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SERVIER
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Drug

CFDA Issued *Announcement on Several Policies Pertaining to the Review & Approval of Drug Registration*

On November 11, 2015, CFDA issued the *Announcement on Several Policies Pertaining to the Review & Approval of Drug Registration* ([2015] No. 230), which reads as follows:

According to relevant regulations of the *Drug Administration Law of the People's Republic of China*, *Opinions of the State Council on the Reform of the Review & Approval System for Drugs and Medical Devices* (GF [2015] No. 44), etc. to de-stock the backlog of registration applications, improve the quality and efficiency of drug review & approval, the following policies will be implemented as consented by the State Council, and are hereby announced:

I. Escalate the standards for approval of generic drugs

The acceptance, review & approval of generic drug registration application should follow the principle of consistent quality and efficacy with the originators. Among them, for generic drugs already marketed at abroad but not marketed in China yet, bioequivalence study with the originators as well as clinical trials as per internationally accepted technical requirements should be conducted before submitting registration application; the originators used as control should be procured by the enterprises themselves with prior application to CFDA for one-off import. For those fail to carry out comparative study with the originators, it is required to conduct studies in accordance with the technical requirements of innovative drugs.

Generic drug registration applications, once accepted, should be subject to classified processing:

(A)Registration applications for generic drugs with inconsistent quality and efficacy with the originators approved for marketing in China should not be approved.

(B)For drugs generic to the originators marketed overseas but not in China yet, enterprises may submit registration application subject to review & approval in accordance with original regulations, but within three years after the drug is approved for marketing, quality and efficacy consistency evaluation should be conducted according to the regulations set forth in *Document GF [2015] No. 44*, drug approval numbers for those failed to pass the consistency evaluation should be revoked; the enterprises can also withdraw their submitted registration application, and re-apply when achieved consistent quality and efficacy with the originators after made improvements. Prioritized review & approval will be applied to the above reapplication, and after the drugs are approved for marketing, the quality and efficacy consistency evaluation can be exempted.

For registration application of generic drugs

药品

国家食品药品监督管理总局发布《关于药品注册审评审批若干政策的公告》

2015年11月11日，国家食品药品监督管理总局发布了《关于药品注册审评审批若干政策的公告》(2015年第230号)，全文如下：

根据《中华人民共和国药品管理法》、《国务院关于改革药品医疗器械审评审批制度的意见》（国发〔2015〕44号）等有关规定，为解决药品注册申请积压问题，提高药品审评审批质量和效率，经国务院同意，实行如下药品注册审评审批政策。现予以公告：

一、提高仿制药审批标准

仿制药按与原研药质量和疗效一致的原则受理和审评审批。其中，对已在中国境外上市但尚未在境内上市药品的仿制药注册申请，应与原研药进行生物等效性研究并按国际通行技术要求开展临床试验，所使用的原研药由企业自行采购，向国家食品药品监督管理总局申请一次性进口；未能与原研药进行对比研究的，应按照创新药的技术要求开展研究。

已经受理的仿制药注册申请，实行分类处理：

（一）中国境内已有批准上市原研药，申请注册的仿制药没有达到与原研药质量和疗效一致的，不予批准。

（二）中国境外已上市但境内没有批准上市原研药，申请仿制药注册的企业可以选择按原规定进行审评审批，但在药品批准上市3年内需按照国发〔2015〕44号文件规定进行质量和疗效一致性评价，未通过一致性评价的注销药品批准文号；企业也可以选择撤回已申报的注册申请，改按与原研药质量和疗效一致的标准完善后重新申报。对上述重新申报的注册申请实行优先审评审批，批准上市后免于进行质量和疗效一致性评价。

对申报上市的仿制药注册申请，首先审查药学研究的一致性，药学研究未达到要求的，不再对其他研究资料进行审查，直接作出不予

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applying for marketing, the consistency of pharmaceutical study should be reviewed first and foremost, if pharmaceutical study fails to meet the requirements, a decision of disapproval will be directly made without further review of other research materials.

II. Regulate the review & approval for improved new drugs

For registration application of a drug with alterations of the originators' dosage forms, acid radical, bases and routes of administration, etc. the applicant should demonstrate its distinct advantages in technical innovation and clinical value as compared with the originator; if such advantages cannot be demonstrated, the application will not be approved, except for registration applications for pediatric drugs changing the dosage form and strength.

III. Optimize the review & approval of clinical trial applications

One-time approval will be implemented to applications for clinical trials of new drugs, with no more implementation of phased application and phased review & approval; the focus of review should be shifted to the scientificity of clinical trial protocol and the control of safety risks to protect the safety of subjects. The communication before the application of clinical trials and during the review between reviewer and applicant should be strengthened to timely resolve the problems existing in the processes of registration application and clinical trial. Applicants should timely supplement the latest research data as required. Upon completion of Phase I & II clinical trials, the applicant should promptly submit trial results and the protocol of next phase. The next phase cannot be started until clearance of all safety risks and obtain the consent from the Center for Drug Evaluation (CDE). The applicant should truthfully report any serious adverse events in clinical trials, and timely submit the Annual Report; if safety risks are beyond control, the clinical trials should be stopped immediately. CDE will communicate with the applicant face to face, and form minutes of meeting to record agreed issues on the spot.

Since December 1, 2015, bioequivalence studies of generic drugs will be reformed from the review & approval system to a record-filing system. The applicant should conduct a comprehensive comparative study of quality with the originators in accordance with relevant guidelines issued by CFDA and internationally accepted technical requirements, to ensure quality consistency; the prescription, process, and production line of bioequivalence study samples should be consistent with those in commercial production. The applicant should submit record filing materials to CFDA as per CFDA management regulation and technical requirements 30 days before the bioequivalence studies. During the study, CFDA may, at any time, require the applicant to suspend the study if any non-conformances are found.

IV. Implement centralized review for drugs of the same variety

For drugs of the same variety whose applications have been accepted prior to the release of this Announcement, a centralized review should be conducted according to uniform review criteria and standards by CFDA by organizing relevant personnel. For non-compliance cases, a decision of disapproval should be made timely; for compliance cases, approval decision will be made and approval documents will be formulated and issued according to the time sequence of applications.

V. Allow the applicant to voluntarily withdraw non-compliance drug registration applications

The applicants are allowed to actively withdraw their drug registration applications accepted but with such major defects as

批准决定。

二、规范改良型新药的审评审批

对改变原研药剂型、酸根、碱基和给药途径等的药品注册申请，申请人需证明其技术创新性且临床价值与原品种比较具有明显优势；无法证明具备上述优势的，不予批准。改变剂型和规格的儿童用药注册申请除外。

三、优化临床试验申请的审评审批

对新药的临床试验申请，实行一次性批准，不再采取分期申报、分期审评审批的方式；审评时重点审查临床试验方案的科学性和对安全性风险的控制，保障受试者的安全。加强临床试验申请前及过程中审评人员与申请人的沟通交流，及时解决注册申请和临床试验过程中的问题。申请人需按要求及时补报最新研究资料。在Ⅰ期、Ⅱ期临床试验完成后，申请人应及时提交试验结果及下一期临床试验方案。未发现安全性问题的，可在与药审中心沟通后转入下一期临床试验。申请人应如实报告临床试验中发生的严重不良事件，按时提交研究年度报告；对不能控制临床试验安全性风险的，应立即停止临床试验。药审中心与申请人当面沟通，应当场形成会议纪要列明议定事项。

自2015年12月1日起，仿制药生物等效性试验由审批制改为备案制。申请人应按照国家食品药品监督管理总局发布的相关指导原则和国际通行技术要求与原研药进行全面的质量对比研究，保证与原研药质量的一致性；生物等效性试验用样品的处方、工艺、生产线应与商业化生产保持一致。申请人开展生物等效性试验前，应按国家食品药品监督管理总局制定的管理规定与技术要求于试验前30天向国家食品药品监督管理总局提交备案资料。试验过程中，国家食品药品监督管理总局发现不符合相关规定的，可随时要求申请人暂停试验。

四、实行同品种集中审评

对本公告公布之日前已经受理的相同品种，按照统一的审评标准和尺度组织力量进行集中审评。对不符合规定的，及时作出不予批准的决定；符合规定的，按申报顺序依次作出审批决定并制发批准证明文件。

五、允许申请人主动撤回不符合条件的药品注册申请

对已经受理的存在研究资料缺项、数据不全、试验未完成、未与原研药进行全面比对研究、未对杂质和毒性物质进行全面评价、处方工艺试验不完整等重大缺陷的药

inadequate research materials and data, uncompleted clinical trial, imperfect formulation process testing, fail to conduct comprehensive comparative study with originators or comprehensive evaluation on impurities and toxic substances, and reapply after made improvements. In the case of any of the above defects is found during technical review, an outright decision of disapproval should be made. For application dossiers that are incomplete but meet the conditions for review, CFDA Center for Drug Evaluation should notify the applicant for once the materials to be supplemented; after submission of supplementary materials, the applicants are, in principle, no longer required to make further supplementation and CFDA will directly made decision of approval or disapproval.

VI. Rigorously review of the safety and efficacy of drugs

Under the following circumstances, CFDA will promptly announce the list of related drug varieties which have: (1) unclear active ingredients, unclear structure, or imprecise efficacy; and (2) potential safety risks.

From the date of public announcement, all drug varieties on the above list will be subject to the following process:

(A) CFDA Center for Drug Evaluation will incorporate the drug varieties into the scope of focused monitoring on safety risks. Where there is evidence of inexact efficacy, serious adverse reactions, or other hazardous effects on human health, the drug approval number should be immediately revoked.

(B) The relevant manufacturers should promptly carry out re-evaluation of the related product, and submit re-evaluation results to CFDA within three years. The approval numbers of drugs which re-evaluation results are overdue or failed should be revoked.

(C) The registration application for generics of the above varieties will not be accepted; if already accepted, they should not be approved.

Disapproval decision will be made for all the registration applications unresolved in 2008 Centralized Review, if the applicant still cannot resolve the issues of safety, efficacy and quality control, or the authenticity of their research and development information is difficult to confirm.

VII. Speed up the review and approval of drugs urgently needed in clinical practice

The applications for drugs meeting one of the following conditions will be arranged in a separated waiting list to accelerate the review & approval of registration application for:

(A) Innovative drugs to combat AIDS, cancers, major infectious diseases, rare diseases and other diseases;

(B) Pediatric drugs;

(C) Drugs for elderly-specific and frequently-occurring diseases;

(D) Drugs included in the national science and technology major projects and key national R&D plans;

(E) Drugs with advanced technology, innovative treatment approaches, and significant therapeutic advantages and are urgently needed in clinical practice;

(F) Innovative drugs that are manufactured within the territory of China upon entrustment;

(G) Drugs which clinical trials have been simultaneously applied and approved in the European Union and the United States, or drugs that are manufactured in China with the same production line and simultaneously applied for marketing in EU and US and have passed the on-site inspection conducted by their drug review and approval authorities;

(H) Clinical trial applications for drugs

品注册申请，允许申请人主动撤回，完善后重新申报。技术审评过程中发现上述问题之一的，直接作出不予批准的决定。对申报资料不完整但具备审评条件的药品注册申请，由国家食品药品监督管理总局药品审评中心一次性告知申请人补充资料；补充资料提交后，原则上不再要求申请人补充资料，只作出批准或不予批准的决定。

六、严格审查药品的安全性和有效性

发现有下列情形的，国家食品药品监督管理总局及时公布相关品种名单：（1）活性成分不明确、结构不清楚或疗效可能不确切的；（2）安全性可能存在风险的。

自名单公布之日起，对列入上述名单的品种作以下处理：

（一）国家食品药品监督管理总局药品评价中心将其纳入安全风险重点监测范围。凡有证据证明该药品疗效不确切、不良反应大或者其他原因危害人体健康的，立即撤销药品批准文号。

（二）相关生产企业应及时开展相关产品再评价，并于3年内向国家食品药品监督管理总局提交再评价结果。逾期未提交再评价结果或未通过再评价的，撤销药品批准文号。

（三）仿制上述品种的注册申请，不予受理；已经受理的，不予批准。

对2008年集中审评遗留的未批准的药品注册申请，目前申请人仍未解决安全性、有效性和质量可控性问题的，以及难以确认研制资料真实性的，一律作出不予批准的决定。

七、加快临床急需等药品的审批

符合下列条件之一的，实行单独排队，加快审评审批。

（一）防治艾滋病、恶性肿瘤、重大传染病和罕见病等疾病的创新药注册申请；

（二）儿童用药注册申请；

（三）老年人特有和多发疾病用药注册申请；

（四）列入国家科技重大专项和国家重点研发计划的药品注册申请；

（五）使用先进技术、创新治疗手段、具有明显治疗优势的临床急需用药注册申请；

（六）转移到中国境内生产的创新药注册申请；

（七）申请人在欧盟、美国同步申请并获准开展药物临床试验的新药临床试验申请，或在中国境内用同一生产线生产并在欧盟、美国同步申请上市且已通过其药品审批机构现场检查的药品注册申请；

（八）临床急需且专利到期前3年的药

under urgent clinical needs and whose originator's patent is to expire in three years; and production applications for drugs whose originator's patent is to expire in one year.

Since December 1, 2015, the applicant may propose to CFDA Center for Drug Evaluation the application for accelerated review.

CFDA, together with relevant departments, will develop and release relevant policies for prioritizing review & approval of drug registration applications, to encourage the R&D and production of drugs in short supply and innovative drugs. National Health and Family Planning Commission and Ministry of Industry and Information Technology will establish regular communication mechanism for procurement, production and supply of drugs in short supply, propose suggestions for accelerating review & approval. CFDA will determine the scope of accelerated review & approval together with relevant departments.

VIII. Severe Punishment for frauds in clinical trial data

For the accepted registration application of drugs which clinical trials have completed and now apply for production or importation, if the applicant has completed self-examination and report the results as required, CFDA will, in accordance with the review progress, perform stepwise clinical trial data verification; if any frauds are found, investigation will ensue and the corresponding application for registration will not be approved.

The applicants, clinical trial institutions, contract research organizations involved in clinical trial data frauds and the persons directly responsible, should be held accountable and blacklisted in accordance with Article 78 of the *Drug Administration Law of the People's Republic of China*, and the relevant provisions of CFDA on Self-Examination & Verification of Drug Clinical Trial Data; the relevant organization code, personnel ID Numbers and other information should be publicly notified. Suspected criminal cases should be transferred to public security organs for investigation.

For Applicants involved in clinical trial data frauds, according to Article 70 of the *Regulations for Implementation of the Drug Administration Law of the People's Republic of China*, and Article 167 of the *Provisions for Drug Registration*, from the date of acknowledgment of such frauds, their applications for registration of drugs of the same variety will be rejected within 3 years; their applications for registration of any drug will be rejected within 1 year, and those cases already accepted will not be approved. Food and drug regulatory authorities will organize retrospective examination on drug approval documents previously acquired by the applicant, where frauds are found, according to Article 82 of the *Drug Administration Law of the People's Republic of China*, the relevant approval documents should be revoked, and all drug registration applications the applicant submitted will be rejected within 5 years.

Clinical trial institutions involved in data fraud should be ordered to make rectifications within a time limit; before the rectifications are completed, the application dossiers involving the studies they participated in will be rejected; if still fail to meet the requirements after rectification, they will be disqualified for related trials. All accepted registration applications involving the principal investigators who have data fraud behaviors will not be approved. All accepted registration applications of one specialty with two or more fraudulent clinical trial data will not be approved; and all accepted registration applications involving clinical trial institutions which have three or more fraudulent clinical

品临床试验申请和专利到期前1年的药品生产申请。

自2015年12月1日起，申请人可向国家食品药品监督管理总局药品审评中心提出加快审评的申请。

国家食品药品监督管理总局会同有关部门制定和发布药品注册申请优先审评审批的有关政策，鼓励市场短缺和创新药品的研发和生产。国家卫生计生委、工业和信息化部根据药品采购情况和生产供应情况建立短缺药品定期沟通机制，提出加快审批的建议，国家食品药品监督管理总局会同有关部门确定纳入加快审批的范围。

八、严惩临床试验数据造假行为

对已经受理的完成临床试验申报生产或进口的药品注册申请，申请人已按要求完成自查并报告结果的，国家食品药品监督管理总局将根据审评进度，逐一进行临床试验数据核查;发现存在弄虚作假问题的即立案调查，相应注册申请不予批准。

对参与临床试验数据弄虚作假的申请人、临床试验机构、合同研究组织及其直接责任人，依据《中华人民共和国药品管理法》第七十八条以及国家食品药品监督管理总局关于临床试验数据自查核查的有关规定查处，并将其列入黑名单，向社会公布相关组织机构代码、人员身份证号码等信息。涉嫌犯罪的，移交公安机关调查处理。

对临床试验数据弄虚作假的申请人，依据《中华人民共和国药品管理法实施条例》第七十条和《药品注册管理办法》第一百六十七条的规定，自发现之日起，3年内不受理其申报该品种的药品注册申请，1年内不受理其所有药品注册申请，已经受理的不予批准。食品药品监管部门将组织对该申请人此前获得的药品批准证明文件进行追溯检查，发现弄虚作假行为的，依据《中华人民共和国药品管理法》第八十二条的规定，撤销相关药品批准证明文件，5年内不受理其所有药品注册申请。

对参与临床试验数据弄虚作假的临床试验机构，责令限期整改，整改完成前不接受其参与研究的申报资料，经整改仍不符合要求的，取消其相关试验资格。对弄虚作假主要研究者参与研究并已受理的所有注册申请不予批准。对同一专业出现两个及以上临床试验数据弄虚作假行为的，其专业内已受理的所有注册申请不予批准；对临床试验机构出现三个及以上临床试验数据弄虚作假行为的，涉及该机构已受理的所有注册申请不予批准。对参与临床试验数据弄虚作假的主要研究者，食品药品监管部门将有关信息通报

trial data will not be approved. Food and drug regulatory authorities will notify the information relevant to the Principal Investigator involved in fraud of clinical trial data, to health administrative departments, who shall, in accordance with relevant provisions of the *Law of the People's Republic of China on Medical Practitioners* etc. hold accountable those directly responsible.

Where the applicant take the initiative to apply for withdrawal of drug registration applications before CFDA verification, CFDA will announce the list of applicants and varieties withdrawn, no further verification and investigation will be conducted.

IX. Guide the applicants for rational application

The *Directory of Drugs Subject to Restricted Review and Approval* has been issued to restrict the registration application for drugs with multiple drug approval numbers and multiple manufacturers, with production capacity far exceeding the clinical needs; and, the Directory will be updated regularly. The information of drug registration application acceptance and review will be timely released to the public to guide enterprises' orderly R&D and rational application.

X. Standardize re-review of drug registration

CFDA Center for Drug Evaluation will notify the applicant of the Review Comments for failed the technical review; dissenting applicant may submit an application for re-review, CDE will organize clinical experts, pharmacologists, toxicologists, statisticians, legal experts, patient representatives, etc. in related fields to hear the opinions of review experts and the applicants, public argumentation will be performed to reach a final opinion of re-review on the principle whereby the minority is subordinate to the majority.

This Announcement will come into force as from the date of promulgation. In the case of any discrepancies with the provisions of previously published *Provisions for Drug Registration* (formerly the SFDA Order No. 28), the Announcement will prevail.

(November 11, 2015)

卫生行政部门，由卫生行政部门依照《中华人民共和国执业医师法》等有关规定，追究临床试验机构直接责任人的责任。

申请人在国家食品药品监督管理总局核查前主动申请撤回的，国家食品药品监督管理总局公布撤回的申请人和品种名单，不予核查及立案调查。

九、引导申请人理性申报

发布《限制类药品审批目录》，对已有多个药品批准文号且有多家企业生产，生产供应能力已远超临床使用需求的药品注册申请予以限制；限制类目录将定期更新。及时向社会公开药品注册受理及审评信息，引导企业有序研发和理性申报。

十、规范药品注册复审工作

国家食品药品监督管理总局药品审评中心应将技术审评不予通过的审评意见告知申请人；申请人持有异议的，可提出复审申请，由药品审评中心组织相关领域的临床专家、药理学家、毒理学家、统计学家、法律专家、患者代表等，听取审评专家和申请人的意见，公开论证，按少数服从多数的原则形成最终复审意见。

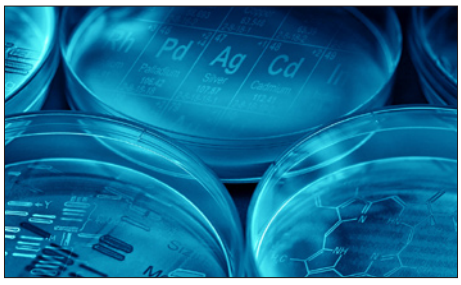
本公告自发布之日起实施。此前发布的《药品注册管理办法》（原国家食品药品监管管理局令第28号）等相关规定，与本公告不一致的，以本公告为准。（2015-11-11）

CFDA issued the *Announcement on Key Points for On-Site Verification of Drug Clinical Trial Data*

In order to standardize the on-site verification of drug clinical trial data, CFDA organized the formulation of *Key Points for On-Site Verification of Drug Clinical Trial Data* ([2015] No. 228), on November 11, 2015, the relevant matters are announced as follows:

I. CFDA will perform, according to the *Key Points for On-Site Verification of Drug Clinical Trial Data*, stepwise on-site verification of drug clinical trial data for registration applications with completed self-examination information form.

II. The on-site verification of some drug clinical trial data showed that some clinical trial institutions are involved in unauthorized modification of data, concealment of data, untraceable data and other fraudulent behaviors, CFDA will announce every fraud, once it was found, and severely punish the related applicant, clinical trials institutions, clinical trials contract research organizations and those responsible according to law.



国家食品药品监督管理总局发布《关于药物临床试验数据现场核查要点的公告》

为了规范药物临床试验数据现场核查，国家食品药品监督管理总局组织制定了《药物临床试验数据现场核查要点》（2015年第228号），于2015年11月11日发布。有关事宜公告如下：

一、国家食品药品监督管理总局将根据《药物临床试验数据现场核查要点》，对完成自查资料填报的药品注册申请逐一进行临床试验数据现场核查。

二、从已经完成的部分药物临床试验数据现场核查情况看，部分药物临床试验机构存在擅自修改数据、瞒报数据以及数据不可溯源等弄虚作假问题，国家食品药品监督管理总局将发现一起公布一起，并对注册申请人、临床试验机构、临床试验合同研究组织及相关责任人依法严肃处理。

三、临床试验机构或临床试验合同研

III. Clinical trials institutions or clinical trials contract research organizations should perform self-examination of the authenticity and integrity of trial data in accordance with the *Key Points for On-Site Verification of Drug Clinical Trial Data*, where untrue items are found, they should take the initiative to report to CFDA and urge the applicants to voluntarily withdraw the applications. Clinical trial institutions or contract research organization who proactively reports such problems can be exempted from accountability.

IV. If the drug registration applicants found inauthentic clinical trial data, they can apply to CFDA for withdrawal. Where the applicant take the initiative to apply for withdrawal before CFDA's notice of on-site verification, CFDA will announce the list of applicants and varieties withdrawn without affixing accountability; once the notice of on-site verification is issued, CFDA will not accept any application for withdrawal.

(November 11, 2015)

究组织应继续按照《药物临床试验数据现场核查要点》，对试验数据的真实性、完整性进行自查，发现存在不真实问题的，应主动将情况报告国家食品药品监督管理总局，并督促申请人主动撤回申请。临床试验机构或合同研究组织主动报告问题的，可免予追究责任。

四、药品注册申请人发现临床试验数据存在真实性问题的，可向国家食品药品监督管理总局申请撤回。在国家食品药品监督管理总局通知现场核查前主动申请撤回的，公布申请人和品种名单，不予追究责任；通知现场核查后不再接受撤回申请。

（2015-11-11）

CFDA Released *Announcement on Disapproval of Registration Applications for 11 Drugs of Eight Enterprises*

On November 6, 2015, CFDA issued the *Announcement on Disapproval of Registration Applications for 11 Drugs of Eight Enterprises*, which states that, from October 26 to 31, CFDA performed on-site verification for the registration applications of some drugs, and found untrue, incomplete items in clinical trial data of the registration applications for 11 drugs of 8 enterprises, therefor, decisions of disapproval are thereby made for them.

Relevant personnel of CFDA expressed that, all applicant enterprises, clinical trial institutions and contract research organizations whose applications for production are pending for CFDA review should continue their self-examination and take the initiative to report varieties with inauthentic problems found during self-examination to CFDA, and apply for withdrawal of the relevant applications. Clinical trial institutions or contract research organizations who take the initiative to report the varieties with problems will be exempt from punishments. CFDA will further organize personnel to verify the applications pending for review, and severely punish those with inauthentic items and fraudulent behaviors, to ensure the authenticity and efficacy of the approved drugs. (November 11, 2015)

国家食品药品监管总局发布《关于8家企业11个药品注册申请不予批准的公告》

2015年11月6日，国家食品药品监管总局发布了《关于8家企业11个药品注册申请不予批准的公告》。公告显示，国家食品药品监管总局10月26日至31日对部分药品注册申请进行现场核查，发现8家企业11个药品注册申请的临床试验数据存在不真实、不完整的问题，决定对其注册申请不予批准。

食品药品监管总局有关人士表示，所有已申报生产并在总局待审的申报企业、临床试验机构和临床试验合同研究组织要继续进行自查，凡自查发现存在不真实问题的品种，应主动报告食品药品监管总局，撤回相关申请。临床试验机构或临床试验合同研究组织主动报告问题的品种，将免予对临床试验机构或临床试验合同研究组织的处罚。食品药品监管总局将继续组织力量对待审的申请进行核查，对查明真实性存在问题的弄虚作假行为严厉处罚，确保审批药品的真实、有效。（2015-11-11）

Medical Devices

CFDA issued *Announcements on Regulating the Registration Management of AgX-Containing Medical Devices and Related Issues*

To address the issues related to the registration of AgX-Containing medical devices (AgX: such as silver nitrate, silver sulfadiazine, etc.), and further standardize the application and approval procedures, CFDA issued on November 9 the Announcements on Regulating the Registration Management of AgX-

医疗器械

国家食品药品监督管理总局发布《关于规范含银盐医疗器械注册管理有关事宜的公告》

为解决含银盐（如硝酸银、磺胺嘧啶银等）医疗器械注册管理的有关问题，进一步规范申报和审批程序，国家食品药品监管总

Containing Medical Devices and Related Issues ([2015] No. 225), to clarify the related management properties, and the requirements for the acceptance, approval and transition of registration applications for products containing silver nitrate, silver sulfadiazine and other silver salts.

(November 12, 2015)

局11月9日发布了《关于规范含银盐医疗器械注册管理有关事宜的公告》（2015年第225号），对于含有硝酸银、磺胺嘧啶银等银盐的产品，明确了相关管理属性、注册申请受理、审批和过渡期要求。 （2015-11-12）

CFDA Issued *Notice on Issues Related to the Implementation of Provisions for the Registration of Medical Devices and In Vitro Diagnostic Reagents*

The newly revised *Provisions for Medical Device Registration (CFDA Order No. 4) and Management Methods of In Vitro Diagnostic Reagents Registration (CFDA Order No. 5)* have been implemented as from October 1, 2014. To further improve the integration of the rules and regulations, on November 4, 2015, CFDA issued *Notice on Issues Related to the Implementation of Provisions for the Registration of Medical Devices and In Vitro Diagnostic Reagents*, to notify the relevant issues as follows:

I. Issues pertaining to the review of product registration application accepted prior to the implementation of new mandatory standards

For medical devices applying for registration, if the mandatory standards referred in product technical specification have changed, except as otherwise provided in standards released and implemented by CFDA, the registration testing of products accepted prior to the implementation date of the new standards should be still subject to the original standards for testing, review & approval. As from the date of the implementation of new standards, enterprises should implement, and the products should comply with, the new standards.

II. Issues pertaining to registration renewal involving change of mandatory standards

In registration renewal, where products remains unchanged, if the enterprises modify product technical specification and other licensed matters set forth in the registration certificate (such as performance, structure and composition, etc.) to adapt to changes in mandatory standards, they may submit an application in accordance with registration renewal procedures, however, test reports issued by medical device testing institutions should be submitted to testify its compliance with the mandatory standards.

While reviewing the application for registration renewal, where supplementary information is required as per the new mandatory standards, food and drug regulatory authorities will require the enterprises to make supplementation and will disapprove the registration renewal application for products not complying with the new mandatory standards.

III. Issues pertaining to the biological tests of medical devices

(A) Where biological tests are involved in biological evaluation of medical devices, the biological tests reports should be submitted by the applicant as research data upon registration application.

国家食品药品监管总局发布《关于执行医疗器械和体外诊断试剂注册管理办法有关问题的通知》

新修订《医疗器械注册管理办法》（国家食品药品监督管理总局令第4号）和《体外诊断试剂注册管理办法》（国家食品药品监督管理总局令第5号）已于2014年10月1日起实施。为进一步做好规章实施的衔接工作，2015年11月4日，国家食品药品监管总局发布《关于执行医疗器械和体外诊断试剂注册管理办法有关问题的通知》，将有关问题通知如下：

一、关于新的强制性标准实施之日前受理产品审查问题

对于申报注册的医疗器械，其产品技术要求中引用的强制性标准发生变化的，除总局在发布、实施标准文件中另有规定外，在新标准实施之日前受理注册检验的产品，仍按照原标准进行检验、审评和审批。自新标准实施之日起，企业应实施新标准，产品应符合新标准要求。

二、关于延续注册涉及强制性标准变化的问题

延续注册时，企业在产品不变的情况下，为适应强制性标准变化而修改产品技术要求和注册证载明的其他许可事项（如性能结构组成等）的情形，可以按照延续注册提交申请，但应提交由医疗器械检验机构出具的符合强制性标准的检验报告。

延续注册审查时，需要根据新的强制性标准补充资料的，食品药品监督管理部门可要求企业补充相关资料，经审查确认产品不符合新的强制性标准的不予延续注册。

三、关于医疗器械生物学试验

（一）医疗器械生物学评价中涉及生物学试验的，其生物学试验报告由申请人在申请注册时作为研究资料提交。

（二）开展生物学试验，应委托具有医疗器械检验资质认定、在其承检范围之内的生物学实验室按照相关标准进行试验。国外实验室出具的生物学试验报告，

(B) The biological tests should be entrusted to biology laboratories with medical device testing qualification accreditation and corresponding testing capacity, to test in accordance with the relevant standards. Biology test reports issued by overseas laboratories should be accompanied by their quality assurance documents indicating compliance with GLP laboratory requirements.

IV. Issues pertaining to the testing institutions for supplementary test

Where a supplementary test is involved during the review of registration application, the test should be conducted in the original testing institution.

V. Issues pertaining to the connection of registration renewal with the change of original registration certificate

Where an enterprise applies for change of the original registration certificate, the certificate number set forth on the registration change document should be the original certificate number; if the enterprise applies for registration renewal at the same time, a new certificate number is thence required. In this case, in order to associate the renewed certificate with the registration change document, the original certificate number should be recorded in the remarks column of the renewed certificate, regardless of the approval time for registration change based before or after the approval time for registration renewal, and the registration change documents can be used in conjunction with the certificate approved for registration renewal.

VI. Issues pertaining to the submission of medical device clinical evaluation materials

Where clinical evaluation is performed according to Article 6 of the *Technical Guideline for Clinical Evaluation of Medical Devices*, if the production process, clinical data and other information of similar medical devices are used, the applicant should submit the corresponding authorization certificate for using such information.

VII. Issues pertaining to reissuance of certificates

Where reissuance of medical device registration certificate is required, the new certificate should mark in the remarks column: *Reissued on (date). The original registration certificate issued on (date) is invalidated.*

VIII. Issues pertaining to medical devices approved for registration

The medical devices approved for registration refer to those consistent with the content limited in Registration Certificate for Medical Device and attachments thereof and are manufactured within the validity period of Registration Certificate for Medical Device. ((November 6, 2015)

应附有国外实验室表明其符合GLP实验室要求的质量保证文件。

四、关于补充检验的检验机构

注册审查时提出补充检验要求的，应在原检验机构进行检验。

五、关于延续注册和原注册证变更的衔接

企业对原注册证申请注册变更，注册变更文件登载的注册证编号为原注册证编号；如企业同时又对原注册证申请延续注册，延续注册需核发新的注册证编号。此种情况下，为了使延续注册的注册证关联到注册变更文件，可在延续注册证备注栏中载明原注册证编号，而无论本次注册变更文件批准时间在延续注册批准时间之前或之后，均可以与其延续注册批准的注册证共同使用。

六、关于医疗器械临床评价资料提交

依据《医疗器械临床评价技术指导原则》第六条开展临床评价的，如使用了同品种医疗器械的生产工艺、临床数据等资料，申请人应提交同品种医疗器械生产工艺、临床数据等资料的使用授权书。

七、关于补证

补发医疗器械注册证的，应在补发的医疗器械注册证备注栏中载明“xxxx年xx月xx日补发。原xxxx年xx月xx日发放的注册证作废”。

八、关于获准注册的医疗器械

获准注册的医疗器械，是指与该医疗器械注册证及附件限定内容一致且在医疗器械注册证有效期内生产的医疗器械。

(2015-11-06)

Notes: • All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version.
• For electronic version of the Newsletter please visit http://www.ccpie.org

备 注： • Newsletter中所有中文信息摘自报刊及网络。英文均系中文翻译。
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