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中国食品药品国际交流中心
SERVIER
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Decision on Authorizing the State Council to carry out the Pilot of Drug Market Authorization Holder System in Some Regions and Related is Issues

In order to promote the reform of review and approval system for drugs, to encourage pharmaceutical innovation, improve drug quality, and provide practical experience to further reform and improve the drug administration system, the Seventeenth Session of the Twelfth NPC Standing Committee has approved *Market Authorization Holder,* decided:

I. Authorize the State Council to carry out the Pilot of Drug Market Authorization Holder System in ten provinces and municipalities directly under the central government: Beijing, Tianjin, Hebei, Shanghai, Jiangsu, Zhejiang, Fujian, Shandong, Guangdong, and Sichuan, to allow pharmaceutical R&D institutions and researchers to obtain drug approval numbers, and correspondingly be held accountable for drug quality.

II. Permit the State Council to organize and conduct reform of drug registration classification, to improve drug quality, and promote the transformation and upgrading of China pharmaceutical industry. To this end, in accordance with the relevant provisions of *the Drug Administration Law of the People's Republic of China*, for approval for production of drugs subject to current national standards, they shall meet national drug standards and achieve the quality and efficacy consistent with those of the originators; for approval for production of drugs already marketed overseas but not yet in China, if there are no corresponding national drug standards yet, these drugs shall ensure their consistency of quality and efficacy with those of the originators. CFDA should promptly develop and revise applicable national drug standards in accordance with the above requirements.

The term for the authorized pilot in the *Decision* is three years, starting from the effective date of the *Decision*. CFDA shall develop specific pilot programs, which are to be approved by the State Council, and then submitted to the NPC Standing Committee for filing. During the course of the pilot, the State Council shall strengthen its organization, guidance, supervision and inspection for the pilot, to ensure drug quality and safety. Upon expiry of the pilots, for those proven feasible in practice, the corresponding provisions of the *Drug Administration Law* shall be revised and improved; for those proven to be inadvisable for adjustments, the relevant provisions of the *Drug Administration Law* shall be restored for implementation. The valid period of drug approval numbers acquired during the course of the pilot shall survive the termination of the pilot. Before the expiration of the pilot period, the State Council shall submit to the NPC Standing Committee a report on the implementation status of this *Decision*.

This Decision shall become effective as from November 5, 2015. (November 5, 2015)

《关于授权国务院在部分地方开展药品上市许可持有人制度试点和有关问题的决定》发布

为了推进药品审评审批制度改革，鼓励药品创新，提升药品质量，为进一步改革完善药品管理制度提供实践经验，第十二届全国人民代表大会常务委员会第十七次会议通过了《关于授权国务院在部分地方开展药品上市许可持有人制度试点和有关问题的决定》，决定：

一、授权国务院在北京、天津、河北、上海、江苏、浙江、福建、山东、广东、四川十个省、直辖市开展药品上市许可持有人制度试点，允许药品研发机构和科研人员取得药品批准文号，对药品质量承担相应责任。

二、同意国务院组织开展药品注册分类改革，提升药品质量，推进我国药品产业转型升级。为此，依照《中华人民共和国药品管理法》相关规定，批准生产已有国家药品标准的药品，应当符合国家药品标准，并达到原研药品的质量和疗效；批准生产在境外已经上市在境内尚未上市的药品，尚无国家药品标准的，应当达到原研药品的质量和疗效。国家食品药品监督管理总局应当按照上述要求及时制定、修订相关国家药品标准。

本决定授权的试点期限为三年，自本决定施行之日起算。国家食品药品监督管理总局制定具体试点方案，经国务院批准后报全国人民代表大会常务委员会备案。试点期间，国务院要加强对试点工作的组织指导和监督检查，保证药品质量和安全。试点期满后，对实践证明可行的，修改完善《中华人民共和国药品管理法》；对实践证明不宜调整的，恢复实施《中华人民共和国药品管理法》的规定。试点期间取得的药品批准文号，在试点期满后继续有效。试点期限届满前，国务院向全国人民代表大会常务委员会提出本决定实施情况的报告。

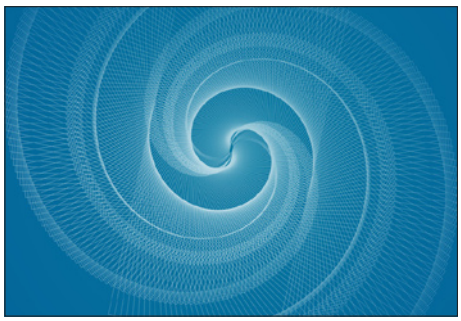
本决定自2015年11月5日起施行。

（2015-11-05）

Published by
China Center for Food and Drug International Exchange & Servier (Tianjin) Pharmaceutical Co., Ltd.

CFDA Issued *Announcement on the Review & Inspection over Drug Clinical Trial Institution Qualification*

On October 21, 2015, CFDA issued the *Announcement on the Verification & Inspection over Drug Clinical Trial Institution Qualification* ([2015] No. 202). It reads as follows:



According to relevant provisions of *Drug Administration Law of the People's Republic of China, Provisions for Drug Clinical Trial Institution Qualification* (Interim) and *Work Program for the Review & Inspection over Drug Clinical Trial Institution Qualification*, after on-site inspection, technical review and joint review & inspection by CFDA and NHFPC, 76 medical institutions and their listed specialities passed the review & Inspection, while two specialities of two medical institutions failed in the review & Inspection and were thereby canceled (Annex omitted).

(October 23, 2015)

国家食品药品监督管理总局发布《药物临床试验机构资格认定复核检查公告》

2015年10月21日，国家食品药品监督管理总局发布《药物临床试验机构资格认定复核检查公告》（2015年第202号）。内容如下:

根据《中华人民共和国药品管理法》、《药物临床试验机构资格认定办法（试行）》及《药物临床试验机构资格认定复核检查工作方案》的有关规定，经现场检查、技术审核以及国家食品药品监督管理总局、国家卫生和计划生育委员会联合会审，认定76家医疗机构及所列专业通过药物临床试验机构资格认定复核检查，2家医疗机构的2个专业未通过药物临床试验机构资格认定复核检查，予以取消（附件略）。 （2015-10-23）

CFDA Issued the Announcement on *Withdrawal of Registration Application upon Self-Examination & Verification of Drug Clinical Trial Data*

On October 15, 2015, China Food and Drug Administration (CFDA) issued the Announcement on *Withdrawal of Registration Application upon Self-Examination & Verification of Drug Clinical Trial Data*, to announce 18 withdrawn cases of drug registration application in the wake of the *Announcement on Status Quo of Self-Examination of Drug Clinical Trial Data* (CFDA Announcement [2015] No. 169).

Of the 8 registration applications concurrently filed by multiple applicants but withdrawn with disagreements, six registration applications, including that for rupatadine fumarate tablets, were subject to withdrawal process due to relevant applicants' failure to submit descriptive statements within the specified time limit. While the relevant applicants for registration of Golden Grass Antitussive Oral Liquid and Anti-TNF-α Human-mouse Chimeric RcMAb Injection have reached a consensus and submitted descriptive statements to retain the application for registration of related drug varieties.

In addition, relevant applicants have applied for Withdrawal of 12 drug registration applications, which have been handled by CFDA accordingly and exempted from further verification and investigation.

(October 15, 2015)

国家食品药品监督管理总局发布《关于药物临床试验数据自查核查撤回注册申请情况的公告》

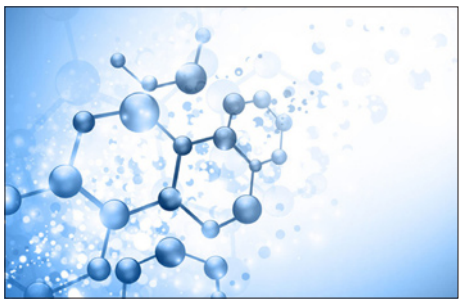
2015年10月15日，国家食品药品监督管理总局发布了《关于药物临床试验数据自查核查撤回注册申请情况的公告》，就《关于药物临床试验数据自查情况的公告》（国家食品药品监督管理总局公告2015年第169号）之后，18个药品注册申请撤回情况给予公告。

其中，多个申请人共同申报但撤回意见不一致的8个注册申请中，富马酸卢帕他定片等6个注册申请相关申请人逾期未提交情况说明，按撤回注册申请处理。金草止咳口服液和注射用重组抗肿瘤坏死因子α人鼠嵌合单克隆抗体的注册申请相关申请人达成一致意见，提交了情况说明，要求保留相关品种注册申请。

另外，12个药品注册申请的相关申请人主动申请撤回，国家食品药品监督管理总局予以办理撤回注册申请，不予核查及立案调查。 （2015-10-15）

CFDA, National Health and Family Planning Commission, and the Health Department of PLA General Logistics Department Jointly Issue *Announcement on Conducting Self-Examination by Drug Clinical Trial Institutions*

Drug clinical trial institutions play an important role in drug clinical trials. The quality of clinical trials and the accuracy of clinical trial data submitted by investigators are directly related to the evaluation results of safety and effectiveness for marketed drugs, and are of particular importance to ensuring drug safety for the public. Recently China Food and Drug Administration (CFDA) issued the *Announcement on Conducting Self-Examination & Verification of Drug Clinical Trial Data* (2015, No. 117, hereinafter referred to as "Announcement No. 117"), which laid out a plan to conduct drug clinical trial data verification on drug registration applications for production or importation that are submitted but pending review. To better fulfill the task of self-examination & verification, on September 24, 2015, CFDA, the National Health and Family Planning Commission, and the Health Department of PLA General Logistics Department jointly issued the *Announcement on Conducting Self-Examination by Drug Clinical Trial Institutions*. The relevant issues are announced as follows:



I. Take the initiative to carry out self-examination of clinical trial data. Drug clinical trial institutions shall, as per Announcement No. 117, cooperate with drug registration applicants to effectively perform self-examination of clinical trial data. Clinical trial institutions should sort out the drug varieties that they have conducted clinical trials on, and evaluate the authenticity and integrity of their own clinical trial data on the basis of self-examination and the results of previous drug clinical trial supervision and inspections.

II. Coordinate in the preparation for on-site inspection. Drug clinical trial institutions shall, as per Announcement No. 117, prepare the records and documents related to drug clinical trials, and cooperate with inspectors for effective verification.

III. Seriously deal with violations against laws and regulations. All drug clinical trial institutions should strengthen the management of drug clinical trials and impose heavy penalties on frauds in drug clinical trials. Fraudulent acts identified in on-site inspections shall be severely punished as per Announcement No. 117 and relevant regulations.

(September 24, 2015)

国家食品药品监督管理总局 国家卫生和计划生育委员会 中国人民解放军总后勤部卫生部发布《关于开展药物临床试验机构自查的公告》

药物临床试验机构在药物临床试验中承担着重要作用，临床试验的质量、研究者提交的临床试验数据的准确性直接关系到上市药品安全、有效评价结果，对保证公众用药安全具有特别重要的意义。近期国家食品药品监管总局发布了《关于开展药物临床试验数据自查核查工作的公告》（2015年第117号，以下简称第117号公告），将对已申报生产或进口的待审药品注册申请开展药物临床试验数据核查，为了做好自查核查工作，2015年9月24日，国家食品药品监督管理总局、国家卫生和计划生育委员会、中国人民解放军总后勤部卫生部三部门联合发布《关于开展药物临床试验机构自查的公告》，就涉及药物临床试验机构的有关事宜公告如下：

一、主动开展临床试验数据的自查。药物临床试验机构应按照第117号公告，配合药品注册申请人做好临床试验数据自查工作。要梳理所承担临床试验的品种，结合自查情况以及既往药物临床试验机构监督检查结果，对本机构药物临床试验数据的真实性、完整性作出评价。

二、认真配合做好接受现场检查准备。药物临床试验机构应按照第117号公告，准备药物临床试验相关记录、文件资料，配合检查人员做好核查工作。

三、严肃处理违法违规行为。各药物临床试验机构要加强对药物临床试验的管理，对药物临床试验弄虚作假的，要严厉追究责任。在现场检查中发现上述问题的，将按照第117号公告及相关的规定严肃处理。（2015-09-24）

Food

CFDA Issues Notice *on the Implementation of Administrative Measures for Food Production Licensing*

The newly revised *Administrative Measures for Food Production Licensing* (CFDA Order No. 16, hereinafter referred to as the "Measures") will be formally implemented as of October 1, 2015. To provide guidance for local food and drug regulatory authorities at all levels to implement the food (including food additives, the same below) production licensing system, on September 30, 2015, CFDA issued a *Notice on the*

食品

国家食品药品监督管理总局发布《关于贯彻实施<食品生产许可管理办法>的通知》

新修订的《食品生产许可管理办法》（国家食品药品监督管理总局令第16号，以下简称《办法》）将于2015年10月1日正式实施。为指导地方各级食品药品监督

Implementation of Administrative Measures for Food Production Licensing to notify of issues related to the implementation of the Measures, including: the relationship between the Measures and the original regulations; the delegation and smooth transfer of approval authority for food production licensing; the implementation of "One Enterprise, One License" policy; the alterations and renewal of old version of food production licenses; the markings of Food Production License numbers and "QS" signs; the food category codes in the Food Production License numbers; the review of food testing reports; the implementation of industry policies; the implementation of supportive measures; and the strengthening of supervision over administrative licensing, etc. (September 30, 2015)

管理部门认真贯彻执行食品（含食品添加剂，下同）生产许可制度，2015年9月30日，国家食品药品监督管理总局发布《关于贯彻实施〈食品生产许可管理办法〉的通知》，就《办法》实施的有关事项进行通知。通知包括，关于《办法》与原有规章制度的关系、食品生产许可审批权限下放许可审批权限的平稳移交、“一企一证”的实施、旧版食品生产许可证变更及延续、食品生产许可证编号标注及“QS”标志、食品生产许可证编号的食品类别编码、食品检验报告的核查、产业政策的执行、落实工作保障、加强行政许可监督等事项。（2015-09-30）

Food Distribution License Will Be Used

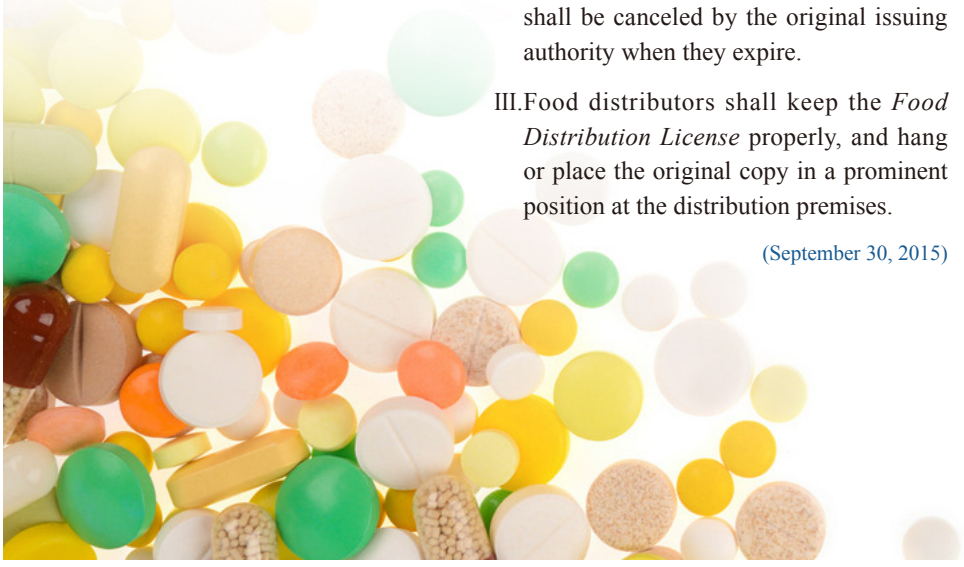
To fully implement the requirements of *Food Safety Law of the People's Republic of China*, the *Administrative Measures for Food Distribution Licensing* (CFDA Order No. 17) and other laws, regulations and provisions, China Food and Drug Administration (CFDA) decided to officially start using the *Food Distribution License* from October 1, 2015. The related matters are announced as follows:

I. CFDA shall be responsible for designing the original and duplicate copies of the *Food Distribution License*. Food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government shall be responsible for organizing the printing and issuing of the *Food Distribution License* within their respective administrative areas.

II. The original Food Circulation License and Catering Service License, if not expired, shall remain valid; if a food distributor applies to replace the original license that is still within its term of validity with the *Food Distribution License*, the competent licensing authorities shall issue the new license in accordance with the relevant regulations; the original Food Circulation License and Catering Service License shall be canceled by the original issuing authority when they expire.

III. Food distributors shall keep the *Food Distribution License* properly, and hang or place the original copy in a prominent position at the distribution premises.

(September 30, 2015)



国家食品药品监督管理总局启用《食品经营许可证》

为全面贯彻落实《中华人民共和国食品安全法》、《食品经营许可管理办法》（国家食品药品监督管理总局令第17号）等法律、法规及规章要求，国家食品药品监督管理总局决定自2015年10月1日起，正式启用《食品经营许可证》，并将有关事宜公告如下：

一、国家食品药品监督管理总局负责制定《食品经营许可证》正本、副本式样。各省、自治区、直辖市食品药品监督管理部门负责组织本行政区域《食品经营许可证》的印制、发放等工作。

二、原食品流通、餐饮服务许可证有效期未届满的继续有效；食品经营者在原食品流通、餐饮服务许可证有效期内申请更换为食品经营许可证的，许可机关应按照有关规定予以更换；原食品流通、餐饮服务许可证有效期届满，由原发证机关予以注销。

三、食品经营者应当妥善保管《食品经营许可证》，应当在经营场所的显著位置悬挂或者摆放《食品经营许可证》正本。（2015-09-30）

New Version of *Food Production License* Will Be Used

To fully implement the *Food Safety Law of the People's Republic of China and the Administrative Measures for Food Production Licensing* (CFDA Order No. 16), China Food and Drug Administration (CFDA) decided to officially start using the new version of *Food Production License* from October 1, 2015. The relevant matters are announced as follows:

I. CFDA shall be responsible for designing the original and duplicate copies of the new *Food Production License*. Food and drug regulatory authorities of the provinces, autonomous regions and municipalities directly under the central government shall be responsible for printing and issuing the *Food Production License* within their respective administrative areas.

II. The old version food & food additive production license, if not expired, shall remain valid; if a producer applies to replace the old version of license that is still within its term of validity with the new *Food Production License*, the competent licensing authorities shall issue the new license in accordance with relevant regulations.

III. When a producer who holds the old version food & food additive production license applies for alteration and renewal of the production license, the new *Food Production License* shall be issued to replace the original license. A producer who holds more than one Food Production Licenses of the old version can either apply for an all-in-one new version of *Food Production License*, or apply separately for different licenses, with the changed food production categories renewed on the duplicates of the new *Food Production Licenses*.

IV. Licensing authorities for food and food additive production shall timely disclose the issuance, alteration, and renewal of food & food additive production license and other information in accordance with relevant government provisions on information disclosure.

V. Food manufacturers shall keep the *Food Production License* properly, and hang or place the original copy in a prominent position at the production sites.

(September 30, 2015)

国家食品药品监督管理总局启用新版《食品生产许可证》

为全面贯彻落实《中华人民共和国食品安全法》、《食品生产许可管理办法》（国家食品药品监督管理总局令第16号）要求，国家食品药品监督管理总局决定自2015年10月1日起，正式启用新版《食品生产许可证》。将有关事宜公告如下：

一、国家食品药品监督管理总局负责制定新版《食品生产许可证》正本、副本式样。各省、自治区、直辖市食品药品监督管理部门负责本行政区域《食品生产许可证》的印制、发放等管理工作。

二、旧版食品、食品添加剂生产许可证有效期未届满的，继续有效；生产者在旧版食品、食品添加剂生产许可证有效期内申请更换新版《食品生产许可证》的，许可机关应按照有关规定予以更换。

三、持有旧版食品、食品添加剂生产许可证的生产者，提出生产许可变更、延续等申请的，一律换发新版《食品生产许可证》。持有多张旧版食品生产许可证的，可以一并申请换发一张新版《食品生产许可证》；也可以分别申请，其生产的食品类别在已换发的新版《食品生产许可证》副本上予以变更。

四、食品、食品添加剂生产许可机关应按照政府信息公开有关规定，及时公布食品、食品添加剂生产许可证颁发、变更、延续等信息。

五、食品生产者应当妥善保管《食品生产许可证》，并在其生产场所的显著位置悬挂或者摆放《食品生产许可证》正本。

（2015-09-30）

CFDA Issues *General Provisions for Examination of Food Distribution Licensing (Interim)*

Administrative Measures for Food Distribution Licensing (hereinafter referred to as the "Measures") shall be formally implemented as of October 1, 2015. For smooth implementation of the Measures, China Food and Drug Administration (CFDA) developed the *General Provisions for Examination of Food Distribution Licensing*, which was issued on September 30, 2015 and took effective thenceforward. Food and drug regulatory authorities of all provinces, autonomous regions and municipalities directly under the central government, Xinjiang Production and Construction Corps Food and Drug Administration are requested to act accordingly.

(September 30, 2015)

国家食品药品监督管理总局印发《食品经营许可审查通则（试行）》

《食品经营许可管理办法》（以下简称《办法》）将于2015年10月1日正式实施。为保障《办法》的顺利贯彻实施，国家食品药品监督管理总局制定了《食品经营许可审查通则（试行）》，于2015年9月30日印发，要求各省、自治区、直辖市食品药品监督管理局，新疆生产建设兵团食品药品监督管理局遵照执行。《食品经营许可审查通则（试行）》自发布之日实行。（2015-09-30）

Medical Devices

CFDA issued the *Administrative Measures for Quality Supervision on the Use of Medical Devices*

On October 21, 2015, CFDA issued the *Administrative Measures for Quality Supervision on the Use of Medical Devices* (CFDA Order No. 18) (hereinafter referred to as the "*Measures*"), which consist of 35 Articles in six Chapters and will take effect as from February 1, 2016.

To address the current salient problems in medical device consumption units as improper procurement channels, unfulfilled in-coming inspection, lackadaisical maintenance & repair, and imperfect quality management, the *Measures* refined, reinforced and improved the quality management obligations in use process as stipulated in the *Regulations for the Supervision and Administration of Medical Devices*, including in-coming inspection, information recording, storage & transportation, quality inspection, maintenance & repair, and etc.

By clarifying the management regulations of all aspects related to the quality in use, such as medical device procurement, acceptance inspection, storage, use, maintenance, transfer and etc. the *Measures* require medical device consumption units to establish medical devices use management system covering the whole process of quality management, and to conduct comprehensive QMS self-inspection annually. First, establish more stringent requirements for quality inspection management. The consumption units shall perform unified management of medical device procurement, strictly inspect the supplier qualification and product documentation, keep relevant records and information, and establish pre-use quality inspection system for medical devices. Second, strengthen the maintenance & repair management. To address the outstanding problems exist in practice, the *Measures* specified the management requirements for maintenance & repair by consumption units themselves, service agencies upon entrustment, manufacturers/distributors upon agreement, as well as other circumstances. It is clearly defined that, for maintenance & repair by consumption units themselves, or by service agencies upon entrustment, manufacturers/distributors shall strictly abide by the contract terms to provide maintenance manuals, fault codes, maintenance passwords and other maintenance materials and information necessary for maintenance & repair service. Third, improve the management of transfer and donation of in-use medical devices. The *Measures* require that the consumption units should ensure the safety and effectiveness of their transferred medical devices, and timely transfer the instructions, maintenance records and other materials; in the meantime, the transferee shall perform in-coming inspection as required. In the view of the growing number of medical device donations, the *Measures* raised requirements for both donors and grantees, stipulating that the donations between consumption units shall refer to the transfer management. Fourth, strengthen classified supervision and credit regulation. The *Measures* stressed the principle of risk-based regulation, to implement intensive supervision over medical devices with high risk or those with special storage and transportation requirements, as well as over medical device consumption units with bad credit records.

The introduction of the *Measures* further enriched the supporting regulation system of the *Regulations for the Supervision and Administration of Medical Devices*, it is of great significance for strengthening the supervision and administration of medical devices and securing the safe use of medical devices. (October 23, 2015)

医疗器械

国家食品药品监督管理总局发布《医疗器械使用质量监督管理办法》

2015年10月21日,国家食品药品监督管理总局发布《医疗器械使用质量监督管理办法》（国家食品药品监督管理总局令第18号）（以下简称《办法》）。《办法》共六章35条，将于2016年2月1日起施行。

《办法》针对当前医疗器械使用单位采购渠道不规范、进货查验不落实、维护保养不严格、质量管理不完善等问题，对《医疗器械监督管理条例》规定的进货查验、信息记录、贮存运输、质量检查、维护保养等使用环节质量管理义务作了细化和补充完善。

《办法》明确了医疗器械采购、验收、贮存、使用、维护、转让等与使用质量密切相关的各个环节的管理规定，要求医疗器械使用单位建立覆盖质量管理全过程的医疗器械使用管理制度，并每年对质量管理工作进行全面自查。一是严格质量查验管理要求。规定使用单位要对医疗器械采购实行统一管理，严格查验供货商资质和产品证明文件，妥善保存相关记录和资料，并建立医疗器械使用前质量检查制度。二是加强维护维修管理。针对实践中存在的突出问题，详细规定了使用单位自行维护维修、委托维修服务机构维护维修、约定生产经营企业维护维修等不同情形的管理要求，明确规定在使用单位自行维护维修或者委托维修服务机构维护维修时，生产经营企业应当严格按照合同约定，提供维护手册、故障代码表、维修密码等维护维修必需的材料和信息。三是完善在用医疗器械转让和捐赠管理。规定使用单位转让医疗器械应当确保所转让的医疗器械安全、有效，及时移交说明书、维修记录等资料，受让方应当参照相关要求进行进货查验。针对越来越多的医疗器械捐赠行为，《办法》对捐赠方和受赠方均提出了要求，并规定使用单位之间的捐赠参照转让管理。四是强化分类监管和信用监管。强调依风险实施监管的原则，对较高风险或者有特殊储运要求的医疗器械，以及有不良信用记录的医疗器械使用单位等实施重点监管。

《办法》的出台进一步丰富了《医疗器械监督管理条例》配套规章体系，对加强医疗器械监督管理，保障用械安全具有重要意义。（2015-10-23）

CFDA Issued *Guidelines for Medical Device Good Supply Practice On-Site Inspection*

To strengthen the supervision and management of medical device distribution, standardize and guide medical device GSP on-site inspection, according to the *Medical Device Good Supply Practice*, CFDA formulated and issued the *Guidelines for Medical Device Good Supply Practice On-Site Inspection* (hereinafter referred to as Guidelines) on October 15, 2015.

The *Guidelines* apply to food and drug regulatory authorities' on-site inspection over the licensing (including alteration and renewal) of wholesale/retail distributors of Class III medical devices; to on-site inspection after record filing of wholesale/retail distributors of Class II medical devices; as well as to a variety of supervision and inspection over medical device distributors. Food and Drug Administration of all provinces, autonomous regions, and municipalities directly under the central government, and the Xinjiang Production and Construction Corps shall inspect medical device distributors' implementation of *Medical Device Good Supply Practice* in light of the inspection items and corresponding focuses.

(October 15, 2015)

国家食品药品监督管理总局印发《医疗器械经营质量管理规范现场检查指导原则》

为强化医疗器械经营质量监督管理，规范和指导医疗器械经营质量管理规范现场检查工作，根据《医疗器械经营质量管理规范》，国家食品药品监督管理总局组织制定了《医疗器械经营质量管理规范现场检查指导原则》（以下简称《指导原则》），于2015年10月15日印发。

《指导原则》适用于食品药品监管部门对第三类医疗器械批发/零售经营企业经营许可（含变更和延续）的现场核查，第二类医疗器械批发/零售经营企业经营备案后的现场核查，以及医疗器械经营企业的各类监督检查。现场检查时，各省、自治区、直辖市食品药品监督管理局，新疆生产建设兵团食品药品监督管理局应当按照《指导原则》中包含的检查项目和所对应的重点检查内容，对医疗器械经营企业实施《医疗器械经营质量管理规范》情况进行检查。

（2015-10-15）

CFDA Issues Four Guidelines for Medical Device GMP On-Site Inspection

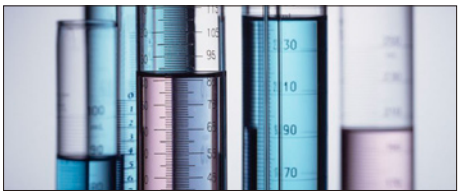
To promote the implementation of Good Manufacturing Practice (GMP) for Medical Devices, strengthen the supervision and management of medical device manufacturing, and offer guidance to regulatory departments in on-site inspection of the implementation of *GMP for Medical Devices* and its appendices for medical device manufacturers, and evaluation of inspection results, in accordance with GMP for Medical Devices and its Appendices, China Food and Drug Administration (CFDA) organized the formulation of the *Guideline for Medical Device GMP On-site Inspection*, the *Guideline for Medical Device GMP On-site Inspection for Sterile Medical Devices*, the *Guideline for Medical Device GMP On-site Inspection for Implantable Medical Devices*, and the *Guideline for Medical Device GMP On-site Inspection for In Vitro Diagnostic Reagents*, which were issued on October 10, 2015. The Guidelines aim to guide regulatory departments in on-site inspection of medical device manufacturers' implementation of GMP for Medical Devices and its appendices, and evaluation of the inspection results; they apply to on-site inspection for medical device registration and production licensing (including the renewal or alteration of license), and a variety of supervision and inspection on medical device manufacturers as required.

The successive introduction of *GMP for Medical Devices* and corresponding inspection guidelines marks the formation and continuous improvement of the regulatory system for medical device production, which centers around the *Regulations on Supervision and Administration of Medical Devices* and

国家食品药品监督管理总局印发《医疗器械生产质量管理规范现场检查指导原则》等4个现场检查指导原则

为推进《医疗器械生产质量管理规范》实施，加强医疗器械生产监督管理，指导监管部门对医疗器械生产企业实施《医疗器械生产质量管理规范》及其相关附录的现场检查和对检查结果的评估，根据《医疗器械生产质量管理规范》及其相关附录，国家食品药品监督管理总局组织制定了《医疗器械生产质量管理规范现场检查指导原则》《医疗器械生产质量管理规范无菌医疗器械现场检查指导原则》《医疗器械生产质量管理规范植入性医疗器械现场检查指导原则》《医疗器械生产质量管理规范体外诊断试剂现场检查指导原则》，于2015年10月10日印发。指导原则用于指导监管部门对医疗器械生产企业实施《医疗器械生产质量管理规范》及相关附录的现场检查和对检查结果的评估，适用于医疗器械注册现场核查、医疗器械生产许可（含延续或变更）现场检查，以及根据工作需要对医疗器械生产企业开展的各类监督检查。

builds on the basis of such regulations and provisions as the *Administrative Measures for the Supervision of Medical Device Production*, the *Catalogue of Medical Devices under Intensive Regulation,* the *Catalogue of Medical Devices Prohibited from Contract Production,* and the *Provisions for the Supervision and Administration of Medical Device Manufacturing Enterprises Classification and Grading*; the system adopts the GMP, the guidelines for GMP inspection, GMP Appendixes for sterile medical devices, implantable medical devices and in vitro diagnostic reagents, their respective inspection guidelines and other normative documents as effective supervisory tools; it is also supplemented by other related guidelines such as the Guidelines for Qualification of Suppliers for Manufacturers, the Guidelines for Water Making, etc. (October 10, 2015)



随着《医疗器械生产质量管理规范》和相应检查指导原则的陆续出台，标志着一个以《医疗器械监督管理条例》为核心，医疗器械生产监督管理办法、国家重点监管医疗器械目录、禁止委托生产医疗器械目录、医疗器械生产企业分类分级管理规定等法规规章为基础，《规范》、规范检查指导原则，无菌、植入性医疗器械、体外诊断试剂规范附录及检查指导原则等规范性文件为手段，其他相应生产企业供应商审核指南、制水环节指南等指南性文件为补充的医疗器械生产环节监管的法规制度体系已形成并在不断完善中。 (2015-10-10)

Special Focus 业界专题

Pharmaceutical Retail Market Analysis in the First Half of 2015

According to China Pharmaceutical Retail System monitoring data of Guangzhou Pharmaceutical Information Co., Ltd. (PICO) of CFDA Southern Medicine Economic Research Institute, in the first half of 2015, in the pharmaceutical retail market, the sales market shares of chemical drugs, Chinese patent drugs and health products are 42.8%, 28.5% and 8.6%.

(Source: Medicine Economic Report, October 23, 2015)

2015年上半年药品零售市场分析

根据CFDA南方所广州标点医药信息有限公司中国药品零售系统监测数据显示，2015年上半年药品零售市场化学药、中成药和保健品的销售额占比分别为42.8%、28.5%和8.6%。

（摘自：医药经济报 2015-10-23）

	器械类 Medical devices	药材类 Medicinal materials	其他 Others	保健品 Health product	中成药 Chinese patent medicine	化学药 Chemical drugs
2005年上半期 1st half of 2005	5.8%	4.1%	5.8%	12.7%	29.3%	42.3%
2006年上半期 1st half of 2006	3.6%	5.0%	6.0%	10.1%	33.4%	41.5%
2007年上半期 1st half of 2007	4.0%	4.4%	5.7%	104.0%	34.7%	40.9%
2008年上半期 1st half of 2008	4.9%	6.6%	7.3%	10.1%	29.8%	41.3%
2009年上半期 1st half of 2009	5.1%	7.6%	6.3%	9.6%	29.2%	42.4%
2010年上半期 1st half of 2010	4.9%	8.0%	5.8%	9.3%	28.4%	43.6%
2011年上半期 1st half of 2011	4.6%	8.1%	6.4%	8.7%	27.4%	44.8%
2012年上半期 1st half of 2012	5.0%	8.2%	6.3%	8.6%	27.7%	44.2%
2013年上半期 1st half of 2013	5.2%	8.6%	6.9%	8.6%	27.6%	43.2%
2014年上半期 1st half of 2014	5.1%	9.5%	6.6%	8.4%	27.8%	42.7%
2015年上半期 1st half of 2015	4.9%	8.6%	6.7%	8.6%	28.5%	42.8%

Notes: • All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version.
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