2017. Volume 11

CHINA FOOD AND DRUG NEWSLETTER

中国食品药品国际交流中心
SERVIER
施维雅（天津）制药有限公司

CFDA Issued the *Announcement on Adjusting the Acceptance of Drug Registration Applications*

In accordance with the *Opinions of the State Council on the Reform of the Review & Approval System for Drugs and Medical Devices* (SC [2015] No. 44), CFDA hereby decides through discussion that, as from December 1, 2017, CFDA will accept in a centralized manner the drug registration applications that were previously accepted by the food and drug regulatory authorities at the provincial level and then subject to review and approval of CFDA, with a view to establishing a review and approval dominated drug registration technology system and realizing a review and approval mechanism focused on review and approval and technically supported by on-site inspection and product testing. On November 13, 2017, CFDA published the Announcement on Adjusting the Acceptance of Drug Registration Applications to provide details below:

I. Adjusted items

Subsequent to the adjustment, all drug registration applications that should be reviewed, approved and filed by CFDA pursuant to applicable laws, regulations and rules will be accepted by CFDA, covering new drug clinical trial application, new drug manufacturing (or new drug certificate) application, application for generic drug, supplementary application reviewed and approved by CFDA and so on; all drug registration applications that should be reviewed, approved and filed by the food and drug regulatory authorities at the provincial level pursuant to applicable laws, regulations and rules will be still accepted by such food and drug regulatory authorities at the provincial level.

II. Requirements

The said adjustment shall take effect as from December 1, 2017. The drug registration application dossiers may be submitted via email, mailing or personal delivery, the hard copy and electronic copy of which shall be submitted at the same time.

Prior to December 1, 2017, the registration application dossiers signed for receipt but not yet accepted, or already accepted but for which such affairs as on-site inspection for drug clinical trial, research and development site inspection, production site inspection, and sampling, etc. remain outstanding, shall be still handled by the food and drug regulatory authorities at the provincial level.

III. Submissions

The drug registration applicant shall fill in an Application Form and prepare the application dossiers in accordance with the *Provisions for Drug Registration, the Style and Arrangement Specification for Drug Registration Application Dossiers*, and other relevant regulations, and shall ensure the consistency between the hard copy and electronic copy thereof. The drug registration applicant may submit

国家食品药品监督管理总局发布《关于调整药品注册受理工作的公告》

依据《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），为建立审评主导的药品注册技术体系，实现以审评为核心，现场检查、产品检验为技术支持的审评审批机制，国家食品药品监督管理总局研究决定自2017年12月1日起，将现由省级食品药品监督管理部门受理、国家食品药品监督管理总局审评审批的药品注册申请，调整为国家食品药品监督管理总局集中受理。2017年11月13日，发布《关于调整药品注册受理工作的公告》，将有关事宜公告如下：

一、调整范围

凡依据现行法律、法规和规章，由国家食品药品监督管理总局审评审批、备案的注册申请均由国家食品药品监督管理总局受理，包括新药临床试验申请、新药生产（含新药证书）申请、仿制药申请，国家食品药品监督管理总局审批的补充申请等；由省级食品药品监督管理部门审批、备案的药品注册申请仍由省级食品药品监督管理部门受理。

二、调整要求

上述调整自2017年12月1日起实施。药品注册申请可采取电子申报、邮寄或现场提交的方式提交申报资料，同时提交纸质文本和电子文档。

2017年12月1日前，省级食品药品监督管理部门已签收资料但尚未受理或已受理但药物临床试验现场核查、研制现场核查、生产现场检查及抽样等工作尚未完成的注册申请，仍由省级食品药品监督管理部门组织完成相关工作。

三、资料提交

药品注册申请人应按照《药品注册管理办法》《药品注册申报资料的体例与整理规范》等有关规定填写申请表并准备申报资料。申请

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

application dossiers via mailing (which is the preferred method) or personal delivery.

(1) Delivery via mailing. The drug registration applicant shall mail the application dossiers to Center for Drug Evaluation, CFDA (hereinafter referred to as "CDE").

Mailing address: No. 1A, Fuxing Road, Haidian District, 100038 Beijing.

The electronic copy of application dossiers mailed should be technically secured in a storage media to avoid the unacceptability of application dossiers due to damage to such media arising during the mailing process.

(2) Personal delivery. The drug registration applicant shall submit the drug registration application to CDE together with relevant dossiers.

Office address: No. 1A, Fuxing Road, Haidian District, Beijing

Business hours: 9:00 a.m. to 11:30 a.m. from Monday to Friday; 13:00 p.m. to 16:00 p.m. on Monday, Tuesday and Thursday.

(3) Requirements on submissions. The drug registration applicant shall submit the application dossiers in a manner as required by the applicable requirements on drug registration dossiers. If a new drug clinical trial application is submitted, the opinions and suggestions communicated at the meeting with CDE and statements on supplement to application dossiers shall be accompanied.

IV. Acceptance review

CDE shall sign for its receipt of application dossiers and make a registration on that day or immediately when receiving such dossiers, and shall, within five (5) working days thereafter, complete the acceptance review and make a decision thereon (acceptance, rejection or requiring the supplementation of materials). If the application dossiers are reviewed and confirmed to be compliant with the regulations or supplemented and confirmed to be compliant with the regulations, CDE shall issue a Notice of Acceptance and a Notice on Payment; if the application dossiers are reviewed and confirmed to be noncompliant with the regulations, CDE shall issue a Notice on Supplementation of Materials or a Notice on Rejection. Such notices shall be sent to the drug registration applicant within five (5) working days upon receipt.

The drug registration applicant may provide the supplements via personal delivery or mailing. Where CDE fails to receive the supplements within thirty (30) days after the Notice on Supplementation of Materials is served, for which neither a notification nor any justification is provided by the applicant timely, CDE shall issue a Notice on Rejection and return the application dossiers to the registration applicant.

V. Filing review

Upon acceptance of application dossiers, CDE shall conduct a filing review over application dossiers for chemical generic drugs and make a filing for those that are compliant with the requirements within forty-five (45) working days thereafter and disapprove those that are noncompliant with the requirements with justification stated.

VI. On-site verification and test for registration

The drug registration inspectors nationwide shall be organized by the Center for Food and Drug Inspection of CFDA in a unified manner to conduct on-site verification over all drug registration applications newly accepted in a centralized manner by CFDA according to requirements for drug technical review, which will not be subject to the self-inspection and verification of drug clinical

人应保证提交的纸质文本与电子文档内容一致。药品注册申请人可自行选择邮寄或现场提交申报资料，鼓励药品注册申请人通过邮寄方式提交申报资料。

（一）邮寄提交。药品注册申请人将相关资料邮寄至国家食品药品监督管理总局药品审评中心（以下简称总局药审中心）。

邮寄地址：北京市海淀区复兴路甲1号，邮编：100038。

以邮寄形式提交电子文档的申报资料，申请人应做好储存介质的技术防护，避免邮寄过程中介质损坏造成申报资料无法接受。

（二）现场提交。药品注册申请人携相关资料到总局药审中心提交药品注册申请。

办公地址：北京市海淀区复兴路甲1号

办公时间：周一至周五，上午：9:00—11:30；周一、周二、周四，下午：13:00—16:00。

（三）资料提交要求。药品注册申请人应按照现行药品注册资料要求提交申请资料；提交新药临床试验申请的，还需提交与总局药审中心会议沟通意见建议以及申报资料补充完善的情况说明。

四、受理审查

总局药审中心收到资料当日或当场进行签收登记，在5个工作日内完成受理审查并做出审查决定（受理、不予受理或要求补正材料）。经审查符合规定的或者申请人完成补正资料后符合规定的，出具《受理通知书》《缴费通知书》；经审查不符合规定的，出具《补正资料通知书》或《不予受理通知书》。审查决定的通知书应在5个工作日内寄送药品注册申请人。

药品注册申请人按要求完成补正资料后，可以选择现场提交或以邮寄的方式提交补正资料。自《补正资料通知书》送达之日起30日内未收到补正资料，且药品注册申请人未及时与总局药审中心沟通并说明原因的，出具《不予受理通知书》并将申报资料退回申请人。

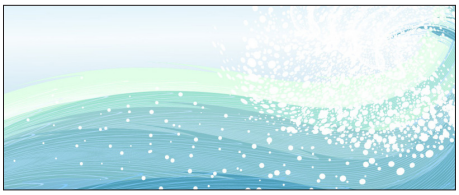
五、立卷审查

受理后总局药审中心对化学药品仿制药申报资料进行立卷审查，符合要求的，于45个工作日内完成立卷；不符合要求的，不予批准，并说明理由

六、现场核查及注册检验

集中受理实施后，国家食品药品监督管理总局新受理的药品注册申请，根据药品技术审评中的需求，由国家食品药品监督管

trial data conducted by CFDA as from July 2015. As for the drug under registration application requiring test for registration or sampling test as deemed necessary during on-site verification, the samples shall be taken and delivered to the National Institutes for Food and Drug Control or the drug testing institution at the provincial level by the inspection department as per the regulations. The verification report, and testing report, etc. shall be still delivered to CDE as per applicable regulations.



Each food and drug regulatory authority at the provincial level shall strengthen the publicity of the Announcement and make a timely report of major problems.

(November 13, 2017)

理总局食品药品审核查验中心统一组织全国药品注册检查资源实施现场核查，并不再列入2015年7月以来国家食品药品监督管理总局开展的药物临床试验数据自查核查范围。需要进行注册检验的或核查中认为需要抽样检验的，由检查部门按规定抽取样品送中国食品药品检定研究院或省级药品检验机构检验。核查报告和检验报告等，仍按现行规定报送总局药审中心。

各省级食品药品监督管理部门要加强宣传贯彻，遇到重大问题应及时报告。

（2017-11-13）

The General Office of CFDA Issued the Notice on Strengthening the Regulation of the Trading of Drugs and Medical Devices on the Internet

To implement the requirements of the *Decision of the State Council on Cancelling A Batch of Administrative Licensing Items* (SC [2017] No. 46) and complete relevant transition work regarding in-process and afterwards supervision and administration measures, on November 1, 2017, the General Office of CFDA issued relevant notice on the matters to strengthen the regulation of the trading of drugs and medical devices on the Internet. (November 2, 2017)

国家食品药品监督管理总局办公厅发布加强互联网药品医疗器械交易监管工作的通知

为贯彻落实《国务院关于取消一批行政许可事项的决定》（国发〔2017〕46号）的要求，做好相关事中事后监管措施的衔接工作，2017年11月1日，国家食品药品监督管理总局办公厅就加强互联网药品、医疗器械交易监管工作发布有关通知。（2017-11-02）

CFDA Issued the *Announcement on Self-inspection & Verification of Drug Clinical Trial Data for Registration Applications*

On October 30, 2017, CFDA Issued the *Announcement on Self-inspection & Verification of Drug Clinical Trial Data for Registration Applications* ([2017] No. 128), decided to conduct verification on the clinical trial data of the newly received drug registration applications of 42 drugs whose clinical trials have been completed and which are applying for production or import, and relevant matters are hereby announced.

(October 30, 2017)

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注册申请情况的公告》

2017年10月30日，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注册申请情况的公告》（2017年第128号），决定对新收到42个已完成临床试验申报生产或进口的药品注册申请进行临床试验数据核查，并将有关事宜进行了公告。

（2017-10-30）

CFDA Released the Lists of the Reference Preparations of Generic Drugs (Ninth Batch) (Tenth Batch)

Upon determination by the Expert Committee of Consistency Evaluation for Quality and Efficacy of Generic Drugs, CFDA after review, CFDA released the Lists of the Reference Preparations of Generic Drugs (Ninth Batch) (Tenth Batch) on October 13, 2017.

(October 13, 2017)

国家食品药品监督管理总局发布仿制药参比制剂目录（第九批）（第十批）

经国家食品药品监督管理总局仿制药质量和疗效一致性评价专家委员会审核确定，国家食品药品监督管理总局于2017年10月13日发布了仿制药参比制剂目录（第九批）（第十批）。（2017-10-13）

CFDA Printed and Issued the Administrative Measures for the Key Laboratories of CFDA

In order to regulate the assessment, operation, evaluation and other management work for key laboratories of CFDA, strengthen the technical support and technical reserve for food and drug supervision and administration and further enhance the regulatory capability for food and drugs, CFDA organized to formulate the *Administrative Measures for the Key Laboratories of CFDA*, which were issued on October 13, 2017. (October 13, 2017)

国家食品药品监督管理总局印发《国家食品药品监督管理总局重点实验室管理办法》

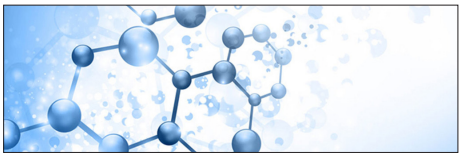
为规范国家食品药品监督管理总局重点实验室的评定、运行和评估等管理工作，加强食品药品监管工作的技术支撑和技术储备，进一步提升食品药品监管能力，国家食品药品监督管理总局组织制定了《国家食品药品监督管理总局重点实验室管理办法》，于2017年10月13日发布。 （2017-10-13）

CFDA and NHFPC Issued the *Announcement on the Conduct of Human Bioequivalence Test by Drug Clinical Trial Institutions*

For the purpose of carrying out the *Opinions of the State Council on the Reform of the Review & Approval System for Drugs and Medical Devices*, and better serving clinical value oriented drug innovation and effectively performing the subject responsibilities of the applicant, on October 13, 2017, CFDA and NHFPC issued the *Announcement on the Conduct of Human Bioequivalence Test by Drug Clinical Trial Institutions* ([2017] No. 119) to provide details below:

I. In accordance with relevant provisions of the *Drug Administration Law of the People's Republic of China and the Measures for the Qualification Recognition of Drug Clinical Trial Institutions (Interim)*, drug regulatory authorities and health administrative authorities have identified 619 medical institutions qualified as drug clinical trial institutions, which are eligible to conduct human bioequivalence test.

II. Any human bioequivalence test conducted by a drug clinical trial institution shall be subject to ethical review and trial management pursuant to the requirements, conditions and procedures of the *Measures for the Ethical Review of Biomedical Research Involving Human*, and relevant guidelines, so as to effectively protect the right and interests and ensure the safety of subjects.



III. The registration applicant shall, prior to commencement of human bioequivalence test, make a filing on the platform (be.chinadrugtrials.org.cn) for filing the information about bioequivalence and clinical trial of chemical generic drugs designated by CFDA in respect of the human bioequivalence test project contemplated to be conducted.

IV. The registration applicants and drug clinical trial institutions shall ensure the authenticity, integrity and reliability of the data as to human bioequivalence test, and bear legal responsibilities for all trial-related data in accordance with the *Good Clinical Practice for Drugs, the Guideline on Management of Phase I Clinical Trial of Drugs (Interim)* and relevant technical requirements. If the trial fails to pass on-site inspection, such trial data shall not be accepted for drug review.

V. All drug regulatory authorities at the

国家食品药品监督管理总局 国家卫生和计划生育委员会发布《关于药物临床试验机构开展人体生物等效性试验的公告》

为落实《国务院关于改革药品医疗器械审评审批制度的意见》，更好地服务以临床价值为导向的药物创新，有效落实申请人主体责任，2017年10月13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发布《关于药物临床试验机构开展人体生物等效性试验的公告》（2017年第119号），就生物等效性试验有关工作公告如下：

一、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）》的有关规定，药品监督管理部门会同卫生行政部门已经认定具有药物临床试验机构资格的医疗机构619家。经认定的药物临床试验机构均可以开展人体生物等效性试验。

二、药物临床试验机构开展人体生物等效性试验，其伦理审查和试验管理应当符合《涉及人的生物医学研究伦理审查办法》及相关指导原则中的要求、条件和程序，有效保护受试者的权益并保障其安全。

三、注册申请人开展人体生物等效性试验前，应当将拟开展的人体生物等效性试验项目在国家食品药品监督管理总局指定的化学仿制药生物等效性与临床试验备案信息平台（网址：be.chinadrugtrials.org.cn）备案。

四、注册申请人和药物临床试验机构应当遵循《药物临床试验质量管理规范》《药物Ⅰ期临床试验管理指导原则（试行）》及相关技术要求，确保人体生物等效性试验数据真实、完整、可靠，并对全部试验数据承担法律责任。现场检查未通过的，其数据在药品审评时将不被接受。

五、各省级药品监督管理部门负责对本

provincial level shall be responsible for the supervision over human bioequivalence test projects conducted by the drug clinical trial institutions within their respective administrative area and on-site inspection over trial projects and shall bear the responsibilities for supervising the authenticity and integrity of the trial data.

Annex: Medical Institutions Qualified as Drug Clinical Trial Institutions (Omitted)

(October 13, 2017)

行政区域内药物临床试验机构开展的人体生物等效性试验项目的监督，负责试验项目的现场检查。对试验数据真实、完整、可靠承担监督责任。

附件：具有药物临床试验机构资格的医疗机构（略） (2017-10-13)

Food

CFDA Issued the *Provisions for the Supervision and Administration of Food Safety of Internet Catering Services*

On November 10, 2017, CFDA issued the *Provisions for the Supervision and Administration of Food Safety of Internet Catering Services* (CFDA Order No. 36), which shall be implemented as of January 1, 2018.

(November 14, 2017)

食品

国家食品药品监督管理总局发布《网络餐饮服务食品安全监督管理办法》

2017年11月10日，国家食品药品监督管理总局公布《网络餐饮服务食品安全监督管理办法》（国家食品药品监督管理总局令第36号），《办法》自2018年1月1日起施行。 (2017-11-14)

Medical Devices

CFDA Issued Five Guidelines for Technical Review of Registration Including the Guidelines for Technical Review of Ultrasound Bone Densitometer Registration

In order to strengthen the supervision and guidance for the registration of medical devices and further improve the quality of registration review, CFDA organized to formulate the *Guidelines for Technical Review of Ultrasound Bone Densitometer Registration, the Guidelines for Technical Review of Electric Wheelchair Registration, the Guidelines for Technical Review of Clinical Infrared Ear Thermometer Registration, the Guidelines for Technical Review of Medical Suction Equipment Registration (2017 Revision)* and the *Guidelines for Technical Review of Small Molecular Sieve Oxygen Generator Registration (2017 Revision)* which were issued on November 15, 2017.

(November 15, 2017)

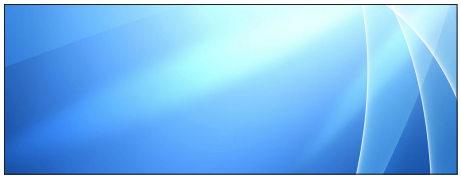
医疗器械

国家食品药品监督管理总局发布超声骨密度仪等5项注册技术审查指导原则

为加强医疗器械产品注册工作的监督和指导，进一步提高注册审查质量，国家食品药品监督管理总局组织制定了《超声骨密度仪注册技术审查指导原则》《电动轮椅车注册技术审查指导原则》《耳腔式医用红外体温计注册技术审查指导原则》《医用吸引设备注册技术审查指导原则（2017年修订版）》《小型分子筛制氧机注册技术审查指导原则（2017年修订版）》，于2017年11月15日 发布。 (2017-11-15)

CFDA Issued Five Guidelines for Technical Review of Registration Including the Guidelines for Technical Review of Ultrasonic Doppler Fetal Heartbeat Detector Registration

In order to strengthen the supervision and guidance for the registration of medical devices and further improve the quality of registration review, CFDA organized to formulate the *Guidelines for Technical Review of Ultrasonic Doppler Fetal Heartbeat Detector Registration (2017 Revision)*, the *Guidelines for Technical Review of Ultrasonic Physiotherapy Equipment Registration (2017 Revision)*,



国家食品药品监督管理总局发布超声多普勒胎儿监护仪等5项注册技术审查指导原则

为加强医疗器械产品注册工作的监督和指导，进一步提高注册审查质量，国家食品药品监督管理总局组织制定了《超声多普勒胎儿监护仪注册技术审查指导原则（2017年修订版）》《超声理疗设备注册技术审查指导原则（2017年修订版）》《超声洁牙设备注册技术审查指导原则（2017年修订版）》

the *Guidelines for Technical Review of Ultrasonics Dental Descaler Equipment Registration (2017 Revision)*, the *Guidelines for Technical Review of Perimeter Registration (2017 Revision)* and the *Guidelines for Technical Review of Bedsore Prevention Mattress Registration (2017 Revision)* which were issued on November 15, 2017.

(November 15, 2017)

《视野计注册技术审查指导原则（2017年修订版）》《防褥疮气床垫注册技术审查指导原则（2017年修订版）》，于2017年11月15日发布。 (2017-11-15)

CFDA Issued the *Announcement on the Communication concerning the Application for the Medical Device Clinical Trial Requiring Review and Approval*

To implement the *Opinions on Deepening the Review and Approval System Reform and Encouraging the Drug and Medical Device Innovation* (CPC & SC [2017] No. 42) of the General Office of the CPC Central Committee and the General Office of the State Council and to further optimize the review and approval procedure for clinical trials, on November 14, 2017, CFDA issued the *Announcement on the Communication concerning the Application for the Medical Device Clinical Trial Requiring Review and Approval* which specified the relevant matters concerning the communication on the application for the medical device clinical trial that requires review and approval.

(November 14, 2017)

国家食品药品监督管理总局发布《关于需审批的医疗器械临床试验申请沟通交流有关事项的通告》

为贯彻落实中共中央办公厅、国务院办公厅《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》（厅字〔2017〕42号），进一步优化临床试验审批程序，2017年11月14日，国家食品药品监督管理总局发布《关于需审批的医疗器械临床试验申请沟通交流有关事项的通告》，就需审批的医疗器械临床试验申请沟通交流有关事项进行了明确。 (2017-11-14)

CFDA Issued the *Announcement on Releasing Five Guidelines for Technical Review of Registration Including the Guidelines for Technical Review of Infrared Therapy Equipment Registration*

In order to strengthen the supervision and guidance for the registration of medical devices and further improve the quality of registration review, CFDA organized to formulate the *Guidelines for Technical Review of Infrared Therapy Equipment Registration (2017 Revision)*, the *Guidelines for Technical Review of Medical Temperature Control Blanket Registration (2017 Revision)*, the *Guidelines for Technical Review of Middle-frequency Electrotherapy Instrument Registration (2017 Revision)*, the *Guidelines for Technical Review of Pulse Oximeter Registration (2017 Revision)* and the *Guidelines for Technical Review of Dental Handpiece Registration (2017 Revision)* which were issued on November 14, 2017. (November 14, 2017)

国家食品药品监督管理总局发布《发布红外线治疗设备等5项注册技术审查指导原则》的通告

为加强医疗器械产品注册工作的监督和指导，进一步提高注册审查质量，国家食品药品监督管理总局组织制定了《红外线治疗设备注册技术审查指导原则（2017年修订版）》《医用控温毯注册技术审查指导原则（2017年修订版）》《中频电疗产品注册技术审查指导原则（2017年修订版）》《脉搏血氧仪注册技术审查指导原则（2017年修订版）》《牙科手机注册技术审查指导原则（2017年修订版）》，于2017年11月14日发布。 (2017-11-14)

CFDA Issued the *Announcement on Filing of Medical Device Distribution*

According to the requirements of the State Council for simplifying administrative procedures, delegating powers, improving regulation and optimizing services, in order to facilitate the medical device distributing enterprises to handle the filing and improve work efficiency, CFDA decides to simplify the filing dossiers to be submitted by medical

国家食品药品监督管理总局发布《关于医疗器械经营备案有关事宜的公告》

按照国务院简政放权、放管结合、优化服务的要求，为方便医疗器械经营企业办理备案、提高工作效率，国家食品药品监督管理总局决定简化医疗器械经营企业提交的备

device distributing enterprises and optimize the handling procedures. On November 3, 2017, CFDA issued the *Announcement on Filing of Medical Device Distribution* which specified the relevant matters.

(November 3, 2017)

案资料，优化办理程序。2017年11月3日，发布《关于医疗器械经营备案有关事宜的公告》，就有关事宜进行了明确。 （2017-11-03）

CFDA Issued the *Announcement on Releasing the Basic Requirements for Clinical Evaluation Materials of the In-vitro Diagnostic Reagents Exempt from Clinical Trial (Interim)*

To implement the *Opinions on Deepening the Review and Approval System Reform and Encouraging the Drug and Medical Device Innovation* (CPC [2017] No. 42) printed and issued by the General Office of the CPC Central Committee and the General Office of the State Council and the *Opinions of the State Council on the Reform of the Review and Approval System for Drugs and Medical Devices* (SC [2015] No. 44) and to further improve the administration on the registration of in-vitro diagnostic reagents and regulate the clinical evaluation of in-vitro diagnostic reagents exempt from clinical trial, in accordance with the *Provisions for In-vitro Diagnostic Reagent Registration* (CFDA Order No. 5), CFDA organized to formulate the *Basic Requirements for Clinical Evaluation Materials of the In-vitro Diagnostic Reagents Exempt from Clinical Trial (Interim)* which were issued on November 8, 2017 and came into effect as of its issuance date.

(November 2, 2017)

国家食品药品监督管理总局发布《关于发布免于进行临床试验的体外诊断试剂临床评价资料基本要求（试行）的通告》

为贯彻落实中共中央办公厅、国务院办公厅印发的《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》（厅字〔2017〕42号）和《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），进一步做好体外诊断试剂注册管理，规范免于进行临床试验的体外诊断试剂临床评价工作，根据《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），国家食品药品监督管理总局组织制定了《免于进行临床试验的体外诊断试剂临床评价资料基本要求（试行）》，于2017年11月8日发布，自发布之日起施行。 （2017-11-02）

CFDA Issued the *Announcement on Using Chinese in the Names of Registration Applicants and Filing Entities of Imported Medical Devices*

In accordance with the *Regulations for the Supervision and Administration of Medical Devices*, the *Provisions for Medical Device Registration*, the *Provisions for In-vitro Diagnostic Reagent Registration*, the *Provisions for Instructions and Labels of Medical Devices* and other regulations, for the application for medical device marketing in China, the names of registration applicants, registrants and filing entities shall be in Chinese. In order to further implement relevant requirements, better meet the needs of the public and accept social supervision, on November 1, 2017, CFDA issued the *Announcement on Using Chinese in the Names of Registration Applicants and Filing Entities of Imported Medical Devices* which specified the relevant issues on using Chinese in the names of registration applicants, registrants and filing entities of imported medical devices. (November 2, 2017)

国家食品药品监督管理总局发布《关于进口医疗器械注册申请人和备案人名称使用中文的公告》

根据《医疗器械监督管理条例》《医疗器械注册管理办法》《体外诊断试剂注册管理办法》和《医疗器械说明书和标签管理规定》等规定，在我国申请医疗器械上市的，注册申请人、注册人和备案人的名称应当使用中文。为进一步落实有关要求，更好地满足公众需要，接受社会监督，2017年11月1日，国家食品药品监督管理总局发布《关于进口医疗器械注册申请人和备案人名称使用中文的公告》，就进口医疗器械注册申请人、注册人和备案人名称使用中文的有关事宜进行了明确。 （2017-11-02）

CFDA Issued the *List of the Third Batch of Medical Devices Exempted from Clinical Trial*

For the purpose of completing the administration of medical device registration, according to the *Regulation for the Supervision and Administration of*

国家食品药品监督管理总局发布《第三批免于进行临床试验医疗器械目录》

为做好医疗器械注册管理工作，根据《医疗器械监督管理条例》（国务院令第

Medical Devices (State Council Decree No. 680), the *Provisions for Medical Device Registration* (CFDA Order No. 4), and the *Provisions for In-vitro Diagnostic Reagent Registration* (CFDA Order No. 5), the *CFDA organized to formulate the List of Class II Medical Devices Exempted from Clinical Trial (Third Batch)*, the *List of Class III Medical Devices Exempted from Clinical Trial (Third Batch)*, and the *List of In-vitro Diagnostic Reagents Exempted from Clinical Trial (Third Batch)* which were issued on October 31, 2017 and came into effect from the issuance date.

(October 31, 2017)

680号）、《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）、《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），国家食品药品监督管理总局组织制定了第三批《免于进行临床试验的第二类医疗器械目录》《免于进行临床试验的第三类医疗器械目录》和《免于进行临床试验的体外诊断试剂目录》，于2017年10月31日发布，自发布之日起施行。 （2017-10-31）

CFDA Issued the *Announcement on the Second Batch of Medical Device Clinical Trial Projects Subject to Supervisory Sampling Inspection in 2017*

In order to strengthen the supervision and management of medical device clinical trials, and, in accordance with the scope of sampling inspection and relevant principles specified under the *Announcement on the Supervisory Sampling Inspection of Medical Device Clinical Trials in 2017 (CFDA Announcement* [2017] No. 103), October 18, 2017, CFDA Issued the Announcement, CFDA has sampled 10 registration applications including resistive magnetic resonance imaging system registration application (acceptance No.: CQZ 1600042) for conducting on-site supervisory inspection over corresponding clinical trial data to ensure their authenticity and compliance. Further notice will be given by the Center for Food and Drug Inspection of CFDA, indicating the inspection schedule and clinical trial institutions to be inspected.

(October 19, 2017)

国家食品药品监督管理总局发布《关于2017年第二批医疗器械临床试验监督抽查项目的通告》

为加强医疗器械临床试验监督管理，根据《关于开展2017年医疗器械临床试验监督抽查工作的通告》（国家食品药品监督管理总局通告2017年第103号）明确的抽查范围和相关原则，2017年10月18日，国家食品药品监督管理总局发布通告，将抽取常导型磁共振成像系统（受理号：CQZ 1600042）等10个注册申请项目，对其临床试验数据的真实性和合规性实施现场监督检查。具体检查时间安排和抽查的临床试验机构由国家食品药品监督管理总局食品药品审核查验中心另行通知。 （2017-10-19）

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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