督管理部门及其工作人员在药品注册过程中索取或者收受他人财物或者谋取其他利益，构成犯罪的，依法追究刑事责任；尚不构成犯罪的，依法给予行政处分。

第一百六十二条 药品监督管理部门在药品注册过程中有下列情形之一的，由其上级行政机关或者监察机关责令改正，对直接负责的主管人员和其他直接责任人员依法给予行政处分；构成犯罪的，依法追究刑事责任：

（一）对不符合法定条件的申请作出准予注册决定或者超越法定职权作出准予注册决定的；

（二）对符合法定条件的申请作出不予注册决定或者不在法定期限内作出准予注册决定的；

（三）违反本办法第九条的规定未履行保密义务的。

第一百六十三条 药品检验所在承担药品审批所需要的检验工作时，出具虚假检验报告的，依照《药品管理法》第八十七条的规定处罚。

第一百六十四条 药品监督管理部门擅自收费或者不按照法定项目和标准收费的，由其上级行政机关或者监察机关责令退还非法收取的费用；对直接负责的主管人员和其他直接责任人员依法给予行政处分。

第一百六十五条 在药品注册中未按照规定实施《药物非临床研究质量管理规范》或者《药物临床试验质量管理规范》的，依照《药品管理法》第七十九条的规定处罚。

第一百六十六条 申请人在申报临床试验时，报送虚假药品注册申报资料和样品的，药品监督管理部门不予受理或者对该申报药品的临床试验不予批准，对申请人给予警告，1 年内不受理该申请人提出的该药物临床试验申请；已批准进行临床试验的，撤销批准该药物临床试验的批件，并处 1 万元以上 3 万元以下罚款，3 年内不受理该申请人提出的该药物临床试验申请。

药品监督管理部门对报送虚假资料和样品的申请人建立不良行为记录，并予以公布。

第一百六十七条 申请药品生产或者进口时，申请人报送虚假药品注册申报资料和样品的，国家食品药品监督管理局对该申请不予受理或者不予批准，对申请人给予警告，1 年内不受理其申请；已批准生产或者进口的，撤销药品批准证明文件，5 年内不受理其申请，并处 1 万元以上 3 万元以下罚款。

第一百六十八条 根据本办法第二十七条的规定，需要进行药物重复试验，申请人拒绝的，国家食品药品监督管理局对其予以警告并责令改正，申请人拒不改正的，不予批准其申请。

第一百六十九条 具有下列情形之一的，由国家食品药品监督管理局注销药品批准文号，并予以公布：

（一）批准证明文件的有效期未满，申请人自行提出注销药品批准文号的；

（二）按照本办法第一百二十六条的规定不予再注册的；

（三）《药品生产许可证》被依法吊销或者缴销的；

（四）按照《药品管理法》第四十二条和《药品管理法实施条例》第四十一条的规定，对不良反应大或者其他原因危害人体健康的药品，撤销批准证明文件的；

（五）依法作出撤销药品批准证明文件的行政处罚决定的；

（六）其他依法应当撤销或者撤回药品批准证明文件的情形。

第十五章 附 则

第一百七十条 中药和天然药物、化学药品、生物制品、补充申请、再注册的申报资料和要求分别见本办法附件1、附件2、附件3、附件4、附件5，监测期的规定见附件6。

第一百七十一条 药品批准文号的格式为：国药准字H（Z、S、J）+4位年号+4位顺序号，其中H代表化学药品，Z代表中药，S代表生物制品，J代表进口

药品分包装。

《进口药品注册证》证号的格式为：H（Z、S）＋4 位年号＋4 位顺序号；《医药产品注册证》证号的格式为：H（Z、S）C＋4 位年号＋4 位顺序号，其中 H 代表化学药品，Z 代表中药，S 代表生物制品。对于境内分包装用大包装规格的注册证，其证号在原注册证号前加字母 B。

新药证书号的格式为：国药证字 H（Z、S）＋4 位年号＋4 位顺序号，其中 H 代表化学药品，Z 代表中药，S 代表生物制品。

第一百七十二条 本办法规定由省、自治区、直辖市药品监督管理部门承担的受理、补充申请的审批、再注册的审批，均属国家食品药品监督管理局委托事项。国家食品药品监督管理局还可以委托省、自治区、直辖市药品监督管理部门承担药品注册事项的其他技术审评或者审批工作。

第一百七十三条 国家食品药品监督管理局对批准上市的药品实行编码管理。药品编码管理的规定另行制定。

第一百七十四条 麻醉药品、精神药品、医疗用毒性药品、放射性药品的注册申请，除按照本办法的规定办理外，还应当符合国家的其他有关规定。

第一百七十五条 实施批准文号管理的中药材、中药饮片以及进口中药材的注册管理规定，由国家食品药品监督管理局另行制定。

第一百七十六条 药品技术转让和委托生产的办法另行制定。

第一百七十七条 本办法自2007年10月1日起施行。国家食品药品监督管理局于2005年2月28日公布的《药品注册管理办法》（国家食品药品监督管理局令第17号）同时废止。

Provisions for Drug Registration

Chapter I

General Provisions

Article 1 The Provisions are formulated for the purposes of ensuring the safety, efficacy and quality of drugs and regulating drug registration in accordance with the Drug Administration Law of the People's Republic of China (hereinafter referred to as the Drug Administration Law), Administrative Permission Law of the People's Republic of China (hereinafter referred to as Administrative Permission Law) and the Regulations for Implementation of the Drug Administration Law of the People's Republic of China (hereinafter referred to as the Regulations for Implementation of the Drug Administration Law).

Article 2 The Provisions apply to the applications for drug clinical trial, drug production or import, and conducting drug approval, relevant testing for drug registration, or regulation thereof, within the territory of the People's Republic of China.

Article 3 Drug registration refers to the process of review and approval on which the State Food and Drug Administration, in accordance with the official procedures, evaluates the safety, efficacy and quality of the drugs applied for marketing, and decides whether or not to approve such an application.

Article 4 The State encourages the research and development of new drugs and adopts the special review and approval with respect to innovative drugs, new drugs for serious and life-threatening diseases and to address unmet medical needs and drugs.

Article 5 The State Food and Drug Administration is in charge of drug registration nationwide, and responsible for reviewing and approving the clinical trial, production and importation of drugs.

Article 6 The drug registration shall follow the principles of openness, fairness and justice.

The State Food and Drug Administration adopts the system of collective responsibility of the chief reviewers, the system of publicizing and challenging relevant persons, and the system of responsibility tracing, with social supervision in such procedures as acceptance, inspection, review and approval and sending.

Article 7 In the process of drug registration, the drug regulatory department shall make known to the general public, and hold hearings on, the matters which it deems of vital importance and involving public interests for the granting of permission.

Prior to making the decision of administrative licensing that has a direct bearing on the vital interest between the applicant and the other party, the drug regulatory department shall inform the applicant and the interested party of their rights of requesting for hearings, making statements and argues.

Article 8 The drug regulatory department shall provide the applicant with access to information on the status of the acceptance, examination, inspection, review and approval of drug registration application and the final resolution.

The drug regulatory department shall publicize the following information on its official websites or at the official premises for accepting applications:

(1) the items, procedures, fees and their basis, and timelines of the drug registration, index of all the data needed to be submitted and model text of the application form;
(2) the name list and other relevant information on the persons involved in the acceptance, examination, inspection, review and approval of drug registration; and
(3) general information about categories of approved drugs, etc.

Article 9 The drug regulatory department, relevant institutions and persons involved in the drug registration have an obligation to keep the technical secrets and trial data submitted by the applicant confidential.

Chapter II
Application for Drug Registration

Article 10 An applicant for drug registration (hereinafter referred to as applicant) refers to the institution that submits a drug registration application and assumes corresponding legal liability.

A domestic applicant shall be an institution legally registered within the territory of People's Republic of China that independently assumes civil liability and an overseas applicant shall be a legal overseas drug

manufacturer. Where an overseas applicant applies for import drug registration, it shall be done by its branch or entrusted agency within the territory of People's Republic of China.

The persons who handle the application for drug registration shall have professional knowledge and be familiar with the laws and regulations on, and the technical requirements for, drug registration.

Article 11 Drug registration applications include applications for new drugs, generic drugs, import drugs and their supplementary applications as well as re-registration applications.

Applications of domestic applicants shall be handled according to the procedures and requirements for new drugs or generic drugs, whereas applications of overseas applicants shall be handled according to those for import drugs.

Article 12 Application for new drugs refers to application for registration of drugs that have not been marketed within the territory of People's Republic of China.

Application for changing dosage form or route of administration, or claiming a new indication for marketed drugs, shall be submitted as the process of new drug application.

Application for generic drugs refers to registration application for producing the drugs having existing national drug standard which is approved to be marketed by the State Food and Drug Administration, whereas the application for biological products shall be submitted as the process of new drug application.

Application for import drugs refers to registration application for drugs manufactured abroad to be marketed within the territory of the People's Republic of China.

Supplementary application refers to application for variation, addition, or cancellation of the items or contents approved in the original application for new drug, generic drug or import drug.

Re-registration application refers to application for continued production or importation of a drug after the expiration of the valid term of the drug approval document.

Article 13 The applicant shall provide sufficient and reliable research data to prove the safety, efficacy and quality of the drug, and be liable for the authenticity of all the dossiers submitted.

Article 14 The cited literature of the dossier of drug registration shall indicate the title of works or the name, volume number, issue and page of the journal. Where the cited references are not published, an author's permission shall be provided. For foreign literatures, Chinese translation shall be provided as required.

Article 15 The State Food and Drug Administration shall obey the development plan and policies on the pharmaceutical industry constituted by the State, and may conduct assessment to the market value of drugs.

Article 16 In the process of drug registration, the drug regulatory department shall conduct on-site inspection and causal inspection to the non-clinical studies and clinical trials, as well as production site inspection for the pre-marketing approval to confirm the authenticity, precision and integrity of the dossier submitted.

Article 17 Where two or more institutions jointly apply for drugs, the application shall be submitted to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government, in which the drug manufacturer is located; where the applicants are all drug manufacturers, the application shall be submitted to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government, in which the manufacturer of pharmaceutical preparations is located; where none of the applicants is a drug manufacturer, the application shall be submitted to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government, in which the site for pilot production of drug samples is located.

Article 18 An applicant shall provide the information on patent and its ownership of the applicant or other parties in China, in respect of the drug applied for registration, its formula, manufacturing processes and/or uses, etc. Where another party owns the patent in China, the applicant shall provide a statement of non-infringement. The drug regulatory department shall publish the information or the statement submitted by the applicant on its official website.

Where a patent dispute occurs in the process of drug registration, it shall be settled in accordance with relevant laws and regulations on patent.

Article 19 For a drug patented in China, applicants other than the patentee may submit the application for registration two years prior to the expiry date of the patent. The State Food and Drug Administration shall review the drug application in accordance with the Provisions, and after the expiry date of the patent, check and issue the drug approval number, Import Drug License or a Pharmaceutical Product License if the application conforms with the provisions.

Article 20 In accordance with the provisions in Article 35 of the Regulations for Implementation of the Drug Administration Law, where a manufacturer or distributor submits undisclosed drug experimental and other data which are independently acquired in order to obtain approval for production or marketing of the drug in question which contains any new chemical entity, the State Food and Drug Administration shall, within six years from the approval date of the drug, reject any application made by any other applicants by using the undisclosed data of the drug in question without permission of the original applicant who has obtained the drug approval, unless the data submitted are independently acquired by the applicants other than the original one.

Article 21 Pre-clinical drug study for drug registration application includes drug synthetic processes, extraction methods, physical and chemical properties, purity, selection of dosage form, screening of formula, preparing processes, testing methods, quality specifications, stability, pharmacology, toxicology and animal pharmacokinetics, etc. For traditional Chinese medicine preparations, in addition to the above-mentioned items, pre-clinical drug study also includes the study in the source of the crude drugs, and of their pre-treatment and processing, etc. For biological products, it also includes study on the source, quality specifications, storage conditions, biological characteristics and genetic stability of the starting materials such as bacterial and viral seeds/strains, cell lines, bio-tissues, and immunological study, etc.

Article 22 A pre-clinical drug study shall be in conformity with relevant requirements, among which the Good Laboratory Practice for Non-Clinical Laboratory Studies shall be implemented in the study of safety evaluation.

Article 23 The drug research institution shall have relevant staff, premises, equipment, instruments and management system, which are appropriate to the research project, and ensure the authenticity of all experimental data. Experimental animals, reagents and raw materials used in the study shall conform with the provisions of the State.

Article 24 An applicant who entrusts other institutions with a drug research, individual experiment, testing, or pilot production, etc. shall conclude a contract with the trustee, and state it clearly in the registration application. The applicant shall be responsible for the authenticity of the research data in the application dossier.

Article 25 Where the application is only for registration of pharmaceutical preparations, any drug substance used for the study shall have a drug approval number, an Import Drug License or a Pharmaceutical Product License, and be acquired through legitimated means. Where a drug substance used for the study has no drug approval number, Import Drug License or Pharmaceutical Product License, the use of drug substance in study shall be approved by the State Food and Drug Administration.

Article 26 The research data in application dossier for drug registration provided by an overseas drug research institution shall be attached with the items and pages of the information, and with notarized documents proving that the said drug research institution is legally registered overseas. The State Food and Drug Administration may send staff to conduct on-site inspection in needs of drug review.

Article 27 The drug regulatory department may request the applicant or the drug research institution responsible for testing to repeat the test based on the items, methods and data specified in the application documents, and may also authorize a drug testing institute or another drug research institution to repeat the test or conduct methodological verification.

Article 28 The drug study shall be conducted according to the relevant technical guidelines issued by the State Food and Drug Administration. Where an applicant conducts the study by adopting other evaluation methods and techniques, supporting data proving the scientific feasibility of such methods and techniques shall be provided.

Article 29 An applicant who obtains the drug approval number shall manufacture according to the manufacturing processes approved by the State Food and Drug Administration.

The drug regulatory department shall supervise and inspect the applicant's manufacture in accordance with the approved manufacturing processes and quality specifications.

Chapter III
Drug Clinical Trials

Article 30 Any drug clinical trial, including bioequivalence study, shall be approved by the State Food and Drug Administration, and shall be in compliance with the Good Clinical Practice.

Drug regulatory department shall supervise and inspect the approved clinical trials.

Article 31 Clinical trials shall be conducted for new drug registration applications. As for generic drug registration applications and supplementary applications, clinical trials shall be conducted in accordance with the requirements in the Annex of the Provisions.

A clinical trial consists of phases I, II, III and IV.

Phase I Clinical Trial: initial clinical pharmacology and safety evaluation studies in humans. These studies are designed to observe tolerability of humans to and pharmacokinetics of a new drug, in order to provide basis for establishing the administration regimen.

Phase II Clinical Trial: preliminary evaluation of therapeutic effectiveness of a drug. The purposes are to preliminarily evaluate the therapeutic effectiveness and safety of the drug for particular indication(s) in patients, and provide evidence for design of Phase III clinical trial and settlement of administrative dose regimen. According to specific trial objectives, this phase of trial may be designed in various forms, including the randomized blind controlled clinical trial.

Phase III Clinical Trial: confirmation of therapeutic effectiveness of a drug. The purposes are to further verify drug therapeutic effectiveness and safety on eligible patients with target indication(s), to evaluate overall benefit-risk relationships of the drug, and to ultimately provide sufficient evidence for the review of drug registration application. The study, in general, shall be a randomized blind controlled trial with an adequate sample size.

Phase IV Clinical Trial: a new drug post-marketing study. The purposes are to assess therapeutic effectiveness and adverse reactions when a drug is widely used, to evaluate overall benefit-risk relationships of the drug when used among general population or specific groups, and to adjust the administration dose, etc.

Bioequivalence study refers to a human study, which applies bioavailability study methods with pharmacokinetic parameters as indicators to compare active ingredient absorption rate and extent of the

preparations in the same or different dosage forms of a drug in terms of statistical differences under the same experimental condition.

Article 32 The sample size of a drug clinical trial shall conform to the objectives of the clinical trial and fulfill statistical requirements, and shall be no smaller than the minimum number of subjects required by the Annex of the Provisions. Where there are circumstances, regarding rare or special diseases, etc., which request clinical sample size reduction or clinical trial exemption, a request shall be made with the clinical trial application, and reviewed and approved by the State Food and Drug Administration.

Article 33 As for vaccines prepared during bacterial or viral strain screening or other special drugs, if confirmed without any suitable animal model and laboratory measurement in terms of curative effectiveness, clinical trials may be applied for to the State Food and Drug Administration, subject to ensuring the safety of trial subjects.

Article 34 When a drug clinical trial is approved, the applicant shall select institutions for the clinical trial from those certified for conducting drug clinical trials.

Article 35 Drugs used for clinical trials shall be manufactured in facilities in compliance with the Good Manufacturing Practice for Pharmaceutical Products (GMP). The manufacturing process shall strictly meet the requirements of the GMP.

The applicant shall be responsible for the quality of the drugs used for clinical trials.

Article 36 The applicant may conduct the testing for clinical trial drugs by itself, or entrust a drug testing institute specified in the Provisions to conduct such testing, according to its proposed specifications. Vaccines, blood products and other biological products specified by the State Food and Drug Administration shall be tested by drug testing institutes designated by the State Food and Drug Administration.

A drug can be used for a clinical trial only after tested as qualified.

Drug regulatory departments may conduct sampling and testing on drugs used for clinical trials.

Article 37 Prior to conducting a clinical trial, the applicant shall report to the State Food and Drug Administration for record while copying to the drug regulatory department of the seat of the clinical trial

institution and that of the province, autonomous region or municipality directly under the Central Government to receive the application a confirmed clinical trial protocol, the name of the principal investigator at the institution in charge of the clinical trial, a list of participating institutions and names of investigators wherefrom, an ethic committee approval letter, and a template of the informed consent form, etc.

Article 38 Where the applicant finds a clinical trial institution violating relevant regulations or failing to implement the clinical trial protocol, it shall urge the institution to make corrections; if the circumstances are serious, the applicant may demand suspension or termination of the clinical trial, and shall report the matter to the State Food and Drug Administration and the drug regulatory departments of the relevant provinces, autonomous regions or municipalities directly under the Central Government.

Article 39 After completion of a clinical trial, the applicant shall submit a clinical trial final report, a statistical analysis report and its database to the State Food and Drug Administration.

Article 40 A clinical trial shall be conducted within three years after approval. If overdue, the original approval documents shall be invalid. If the clinical trial is still needed, the application shall be reapplied for.

Article 41 If any serious adverse event occurs during the clinical trial, the investigators shall report to the drug regulatory departments of the relevant provinces, autonomous regions or municipalities directly under the Central Government and the State Food and Drug Administration and notify the applicant within 24 hours, and report to the ethic committee in time.

Article 42 In any of the following circumstances during a clinical trial, the State Food and Drug Administration may order the applicant to modify the protocol, suspend or terminate the clinical trial,:

(1) the ethic committee fails to perform its duty;
(2) safety of the subjects cannot be adequately ensured;
(3) a serious adverse event is not reported within the specified timeline;
(4) there is evidence to prove that the drug used for the clinical trial is not effective;
(5) a quality problem of the drug used for the clinical trial occurs;
(6) there is a fraud in the clinical trial; or
(7) there is any other case violating the Good Clinical Practice.

Article 43 Where there is any large-scale of and unexpected adverse reaction or serious adverse event, or there is evidence to prove any serious quality problem of the drug used for a clinical trial, the State Food and Drug Administration or the drug regulatory department of the province, autonomous region or municipality directly under the Central Government may take emergency control measures and order to suspend or terminate the clinical trial. The applicant and clinical trial institution must stop the clinical trial immediately.

Article 44 An overseas applicant intending to conduct an international multi-center clinical trial in China shall submit an application to the State Food and Drug Administration in accordance with the Provisions, and fulfill the following requirements:

(1) the drugs used for clinical trials shall be already approved or in phase II or III clinical trial overseas. The State Food and Drug Administration does not accept any overseas applicant's international multi-center clinical trial application for any preventive vaccine not being registered overseas yet;
(2) while approving to conduct an international multi-center clinical trial, the State Food and Drug Administration may require the applicant to conduct phase I clinical trial first in China;
(3) when conducting an international multi-center clinical trial in China, if there are any observed serious adverse reaction and unexpected adverse reaction associated with the drug in any country, the applicant shall, in accordance with relevant regulations, report to the State Food and Drug Administration in time;
(4) the applicant shall submit a complete clinical trial report to the State Food and Drug Administration after the completion of a clinical trial; and
(5) the data obtained from an international multi-center clinical trial for drug registration application in China shall be in conformity with the requirements on clinical trial in the Provisions. All the study materials of the international multi-center clinical trial shall be submitted.

Chapter IV
Application and Approval of New Drugs

Article 45 The State Food and Drug Administration may implement special review and approval in cases of the following applications:

(1) active ingredients extracted from plants, animals and minerals, etc. and their preparations not yet marketed in China, and newly discovered Chinese crude drugs and their preparations;

(2) chemical drug substances and their preparations and biological products not yet approved for marketing in China or abroad;
(3) new drugs for the treatment of diseases such as AIDS, malignant tumors and rare diseases, etc. with significant clinical advantage; and
(4) new drugs for the treatment of diseases, for which effective therapeutic methods are not available.

For drugs specified in the previous clause, applicants may apply for special review and approval in the process of drug registration. The Center for Drug Evaluation of the State Food and Drug Administration shall organize expert meetings to discuss and determine whether or not to conduct special review and approval for the drugs.

Specified measures for special review and approval shall be formulated separately.

Article 46 Where a new drug is co-developed by several institutions, the registration can be applied for by one of the institutions, and its duplicate application shall not be made by the others. If a joint application for registration is needed, the institutions shall co-sign as the applicant of the new drug. Each approved new drug, including its different strengths shall be produced by only one institution.

Article 47 For the registration application to change the dosage form without changing administration route of a marketed drug, new techniques shall be employed to improve the drug quality and safety, and the changed dosage form shall have significant clinical advantage compared with the previous dosage form.

Registration applications to change the dosage form without changing the route of administration or to claim any new indication shall be submitted by certified manufacturers, with exceptions for special dosage forms such as targeting delivery, sustained release and controlled release preparations, etc.

Article 48 In the process of the review and approval of a new drug, the registration classification and technical requirements thereof shall not be changed, even though the preparations of the same active ingredients are approved for marketing abroad.

In the process of the review and approval of a new drug, the registration classification and technical requirements thereof shall not be changed, even though the preparations of the same active ingredients applied for by domestic manufacturers are approved for marketing in China.

Article 49 The dossier for drug registration application shall be submitted at one time. No other technical materials should be added by the applicant after a drug registration application is accepted, with the exceptions for applications of special review and approval, new finding regarding drug safety, or supplementary materials as required. Where an applicant deems it integrant for any new technical material to be supplemented, the submitted application shall be withdrawn. Only if no same product is in the new drug observation period, the applicant may re-apply in compliance with the relevant requirements in the Provisions.

Section 1
Clinical Trials for New Drugs

Article 50 After completing the pre-clinical study, the applicant shall fill the Application Form for Drug Registration, and report authentically relevant materials to the drug regulatory department of the province, autonomous region or municipality directly under the Central Government where the applicant is located.

Article 51 Drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government shall conduct the preliminary review of the application dossiers, and issue a acceptance notice of drug registration application if requirements are met, or issue a non-acceptance notice, in which reasons shall be given, of drug registration application if requirements are not met.

Article 52 Drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government shall organize to conduct on-site inspections of the drug research and development conditions and raw data, make preliminary review of the submitted dossiers, and provide review opinions within five days from the date it accepts an application. Where the drug for which the registration is applied is a biological product, samples from three production batches thereof shall also be collected for testing, and a notice for the testing for registration shall be issued to the drug testing institute.

Article 53 Drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government shall deliver the review opinions, inspection reports and the application dossiers to the Center for Drug Evaluation of the State Food and Drug Administration within the specified timeline, and notice the applicants.

Article 54 The drug testing institute that receives a notice for the testing for registration shall test the samples according to the drug specifications submitted by the applicant, verify the submitted drug

specifications, and submit a certificate of analysis for drug registration to the Center for Drug Evaluation of the State Food and Drug Administration within the specified timeline, and copy to the applicant.

Article 55 After receiving submitted dossiers, the Center for Drug Evaluation of the State Food and Drug Administration shall organize pharmaceutical, medical and other technical personnel to conduct technical review of the submitted dossiers within the specified timeline, and may request, with reasons, applicants to provide supplementary materials when necessary. After completing technical reviews, the Center for Drug Evaluation shall give technical review opinions and report together with relevant documents to the State Food and Drug Administration.

The State Food and Drug Administration shall make review and approval decisions based on the technical review opinions. Where the regulations are conformed to, a Drug Clinical Trial Approval shall be issued; where the regulations are not conformed to, a Disapproval Notice shall be issued with reasons provided.

Section 2
Production of New Drugs

Article 56 After completing drug clinical trials, applicants shall fill the Application Form for Drug Registration, submit production application dossiers to the drug regulatory departments of the provinces, autonomous regions, or municipalities directly under the Central Government where the applicant is located, and at the same time provide the raw materials and research information for preparing reference standards to the National Institute for the Control of Pharmaceutical and Biological Products.

Article 57 Drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government shall conduct the preliminary review of the application dossiers, and issue an acceptance notice of drug registration application if requirements are met, or issue a non-acceptance notice, in which reasons shall be given, of drug registration application if requirements are not met.

Article 58 Drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government shall organize to conduct on-site inspections of the drug research and development conditions and raw data, make preliminary review of the submitted dossiers, and provide review opinions within five days from the date it accepts an application. For the other drugs except biological products, samples of three production batches shall also be collected for testing, and a notice of specifications verification shall be issued to the drug testing institute.

Drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government shall deliver the review opinions, inspection reports and the application dossiers to the Center for Drug Evaluation of the State Food and Drug Administration within the specified timeline, and notice the applicants.

Article 59 Drug testing institutes shall verify the submitted drug specifications and give the verification opinions to the Center for Drug Evaluation of the State Food and Drug Administration within the specified timeline, and at the same time copy to the drug regulatory departments of the provinces, autonomous regions, or municipalities directly under the Central Government that notify them to conduct the verification, and the applicants.

Article 60 After receiving submitted dossiers, the Center for Drug Evaluation of the State Food and Drug Administration shall organize pharmaceutical, medical and other technical personnel to conduct technical review of the submitted dossiers within the specified timeline, and may request, with reasons, applicants to provide supplementary materials when necessary.

Where the regulations are conformed to as reviewed, the Center for Drug Evaluation of the State Food and Drug Administration shall notice the applicant to apply for production site inspection and inform the Center for Drug Certification of the State Food and Drug Administration. Where the regulations are not conformed to as reviewed, the Center for Drug Evaluation of the State Food and Drug Administration shall report the review opinions and relevant documents to the State Food and Drug Administration; the State Food and Drug Administration shall make a disapproval decision to the application based on the technical review opinions, and issue a Disapproval Notice with reasons.

Article 61 The applicant shall apply for on-site inspection to the Center for Drug Certification of the State Food and Drug Administration within six months from the date it receives the notice of production site inspection.

Article 62 The Center for Drug Certification of the State Food and Drug Administration shall, within 30 days from the date it receives the application for production site inspection, organize on-site inspection of large-scale samples production, verify the applicability of the manufacturing processes and at the same time take samples of one batch of products (samples of three batches of products for biological products),

and provide production site inspection report to the Center for Drug Evaluation of the State Food and Drug Administration within ten days after the site inspection.

Article 63 Samples shall be produced at a plant with the GMP Certificate. As for a new manufacturer, a new workshop established or the production of a dosage form added at an existing manufacturer, the sample production shall meet the GMP requirements.

Article 64 Drug testing institutes shall conduct sample testing according to the verified specifications, and within the specified timeline, provide testing reports to the Center for Drug Evaluation of the State Food and Drug Administration, and copy to the relevant drug regulatory departments of the provinces, autonomous regions, or municipalities directly under the Central Government and the applicants.

Article 65 The Center for Drug Evaluation of the State Food and Drug Administration shall make a general opinion based on the technical review opinions, production site inspection reports and sample testing results, and report the general opinion together with relevant documents to the State Food and Drug Administration. The State Food and Drug Administration shall make a review and approval decision based on the general opinion. Where the regulations are conformed to, a New Drug Certificate shall be issued; if the applicant already has a Drug Manufacturing Certificate and possesses the production conditions, a drug approval number shall be issued at the same time; where the regulations are not conformed to, a Disapproval Notice shall be issued with reasons.

A New Drug Certificate shall not be issued to the approved registration applications for changing dosage forms without changing route of administration or claiming for new indications, with exceptions for special dosage forms such as targeting delivery, sustained release and controlled release preparations, etc.

Section 3
New Drug Observation Period

Article 66 In order to protect the public health, the State Food and Drug Administration may set an observation period for any new drug approved for production. The observation period of a new drug shall be no longer than five years from the date the drug is approved for production.

During the observation period of a new drug, the State Food and Drug Administration shall not approve other manufacturers to produce, change dosage form of or import the drug.

Article 67 A drug manufacturer shall investigate the manufacturing processes, quality, stability, therapeutic effect and adverse reactions, etc. of a new drug in the observation period, and report annually to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government, where it is located. Where a drug manufacturer fails to perform its duties in the observation period, the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government shall order it to make rectifications.

Article 68 Where institutions for drug manufacturing, distribution, use, testing or supervision find any critical quality problem, serious or unexpected adverse reaction of a new drug, they shall report to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government in time. Once receiving the report, the drug regulatory department of a province, autonomous region, or municipality directly under the Central Government shall organize prompt investigation, and report to the State Food and Drug Administration.

Article 69 Where a drug manufacturer does not conduct production of the new drug, for which an observation period is set, within two years from the date of the approval, the State Food and Drug Administration may approve the application of another drug manufacturer to produce the new drug and reset the observation period of the drug.

Article 70 Starting from the date a new drug enters the observation period, any other application for the clinical trial of the same drug already approved by the State Food and Drug Administration may proceed along drug registration application, review and approval procedures; where regulations are conformed to, the State Food and Drug Administration shall approve the production or importation of the same drug. The observations of the drugs produced by the domestic manufacturers should be conducted together with the drug already in the observation period.

Article 71 Starting from the date a new drug enters the observation period, other registration applications for the same drug shall no longer be accepted. The other applicants' applications for the same drug already accepted but not yet approved for clinical trials shall be returned; upon the expiration of the observation period of the drug, the registration of a generic or import drug may be applied for.

Article 72 Where an application for an import drug registration is approved first, the domestic application already approved for clinical trial of the drug may proceed along drug registration application, review and

approval procedures; where regulations are conformed to, the State Food and Drug Administration shall approve the production of the drug; or, the applicant may withdraw the application, and submit a generic drug application. The other applications for the same drugs already accepted but not yet approved for clinical trials shall be returned; the registration of a generic drug may be applied for.

Chapter V
Application and Approval of Generic Drugs

Article 73 The applicant applying for registration of a generic drug shall be a drug manufacturer. The applied drug shall be within the production scope specified in the Drug Manufacturing Certificate.

Article 74 The generic drug shall have the identical active ingredients, route of administration, dosage form, strength and therapeutic effects with the registered drug. Where a drug has been produced by more than one manufacturer, the selection of registered drugs for comparative study shall be in accordance with relevant technical guidelines.

Article 75 To apply for the registration of a generic drug, the applicant shall fill the Application Form for Drug Registration, submit relevant dossiers and apply for production site inspection to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government where the applicant is located.

Article 76 Drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government shall conduct the preliminary review of the application dossiers, and issue an acceptance notice of drug registration application if requirements are met, or issue a non-acceptance notice, in which reasons shall be given, of drug registration application if requirements are not met.

As for a drug for which the protection of traditional Chinese medicine preparations has been applied, from the date the application for the protection is accepted through the date an administrative decision is made, the acceptance of the application of its generic drug shall be suspended.

Article 77 Drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government shall organize to conduct on-site inspections of the drug research and development conditions as well as raw data, and production site inspections according to the manufacturing processes and quality specifications provided by the applicant, and take samples of three

consecutive batches of products, and send to the drug testing institutes for testing within five days starting from the date they accept an application.

The production of samples shall be in conformity with the requirements in Article 63 in the Provisions.

Article 78 Drug regulatory departments of the provinces, autonomous regions, or municipalities directly under the Central Government shall review the submitted dossiers within the specified timeline and give review opinions. Where the regulations are conformed to, they shall provide for the Center for Drug Evaluation of the State Food and Drug Administration with the review opinions, the check report, the production site inspection report and the application dossiers, and inform the applicant. Where the regulations are not conformed to, they shall issue a Disapproval Notice with reasons, and notify the drug testing institute to terminate the testing for registration.

Article 79 Drug testing institutes shall conduct sample testing, provide testing reports to the Center for Drug Evaluation of the State Food and Drug Administration within the specified timeline, and copy to the drug regulatory departments of the provinces, autonomous regions, or municipalities directly under the Central Government that notify them to conduct the verification, and the applicants.

Article 80 The Center for Drug Evaluation of the State Food and Drug Administration shall organize pharmaceutical, medical and other technical personnel to conduct technical review of the submitted dossiers within the specified timeline, and may request, with reasons, applicants to provide supplementary materials when necessary.

Article 81 The Center for Drug Evaluation of the State Food and Drug Administration shall make a general opinion based on the technical review opinions, production site inspection reports and sample testing results, and report the general opinion together with relevant documents to the State Food and Drug Administration. The State Food and Drug Administration shall make a review and approval decision based on the general opinion. Where the regulations are conformed to, it shall issue a drug approval number or a Drug Clinical Trial Approval; where the regulations are not conformed to, it shall issue a Disapproval Notice with reasons.

Article 82 After completing drug clinical trials, applicants shall submit clinical trial data to the Center for Drug Evaluation of the State Food and Drug Administration. The State Food and Drug Administration shall issue a drug approval number or a Disapproval Notice based on the technical review opinions.

Article 83 As for a marketed drug with confirmed safety problems, the State Food and Drug Administration may decide to suspend the acceptance or review and approval of the application of its generic drugs.

Chapter VI
Application and Approval of Import Drugs

Section 1
Registration of Import Drugs

Article 84 A drug being applied for importation shall have already obtained the drug marketing authorization in the producing country or region where the overseas pharmaceutical manufacturer is located; those not yet obtained marketing authorization in the producing country or region, however confirmed with safety, efficacy and clinical needs by the State Food and Drug Administration may be approved for importation.

The production of a drug applied for importation shall comply with the GMP requirements of both the producing country or region where the drug manufacturer is located and China.

Article 85 To apply for import drug registration, the applicant shall fill the Application Form for Drug Registration, submit relevant dossiers and samples, provide relevant approval documents, and submit the application to the State Food and Drug Administration.

Article 86 The State Food and Drug Administration shall conduct the preliminary review of the application dossiers, and issue an acceptance notice of drug registration application and notify the National Institute for the Control of Pharmaceutical and Biological Products to conduct testing for registration of samples from three batches if requirements are met; or issue a non-acceptance notice of drug registration application with reasons if requirements are not met.

The State Food and Drug Administration may organize to conduct on-site inspection of development and production conditions, and take samples.

Article 87 The National Institute for the Control of Pharmaceutical and Biological Products shall organize to conduct the testing for drug registration within five days from the date it receives the dossiers and samples.

Article 88 The drug testing institutes undertaking the import drug testing shall complete the testing for registration and submit the certificate of analysis for drug registration to the National Institute for the Control of Pharmaceutical and Biological Products within 60 days from the date they receive the documents, samples and relevant reference standards.

Sample testing and verification of specifications for controlled drugs or vaccines shall be completed within 90 days.

Article 89 The National Institute for the Control of Pharmaceutical and Biological Products shall organize experts to conduct technical review within 20 days from the date it receives the certificate of analysis for drug registration and the verified import specifications, and if necessary, conduct further verification according to the review opinions.

Article 90 After completing the testing for import drug registration, the National Institute for the Control of Pharmaceutical and Biological Products shall give the verified specifications, certificate of analysis and opinions thereof to the Center for Drug Evaluation of the State Food and Drug Administration, and copy the applicants.

Article 91 The Center for Drug Evaluation of the State Food and Drug Administration shall organize pharmaceutical, medical and other technical personnel to conduct technical review of the submitted dossiers within the specified timeline, and may request, with reasons, applicants to provide supplementary materials when necessary.

Article 92 The Center for Drug Evaluation of the State Food and Drug Administration shall make a general opinion based on the technical review opinions and sample testing results, and report the general opinion together with relevant documents to the State Food and Drug Administration. The State Food and Drug Administration shall make a review and approval decision based on the general opinion. Where the regulations are conformed to, a Clinical Trial Approval shall be issued; where the regulations are not conformed to, a Disapproval Notice shall be issued with reasons.

Article 93 After a clinical trial application is approved, the applicant shall conduct the trial in accordance with the requirements in Chapter III of the Provisions and the other relevant requirements.

After a clinical trial is completed, the applicant shall fill the Application Form for Drug Registration, submit the clinical trial data, other altered and supplementary data in accordance with regulations, give in detail the basis and reasons, and provide relevant approved documents.

Article 94 The Center for Drug Evaluation of the State Food and Drug Administration shall organize pharmaceutical, medical and other technical personnel to conduct comprehensive review of the submitted clinical trial data within the specified timeline, and may request, with reasons, applicants to provide supplementary materials when necessary.

The State Food and Drug Administration shall make a review and approval decision based on the general opinion. An Import Drug License shall be issued if regulations are conformed to. For a drug applied for registration by a drug manufacturer in Hong Kong, Macao or Taiwan of China, its application shall be handled in reference to the application procedures for import drug registration. If requirements are met, a Pharmaceutical Product License shall be issued; if requirements are not met, a Disapproval Notice shall be issued with reasons.

Article 95 To apply for importation of pharmaceutical preparations, approved documents for the lawful sources of the immediate packaging materials and containers and those of the drug substances and the excipients used for the pharmaceutical preparations shall be provided. Where drug substances and excipients are not yet approved by the State Food and Drug Administration, relevant data of manufacturing processes, specifications and testing methods, etc. shall be submitted.

Section 2
Registration of Import Drug Repackaging

Article 96 The import drug repackaging refers to dividing a large pack into small ones in China or adding outer-package to a drug with inner-package, placing insert sheets and attaching labels, etc., after the production process of the finished pharmaceutical preparations for the drug are completed overseas .

Article 97 To apply for import drug repackaging, the following requirements shall be met:

(1) the Import Drug License or Pharmaceutical Product License of the drug is already obtained;
(2) the drug shall be one that is not produced within the territory of China, or is produced in China but unable to meet clinical needs;
(3) one drug produced by a drug manufacturer shall be repackaged by only one drug manufacturer. The term allowed for repackaging shall not exceed the expiry date of the Import Drug License or Pharmaceutical Product License;
(4) the inner–packaging of a drug in any dosage form for repackaging, except tablets and capsules, shall be completed overseas;
(5) a drug manufacturer that conducts repackaging shall hold the Drug Manufacturing Certificate. To apply for repackaging of import unpackaged tablets and capsules, the manufacturer shall also hold the GMP certificate covering the dosage forms for repackaging; and
(6) An application for drug repackaging shall be made one year prior to the expiration of the Import Drug License or the Pharmaceutical Product License.

Article 98 An overseas drug manufacturer shall sign a contract for import drug repackaging with a domestic drug manufacturer, and fill in the Drug Supplementary Application Form.

Article 99 To apply for the repackaging of an import drug, the drug manufacturer entrusted with repackaging of the drug shall submit an application to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government where it is located. The trustee shall submit the Supplementary Drug Application Form filled in by the truster, the relevant data and samples as well as the contract of entrustment, etc. The drug regulatory department shall conduct the preliminary review of the submitted documents. Where requirements are met, it shall issue a notice of acceptance; where requirements are not met, it shall issue a notice of non-acceptance with reasons.

The drug regulatory department shall make review opinions, then submit the application documents and review opinions to the State Food and Drug Administration and inform the applicant at the same time.

Article 100 The State Food and Drug Administration shall review the submitted documents. Where the regulations are conformed to, it shall issue an Approval for Supplementary Drug Application and a drug approval number; where the regulations are not conformed to, it shall issue a Disapproval Notice with reasons.

Article 101 The repackaged import drugs shall comply with the registration specifications for import drugs.

Article 102 The insert sheets and labels of a repackaged import drug shall be in conformity with those of the import drug, and shall be indicated with the approval number of the repackaging drug and the name of drug manufacturer.

Article 103 The testing for import of overseas pharmaceutical preparation in large package shall be conducted according to the State Food and Drug Administration regulations. The same specifications shall be used for the testing of both repackaged and import products.

Article 104 The overseas drug manufacturer providing the drug shall be responsible for the quality of the repackaged drug. If there is any quality problem, the State Food and Drug Administration may withdraw the approval number of the repackaged drug, revoke the Import Drug License or the Pharmaceutical Product License when necessary according to the requirements of Article 42 of the Drug Administration Law.

Chapter VII
Application of Non-Prescription Drugs

Article 105 Where the applied generic drug is regulated as a non-prescription drug, the applicant shall indicate the item of non-prescription drug in the “additional application items” of the Application Form for Drug Registration.

Article 106 Where the applied generic drug is regulated as both a prescription and non-prescription drug, the applicant may submit an application for either a prescription or non-prescription drug according to the respective requirements.

Article 107 For any of the following circumstances, the applicant may indicate the item of non-prescription drug in the “additional application items” of the Application Form for Drug Registration. If relevant requirements for non-prescription drugs apply, the drug shall be reviewed and approved, and regulated as a non-prescription drug; if relevant requirements for non-prescription drugs do not apply, it shall be reviewed and approved, and regulated as a prescription drug:

(1) To alter the dosage form of a non-prescription drug determined by the State Food and Drug Administration without changing the indications or functions, dosage and route of administration; or
(2) To formulate a new fixed dose combination using active ingredients of non-prescription drugs determined by the State Food and Drug Administration.

Article 108 For the registration application of a non-prescription drug, the insert sheet and package label shall comply with the relevant regulations on non-prescription drugs.

Article 109 For the registration application of an import drug categorized as non-prescription drug, the application, review and approval procedures for import drugs shall apply, and the technological requirements shall be the same as those for the domestically produced non-prescription drugs.

Chapter VIII
Submission, Review and Approval of Supplementary Application

Article 110 For the variation of the items specified in the approval document and its attachment for approved new drug development, drug production and import drug, supplementary applications shall be made.

The applicant shall assess the implications of the variation to the safety, efficacy and quality of the drug, and conduct corresponding technical studies in reference to relevant technical guidelines.

Article 111 The applicant shall fill in Supplementary Drug Application Form and submit relevant dossier and explanation to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government where the applicant is located. Drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government shall conduct the preliminary review of the application dossiers, and issue an acceptance notice of drug registration application if requirements are met, or issue a non-acceptance notice, with reasons, of drug registration application if requirements are not met.

Article 112 For the supplementary application of an import drug, the applicant shall submit relevant dossier and explanations to the State Food and Drug Administration, and provide documents approving the variation issued by the drug regulatory department of the producing country or region. The State Food and Drug Administration shall conduct the preliminary review of the application dossiers, and issue an

acceptance notice of drug registration application if requirements are met, or issue a non-acceptance notice, in which reasons shall be given, of drug registration application if requirements are not met.

Article 113 For any supplementary application to amend the drug registration specifications, change excipients for pharmaceutical use in the drug formulation, or modify the manufacturing process that affects the drug quality, etc., the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government shall provide a review opinion, report it to the State Food and Drug Administration for review and approval, and inform the applicant at the same time.

For supplementary application to amend the drug registration specifications, the drug testing institute shall verify the specifications when necessary.

Article 114 For any supplementary application to change the name of a domestic drug manufacturer, the shelf-life of a domestically produced drug, or the production site by a domestic drug manufacturer internally, etc., the drug regulatory departments of the provinces, autonomous regions, or municipalities directly under the Central Government shall conduct the acceptance, review and approval. Where the regulations are conformed to, it shall issue an Approval for Supplementary Drug Application, and report to the State Food and Drug Administration for record; where the regulations are not conformed to, it shall issue a Disapproval Notice with reasons.

Article 115 Any supplementary application to alter drug packaging label in accordance with regulations, or amend the insert sheet as required by the State Food and Drug Administration, etc. shall be filed to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government for record.

Article 116 Supplementary applications of import drugs shall be reviewed and approved by the State Food and Drug Administration. Those supplementary applications to change the place of production of the drug substance used for any import drug preparation, change the appearance of an import drug not resulting in specification changes, amend the insert sheet of an import drug according to the national specifications or the requirements of the State Food and Drug Administration, update the safety information in the insert sheet of an import drug, alter drug packaging label in accordance with regulations, or change the registration agent shall be filed to the State Food and Drug Administration for record.

Article 117 For supplementary applications of drug manufacturing technology transfer, altering formula or manufacturing process that may affect product quality, etc., the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government shall organize production site inspection, according to the attachment of the Letter of Approval for Drug Registration or the verified manufacturing process. Drug testing institutes shall conduct testing on samples of three batches of product.

Article 118 While reviewing drug supplementary applications, the State Food and Drug Administration may require, with reasons, the applicants to submit additional documents when necessary. Where the regulations are conformed to, it shall issue an Approval for Supplementary Drug Application and a drug approval number; where the regulations are not conformed to, it shall issue a Disapproval Notice with reasons.

Article 119 After the supplementary application is approved, if a drug approval document is to be renewed, the original one shall be cancelled by the State Food and Drug Administration; if an additional drug approval certificate is to be issued, the original one shall remain valid.

Chapter IX
Drug Re-Registration

Article 120 The valid term of a drug approval number, Import Drug License or Pharmaceutical Product License issued by the State Food and Drug Administration is five years. To continue its drug production or importation, the applicant shall submit a re-registration application six months prior to the expiry date.

Article 121 Within the valid term of a drug approval number, Import Drug License or Pharmaceutical Product License, the applicant shall conduct systematic assessment on the safety, efficacy and quality control of the drug such as relevant research results in the observation period, adverse reaction monitoring, production control and product quality consistency, etc.

Article 122 Where applying for drug re-registration, the holder of a drug approval number shall submit the application to the drug regulatory department of the province, autonomous region, or municipality directly under the Central Government, fill in the Application Form for Drug Re-registration, and provide relevant data.

Where applying for an import drug re-registration, the applicant shall submit the application to the State Food and Drug Administration.

Article 123 Drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government shall review the application dossiers, and issue a acceptance notice of drug re-registration application if requirements are met, or issue a non-acceptance notice, in which reasons shall be given, of drug re-registration application if requirements are not met.

Article 124 Drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government shall review the application dossiers within six months starting from the date of acceptance, and approve the re-registration application if regulations are conformed to, or report to the State Food and Drug Administration if regulations are not conformed to.

Article 125 The State Food and Drug Administration shall deal with import drug re-registration applications, complete the review within six months, and approve the re-registration application if regulations are conformed to, or issue a non-acceptance notice, in which reasons shall be given, if regulations are not conformed to.

Article 126 In any of the following circumstances, a drug shall not be re-registered:

(1) the application for re-registration is not made prior to the expiry date;
(2) the relevant requirements set by the State Food and Drug Administration when approved for marketing are not met;
(3) the phase IV clinical trial is not completed as required;
(4) the adverse drug reaction monitoring is not conducted in accordance with regulations;
(5) there are uncertain therapeutic efficacy, serious adverse reaction or other factors harmful to human health upon re-evaluation by the State Food and Drug Administration;
(6) the drug approval documents shall be withdrawn in accordance with the provisions of the Drug Administration Law;
(7) the production conditions prescribed in the Drug Administration Law are not met;
(8) the obligation of observation period is not fulfilled in accordance with regulations; or
(9) there are other circumstances not in conformity with relevant regulations.

Article 127 After receiving the opinions from the drug regulatory departments of the provinces, autonomous regions, or municipalities directly under the Central Government, the State Food and Drug Administration shall review the application. Where the regulations on drug re-registration are not conformed to, a notice of rejection for re-registration shall be issued with reasons.

Where a re-registration application has been rejected, except where the drug approval document is withdrawn due to lawfully defined reasons, the drug approval number, Dug Import License or Pharmaceutical Production Certificate shall be withdrawn on the expiry date.

Chapter X
Testing for Drug Registration

Article 128 Testing for drug registration consists of sample testing and verification of specifications.

Sample testing refers to the testing of samples conducted by a drug testing institute according to the specifications submitted by an applicant or checked by the State Food and Drug Administration.

Verification of specifications refers to the laboratory testing and review conducted by a drug testing institute on the feasibility and scientific basis of the testing methods and the controllability of the set items and indicators of drug quality in the submitted specifications.

Article 129 The National Institute for the Control of Pharmaceutical and Biological Products or the drug testing institutes of the provinces, autonomous regions, and municipalities directly under the Central Government shall take charge of the testing for drug registration. The National Institute for the Control of Pharmaceutical and Biological Products shall arrange testing for import drug registration.

Article 130 The testing for registration of the following drugs shall be conducted by the National Institute for the Control of Pharmaceutical and Biological Products or the drug testing institutes designated by the State Food and Drug Administration:

(1) drugs prescribed in subparagraph (1) and (2) of Article 45 of the Provisions;
(2) biological products and radioactive pharmaceuticals; and
(3) other drugs specified by the State Food and Drug Administration.

Article 131 Where a drug is permitted entering a special review and approval procedure, the drug testing institute shall give priority to sample testing and specification verification.

Article 132 A drug testing institute engaged in testing for drug registration shall, in compliance with the requirements set forth by the Good Laboratory Practice of drug testing institute and national metrology accreditation, have qualified personnel and adequate equipment, and comply with the quality assurance system and technical requirements of the testing for drug registration.

Article 133 An applicant shall provide the relevant data, samples and reference standards, or assist in sampling, which are required for the testing for drug registration. The amount of samples shall be three times the amount used for testing and, for biological products, manufacturing record for the relevant batches of products shall also be provided.

Article 134 While verifying the specifications of a new drug, the drug testing institute shall, in addition to sample testing, give verification opinions in respect of the specifications and test items, etc., of the drug referring to the study data, the specifications of the same kind of products at home and abroad and relevant requirements.

Article 135 Where the specifications are required to be reestablished, the applicant shall not entrust the drug testing institute that gave verification opinions to conduct the specification study of the drug; and the drug testing institute shall not accept such entrustment.

Chapter XI

Drug Registration Specifications and Insert Sheet

Section 1

Drug Registration Specifications

Article 136 National drug standards refer to the Pharmacopoeia of the People's Republic of China, drug registration specifications, etc. published by the State Food and Drug Administration, including the technical requirements such as specifications, testing methods and manufacturing processes, etc.

Drug registration specifications refer to the specified specifications of the applied drug approved by the State Food and Drug Administration to the applicant. The specifications shall be implemented by the drug manufacturer producing the drug.

Drug registration specifications shall not be lower than those required by the Chinese Pharmacopoeia.

Article 137 The establishment of items and the testing methods for drug registration specifications shall be in conformity with the basic requirements of the Chinese Pharmacopoeia, the technical guidelines and rules for compiling the national drug standards published by the State Food and Drug Administration.

Article138 An applicant shall select representative samples for drug registration specifications study.

Section 2
Drug Reference Standards

Article 139 Drug reference standards refer to the materials used in physical, chemical or biological testing specified in specifications and have assigned values of a quantity, and are used for equipment calibration, method validation or value assignment of drugs to be tested, and include reference standards, reference substances, reference crude drugs and reference reagents.

Article 140 The National Institute for the Control of Pharmaceutical and Biological Products shall be responsible for the characterization of national reference standards.

The National Institute for the Control of Pharmaceutical and Biological Products may organize relevant drug testing institute of provinces, autonomous regions, and municipalities directly under the Central Government, drug research institutions or drug manufacturers to undertake collaborative assays of such standards.

Article 141 The National Institute for the Control of Pharmaceutical and Biological Products shall be responsible for the overall technical evaluation of the characterized reference standards in respect of the data of source material selection, preparation methods, testing methods and results, accuracy of value assignment, traceability, stability, filling and packaging conditions, etc. and shall conclude whether or not the candidate materials can be used as national reference standards.

Section 3

Drug Name, Insert Sheet and Label

Article 142 The name, insert sheet and label of any drug for which the registration is applied, shall comply with the provisions of the State Food and Drug Administration.

Article 143 The drug insert sheet and label shall be provided by the applicant. The Center for Drug Evaluation of the State Food and Drug Administration shall review the contents thereof except the manufacturer information, and the State Food and Drug Administration shall review and approve the data when approving the drug production.

The applicant shall be responsible for making the drug insert sheet and label scientific, standard and accurate.

Article 144 The applicant shall monitor the safety and efficacy of a marketed drug, and submit supplementary application to modify the drug insert sheet in time.

Article 145 The applicant shall print the insert sheets and labels according to the format and requirements established by the State Food and Drug Administration, and in conformity with the contents approved.

Chapter XII

Timeline

Article 146 The drug regulatory department shall follow the provisions on the timeline for drug registration set forth in the Drug Administration Law, the Administrative Permission Law and the Regulations for Implementation of the Drug Administration Law. The timeline for drug registration in the Provisions refers to the maximum time for acceptance, review and approval of drug registration. The time for the suspension of the review and approval prescribed in laws and regulations or for the applicant to supplement data is not included.

The time for the testing for drug registration and for the review shall be kept in accordance with the Provisions. Where there is a need for time extension in particular situation, it, with reasons provided, shall be reported to the State Food and Drug Administration for approval, and the applicant shall be informed thereof.

Article 147 Drug regulatory departments shall conduct preliminary review on applications, and proceed according to the following circumstances respectively:

(1) Where no administrative approval is needed for any application item by law, the non-acceptance of the application thereof shall be informed to the applicant in time;
(2) Where an application item is not subject to the jurisdiction of the concerned departments by law, it shall be decided not to accept the application in time and informed to the applicant to apply to the relevant administrative departments;
(3) Where there is an error that can be corrected on-site in the dossier, the on-site correction shall be allowed;
(4) Where the dossier is incomplete or not conformed with the defined format, the applicant shall be informed on-site or within five days at once of what to be supplemented or corrected; if it is not informed to the applicant within the timeline, the application is regarded as accepted on the date the dossier is received; and
(5) Where the application item is subject to the jurisdiction of the concerned departments, and the dossier is complete and conformed with the defined format or the applicant has submitted all the required supplementary or corrected data, the application of drug registration shall be accepted.

Where a drug regulatory department accepts or rejects a drug registration application, it shall issue a written receipt on which there shall be a stamp of registration and date.

Article 148 The drug regulatory department of a province, autonomous region, or municipality directly under the Central Government shall complete the check of drug development conditions and raw data, the review of application dossiers, sampling, the notice to drug testing institutes for conducting testing for drug registration, the submission of review opinions, inspection report and application dossiers to the State Food and Drug Administration, and the notice to the applicant of the review opinions within 30 days starting from the date an application is accepted.

Article 149 The time for the testing for drug registration shall be kept in accordance with the following provisions:

(1) sample testing: 30 days; sample testing and specifications verification : 60 days; and
(2) sample testing of a controlled drug or vaccine: 60 days; sample testing and specifications verification: 90 days.

The sample testing for a drug used for clinical trial conducted by a drug testing institute, as prescribed in Article 36 of the Provisions, shall be completed within the time for sample testing in the previous clause.

Article 150 The time for technical review shall be kept in accordance with the following provisions:

(1) new drug application for clinical trial: 90 days; any drug permitted to enter the special review and approval procedures: 80 days;
(2) new drug application for production: 150 days; any drug permitted to enter the special review and approval procedures: 120 days;
(3) the application for changing the dosage form of a marketed drug or for a generic drug: 160 days; and
(4) the supplementary application subject to technical review: 40 days.

The time for the technical review of an import drug registration application shall be kept in accordance with the previous clause.

Article 151 Where the applicant is required to supplement data in the process of technical review, a Deficiency Notice should be issued at one time. Where the applicant disagrees on the contents of the Deficiency Notice, the opinions of the applicant may be heard vis-à-vis. The applicant shall provide supplementary data at one time according to the requirements in the notice within four months; where an application enters the special review and approval procedures, it shall be handled in conformity with the requirements of the relevant procedures.

After receiving the supplementing data, the technical review shall be completed in no more than one third of the original time; for applications entering the special review and approval procedures, the review shall be completed in no more than one fourth of the original time.

Where an application is recalled by the applicant in the process of drug registration, the review and approval procedure is terminated henceforth.

Article 152 The State Food and Drug Administration shall make the review and approval decision within 20 days; where a decision cannot be made within 20 days, another ten days may be extended with the approval of the State Food and Drug Administration head in charge, and the applicant shall be informed of the reason of the time extended.

Article 153 The State Food and Drug Administration shall issue and deliver relevant administrative licensing certificates within ten days from the date the review and approval decision is made.

Chapter XIII
Second Review

Article 154 Where there is any of the following circumstances, the State Food and Drug Administration shall not approve the application:

(1) different applicants submit the same or almost the same research data without justified reasons;

(2) when the application dossier is found false in the process of registration, and the applicant cannot prove the authenticity thereof;

(3) the design and performance of the research project are not able to support to evaluate the safety, efficacy and quality of the drug applied for registration ;

(4) there are critical defects regarding the safety, efficacy and quality in the submitted dossier of the drug applied for registration;

(5) an applicant fails to provide supplementary data within the prescribed timeline;

(6) the source of drug substances does not meet the requirements;

(7) the result of production site inspection or sample testing does not meet the requirements;

(8) other circumstances in which applications shall not be approved according to laws and regulations.

Article 155 The written non-acceptance or unapproval decision made by drug regulatory departments by law shall provide the reasons thereof, and inform the applicant of the right to apply for administrative reconsideration or to bring an administrative suit by law.

Article 156 If holding any dispute on the unapproval decision made by the State Food and Drug Administration, an applicant may, within 60 days after receiving the decision, fill in the Application Form for Drug Registration Second Review, and submit the application to the State Food and Drug Administration and provide reasons.

The content of second review shall not exceed the originally applied items and the original application dossier.

Article 157 The State Food and Drug Administration shall make a second review decision, and notify the applicant the decision within 50 days after receiving an application for second review. Where the original decision is affirmed, the State Food and Drug Administration shall not accept any further application for second review thereof.

Article 158 Where there is any need for technical review in second review, the State Food and Drug Administration shall organize relevant technical personnel to conduct review within the timeline as that for the original application.

Chapter XIV
Legal Liabilities

Article 159 In any of the circumstances prescribed in Article 69 of the Administrative Permission Law, the State Food and Drug Administration may withdraw the relevant drug approval documents upon the request of any interest party or according to its responsibilities and authorities.

Article 160 Any drug regulatory department or its staff members that violate the provisions of this Provisions and constitute any of the circumstances below shall be instructed by its superior administrative department or supervisory departments to make rectification. If the circumstances are serious, administrative sanctions shall be given to the persons directly in charge and the other persons directly responsible in accordance with law:

(1) not accepting a drug registration application that is in conformity with regulatory requirements;
(2) not publicizing at the acceptance place the information that shall be publicized by la]w;
(3) in the process of acceptance, review and approval, not fulfilling the regulatory informing obligation to the applicant or interest party;
(4) not informing the applicant at once of all the contents needed to be supplemented or corrected, where the drug application dossier submitted is incomplete or not conformed with the required format;
(5) not stating the reasons of non-acceptance or unapproval of a drug registration application by law; and
(6) not holding hearings that shall be held by law.

Article 161 If any drug regulatory department and its staff members request for or accept money or valuable articles from others, or pursue other interests in the process of drug registrations, where a crime is committed, criminal liabilities shall be investigated by law; where a crime is not committed, administrative sanctions shall be given by law.

Article 162 Any drug regulatory department that constitutes any of the following circumstances in the process of drug registration shall be instructed by its superior administrative department or supervisory departments to make rectification, and administrative sanctions shall be given to the persons directly in charge and the other persons directly responsible by law; if a crime is committed, criminal liabilities shall be investigated by law:

(1) making a decision to approve any registration application that does not meet the regulatory requirements prescribed in the Provisions or acting beyond regulatory responsibilities and authorities to make such a decision;
(2) making a decision to disapprove a registration application conformed with the regulatory requirements, or failing to make a decision to approve a registration application within the regulatory timeline; and
(3) failing to perform the confidentiality obligation in violating the requirements prescribed in Article Nine of the Provisions.

Article 163 When undertaking testing for drug review and approval, a drug testing institute that issues a false certificate of analysis shall be punished in accordance with the provisions in Article 87 of the Drug Administration Law.

Article 164 Any drug regulatory department that charges fees without permission or does not charge fees according to set items and rates shall be instructed by its superior administrative department or supervisory departments to return the illegal charges; and administrative sanctions shall be given to the persons directly in charge and the other persons directly responsible by law.

Article 165 Where the Good Laboratory Practice for Non-Clinical Laboratory Studies or the Good Clinical Practice is not executed in the process of drug registration according to regulations, punishments shall be given in accordance with the provisions in Article 79 of the Drug Administration Law.

Article 166 Where an applicant submits false drug registration dossier and samples when applying for clinical trial, the drug regulatory department shall not accept the application or disapprove the applied

clinical trial, give a disciplinary warning to the applicant, and not accept any further application for clinical trial of the drug made by the applicant within one year; where clinical trial of the drug is already approved, the Drug Clinical Trial Approval shall be withdrawn, a fine of no less than 10,000 yuan but no more than 30,000 yuan shall also be imposed, and no further application for clinical trial of the drug made by the applicant shall be accepted within three years.

The State Food and Drug Administration shall keep records of the fraud acts of applicants that submit false dossier and samples, and publicize such records.

Article 167 Where an applicant submits false drug registration dossier and samples when applying for drug production or importation, the State Food and Drug Administration shall not accept or disapprove the application, give a disciplinary warning to the applicant, and not accept any further application made by the applicant within one year; where the production or importation of the drug is already approved, the drug approval documents shall be withdrawn, no further application made by the applicant shall be accepted within five years, and a fine of no less than 10,000 yuan but no more than 30,000 yuan shall also be imposed.

Article 168 According to the provisions in Article 27 of the Provisions, where a drug testing needs to be repeated but the applicant refuses to do so, the State Food and Drug Administration shall give a warning and instruct to make rectification; if the applicant refuses to make rectification, the application thereof shall not be approved.

Article 169 Where there is any of the following circumstances, the State Food and Drug Administration shall withdraw the drug approval number, and announce to the public:

(1) the applicant requests to annul its own drug approval number before the drug approval document expires;
(2) the re-registration is not allowed according to provisions in Article 126 of the Provisions;
(3) the Drug Manufacturing Certificate is revoked or withdrawn by law;
(4) according to provisions in Article 42 of the Drug Administration Law or Article 41 of the Regulations for Implementation of the Drug Administration Law, the drug approval document is withdrawn for any drug with serious adverse reactions or other factors harmful to human health;
(5) a decision is made to give an administrative sanction of revoking the drug approval document by law;

and

(6) other circumstances in which the drug approval documents shall be withdrawn or recalled by law.

Chapter XV
Supplementary Provisions

Article 170 The application dossier and requirements of traditional Chinese medicines and natural medicines, pharmaceutical products, biological products, supplementary applications and re-registration application shall be referred to Annex 1, 2, 3, 4, 5 of the Provisions, seriatim. Provisions on observation period are prescribed in Annex 6.

Article 171 The format of drug approval number: Guo Yao Zhun Zi H (or Z/S/J)+ four-digit year number+ four-digit sequence number; H standing for pharmaceutical products, Z for traditional Chinese medicines, S for biological products and J for repackaged import drugs.

The format of Import Drug License number: H (or Z/S)+ four-digit year number+ four-digit sequence number; that of Pharmaceutical Product License number: H (or Z/S) C+ four-digit year number+ four-digit sequence number; H standing for pharmaceutical products, Z for traditional Chinese medicines, S for biological products. For a drug repackaged in China using the license for the large package, the letter B shall be added before the registration number of the original license thereof.

The format of new drug certificate number: Guo Yao Zheng Zi H (or Z/S)＋four-digit year number+ four-digit sequence number; H standing for pharmaceutical products, Z for traditional Chinese medicines, S for biological products.

Article 172 The acceptance of applications, review and approval of supplementary applications and of re-registration applications undertaken by the drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government prescribed by the Provisions are items delegated by the State Food and Drug Administration. The State Food and Drug Administration may also delegate the drug regulatory departments of provinces, autonomous regions, or municipalities directly under the Central Government to conduct other technical review and review and approval of drug registration.

Article 173 The State Food and Drug Administration adopts the coding management for drugs approved for marketing. The provisions for coding management are separately formulated.

Article 174 The registration applications for narcotic drugs, psychotropic substances, toxic medicines and radioactive pharmaceuticals, besides complying with the Provisions, shall also conform with other relevant State regulations.

Article 175 The provisions for registration of Chinese crude drugs, prepared slices of Chinese crude drugs and import Chinese crude drugs regulated via approval numbers shall be separately formulated by the State Food and Drug Administration.

Article 176 The provisions for drug technology transfer and entrusted manufacturing shall be separately formulated.

Article 177 The Provisions shall go into effect as of October 1, 2007. The Provisions for Drug Registration (Order No. 17 of the State Food and Drug Administration) issued by the State Food and Drug Administration on February 28, 2005 shall be repealed at the same time.