2017. Volume 5

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

General Office of CFDA Issued the Notice on Implementing the *Decision of the State Council on the Cancellation of the Third Batch of Administrative Licensing Items Implemented by Local Governments as Designated by the Central Government*

On April 7, 2017, the General Office of CFDA issued a Notice on Implementing the *Decision of the State Council on the Cancellation of the Third Batch of Administrative Licensing Items Implemented by Local Governments as Designated by the Central Government* (SYJBF [2017] No. 46), which reads as follows:

To food and drug regulatory authorities of all provinces, autonomous regions and municipalities directly under the central government, and the Xinjiang Production and Construction Corps:

On January 21, 2017, the State Council promulgated the *Decision on the Cancellation of the Third Batch of Administrative Licensing Items Implemented by Local Governments as Designated by the Central Government* (GF [2017] No. 7), which abolished three administrative licensing items implemented by the provincial food and drug regulatory authorities: 1. registration review and approval of pharmaceutical excipients (excluding pharmaceutical excipients for new drugs and imported pharmaceutical excipients); 2. preliminary review of the qualification accreditation of drug clinical trial institutions; 3. review and approval of Internet drug trading service enterprises (excluding third-party platforms). To implement the relevant requirements for the cancellation of administrative licensing items and improve implementation and integration with in-process and afterwards supervision and administration, relevant issues are notified as follows:

I. On the abolition of registration review and approval of pharmaceutical excipients (excluding pharmaceutical excipients for new drugs and imported pharmaceutical excipients) by the provincial food and drug regulatory authorities

The provincial food and drug regulatory authorities shall, in accordance with the requirements of the *Announcement on Associated Review & Approval of Pharmaceutical Packaging Materials and Pharmaceutical Excipients with Drugs* (CFDA Announcement [2016] No. 134), implement associate review and approval of pharmaceutical excipients, and perform on-site verification and sampling of domestic high-risk pharmaceutical excipients. Effectively strengthen the daily supervision and administration of pharmaceutical excipients manufacturers, and strengthen the extended inspections over pharmaceutical excipients, to ensure the quality of drugs.

II. On the abolition of preliminary review of the qualification accreditation of drug clinical trial institutions by the provincial food and drug regulatory authorities

The qualification accreditation and re-review inspection of drug clinical trial institutions shall be subject to China Food and Drug Administration (hereinafter referred to as CFDA), and the application dossiers can do without submitting the

国家食品药品监督管理总局办公厅发布关于落实《国务院第三批取消中央指定地方实施行政许可事项的决定》有关工作的通知

2017年4月7日，国家食品药品监督管理总局办公厅发布了关于落实《国务院第三批取消中央指定地方实施行政许可事项的决定》有关工作的通知（食药监办法〔2017〕46号），全文如下：

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：

2017年1月21日，国务院发布了《第三批取消中央指定地方实施行政许可事项的决定》（国发〔2017〕7号），取消了由省级食品药品监管部门实施的药用辅料（不含新药用辅料和进口药用辅料）注册审批、药物临床试验机构资格认定初审、互联网药品交易服务企业审批（第三方平台除外）三项行政许可事项。为了落实取消行政许可事项的相关要求，做好事中事后监管措施的落实和衔接工作，现就有关事项通知如下：

一、关于取消省级食品药品监管部门实施的药用辅料（不含新药用辅料和进口药用辅料）注册审批

各省级食品药品监管部门应按照《关于药包材药用辅料与药品关联审评审批有关事项的公告》（2016年第134号）要求，落实药用辅料关联审评审批工作，做好国产高风险药用辅料的现场核查、抽样等工作。要切实加强对药用辅料生产企业的日常监管，强化对药用辅料的延伸检查，保证药品质量。

二、关于取消省级食品药品监管部门实施的药物临床试验机构资格认定初审

药物临床试验机构资格认定和复核检查由食品药品监管总局（以下简称总局）受理，申请资料中无需提交省级卫生行政部门和省级食品药品监管部门审核意见。申请人分别登陆总局药物临床试验机构资格认定电子申请系统和复核检查系统，按要求填报申请书和申请材料，纸质资料寄至总局核查中心，总局形式审

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

review comments by provincial health administrative authorities and provincial food and drug regulatory authorities. The applicant may log in the CFDA electronic application system for qualification accreditation of drug clinical trial institutions, and re-review inspection system, and fill in the Application Form and dossiers as required. The paper dossiers shall be sent to Center for Food and Drug Inspection of CFDA, who shall, after preliminary review, inform the applicant in writing the acceptance or rejection of the application. The results of the on-site inspection and review will be notified in writing to the applicant, and CFDA shall announce the status of qualified applicants, who shall be issued with a Certificate.

III. On the abolition of review and approval of Internet drug trading service enterprises (excluding third-party platforms) by the provincial food and drug regulatory authorities

(A) On Internet drug trading

The enterprises that have obtained the qualification of Internet drug trading service shall be engaged in Internet drug trading service in strict accordance with the *Good Supply Practice for Pharmaceutical Products* and relevant documents, strengthen the systems related to storage and distribution, and implement the management responsibility to ensure the quality and safety of the sold drugs.

1. Drug manufacturers and wholesalers may, based on their own websites, conduct Internet drug transactions with other enterprises, but shall refrain from providing Internet drug trading services to individual consumers.

2. Drug retail chain enterprises may provide individual consumers with Internet drug trading services within but not beyond the business scope of the Drug Distributing License, and shall refrain from displaying and selling prescription drugs and non-prescription drugs subject to specialized management by the state on the relevant online trading web pages.

The regulatory policies for Internet drug trading services will be released separately.

(B) On Internet trading of medical devices

The enterprise engaged in Internet medical device trading services shall obtain the distributing license or be recorded on file according to law, and engage in distribution in accordance with the scope of the license or filing, and shall promptly notify the food and drug regulatory authority of the municipality consisting of districts where the enterprise is located the enterprise name, domicile, legal representative, website, Medical Device Distributing License or Filing Certificate Number and other information in writing.

1. Medical device manufacturers may provide Internet trading services of their products via their own websites.

2. Medical device wholesalers may provide Internet medical device trading services to qualified medical device distributors or user units via their own websites, but not to individual consumers.

3. Medical device retailers may provide Internet medical device trading services to individual consumers via their own websites, but the sales of medical devices shall not exceed the business scope prescribed in the Medical Device Distributing License or the Filing Certificate for Class II medical device distribution.

4. Medical device sold in retail to individual consumers should satisfy their self-use, and the instructions should comply with the provisions of Article 10 (8) of the *Provisions for Instructions and Labels of Medical Devices*, with special notes for safe use.

The regulatory policies for Internet medical device trading services will be released separately.

(C) Regulatory requirements

Food and drug regulatory departments at all levels shall further improve the regulation of Internet drug and medical device transactions; regulate the subjects and behaviors of Internet drug transactions; take effective supervision measures to crack down on illegal sales of drugs and medical

查后将书面通知申请人是否受理。现场检查和审核的结果将书面通知申请人，总局对通过资格认定的申请人情况进行公告并颁发证书。

三、关于取消省级食药监管部门实施的互联网药品交易服务企业审批（第三方平台除外）

（一）关于互联网药品交易

已取得互联网药品交易服务资质的企业，应严格按照《药品经营质量管理规范》及有关文件要求从事互联网药品交易服务，强化储存、配送等有关制度，落实管理责任，保证所售药品的质量安全。

1. 药品生产企业、药品批发企业可以通过自身网站与其他企业进行互联网药品交易，但不得向个人消费者提供互联网药品交易服务。

2. 药品零售连锁企业可以向个人消费者提供互联网药品交易服务，但不得超出《药品经营许可证》的经营范围，不得在网站交易相关页面展示、销售处方药以及国家有专门管理要求的非处方药品。

互联网药品交易服务监管相关政策将另行发布。

（二）关于互联网医疗器械交易

从事互联网医疗器械交易服务的企业，应当依法取得经营许可或者办理备案，并按照许可或备案的范围从事经营活动，并及时将企业名称、住所、法定代表人、网址、医疗器械经营许可或备案凭证编号等信息书面告知所在地设区的市级食品药品监督管理部门。

1. 医疗器械生产企业可以通过自身网站提供本企业生产医疗器械的互联网交易服务。

2. 医疗器械批发企业可以通过自身网站向具有资质的医疗器械经营企业或使用单位提供互联网医疗器械交易服务，但不得提供面向个人消费者的医疗器械交易服务。

3. 医疗器械零售企业可以通过自身网站向消费者个人提供互联网医疗器械交易服务，但其销售医疗器械不得超出《医疗器械经营许可证》或第二类医疗器械经营备案凭证的经营范围。

4. 向消费者个人零售的医疗器械，应当是可以由消费者个人自行使用的，其说明书应当符合《医疗器械说明书和标签管理规定》第十条第（八）项的规定，标注安全使用的特别说明。

互联网医疗器械交易服务监管相关政策将另行发布。

（三）监管工作要求

各级食品药品监管部门要继续做好互联网药品、医疗器械交易监管工作，规范互联

devices and other acts on Internet.

IV. Requirements for work integration

The provincial food and drug regulatory authorities should pay close attention to the abolition of administrative licensing items and the integration of work, the decision to cancel the administrative licensing items, and shall no longer accept the applications for the above-said canceled administrative licensing items as from the promulgation of the *Decision of the State Council on the Cancellation of the Third Batch of Administrative Licensing Items Implemented by Local Governments as Designated by the Central Government* (GF [2017] No. 7); for those applications accepted by provincial administrations before the promulgation of the Decision, and not yet completed with the review and approval before that date, the administrative formalities shall be terminated, and the application dossiers shall be returned to the applicants. The original licensing authorities shall not be allowed to implement the aforementioned licensing in other names or in disguise. In-process and afterwards supervision and administration shall be strengthened for effective integration of power delegation and strong regulation.

(April 7, 2017)

网药品交易的主体和行为，采取有效监督措施，严厉打击互联网违法销售药品、医疗器械等行为。

四、衔接工作要求

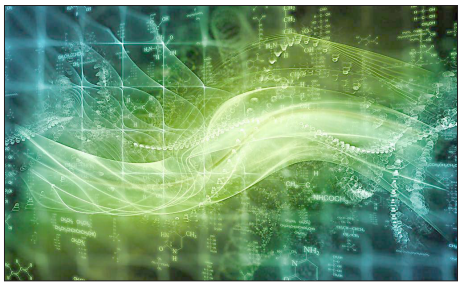
各省级食品药品监管部门应抓紧做好取消行政许可事项的落实和衔接工作，对决定取消的行政许可事项，自《国务院关于第三批取消中央指定地方实施行政许可事项的决定》（国发〔2017〕7号）发布之日起，各省级食品药品监管部门不再受理上述取消的行政许可事项的申请；发布之日前省局已受理，截止发布之日尚未完成审批的，应终止审批，将申请材料退还申请人。原许可部门不得再实施许可或以其他名目变相审批，同时要加强事中事后监管，切实做到放管结合。

（2017-04-07）

CFDA Adjusted Certain Procedures for Administrative Review and Approval of Drugs and Medical Devices

With a view to further optimizing the review and approval processes of drugs and medical devices and improving the efficiency of review and approval, on April 6, 2017, CFDA issued the *CFDA's Decision on Adjusting Certain Procedures for Administrative Review and Approval of Drugs* (CFDA Order No. 31), and the *CFDA's Decision on Adjusting Certain Procedures for Administrative Review and Approval of Medical Devices* (CFDA Order No. 32), which adjusted such procedures for administrative review and approval of drugs and medical devices as review and approval of clinical trials, re-registration and registration renewal, and registration of changes in the charge of CFDA.

As of May 1, 2017, the decision on the review and approval of clinical trials of domestic drugs and imported drugs, supplementary application of domestic drugs and imported drugs, re-registration of imported drugs shall be made by Center



for Drug Evaluation, CFDA in the name of CFDA and shall be issued by the responsible person of CDE.

As of July 1, 2017, the decision on the review and approval of clinical trials of Class III high-risk medical devices, change of licensed items and registration renewal of domestic Class III medical devices and imported medical devices shall be made by Center for Medical Device Evaluation, CFDA in the name of CFDA and shall be issued by the responsible person of CMDE.

(April 6, 2017)

国家食品药品监督管理总局调整部分药品和医疗器械行政审批事项审批程序

为优化药品和医疗器械审评审批流程，提高审评审批效率，2017年4月6日，国家食品药品监管总局发布总局令31号《国家食品药品监督管理总局关于调整部分药品行政审批事项审批程序的决定》和总局令32号《国家食品药品监督管理总局关于调整部分医疗器械行政审批事项审批程序的决定》，对食品药品监管总局负责的临床试验审批事项、再注册和延续注册审批事项、注册变更审批事项等药品和医疗器械行政审批事项的审批程序进行调整。

从2017年5月1日起，国产和进口药物的临床试验审批决定、国产和进口药品的补充申请审批决定、进口药品再注册审批决定，调整为由总局药品审评中心以总局名义作出，审批决定由药品审评中心负责人签发。

从2017年7月1日起，第三类高风险医疗器械临床试验审批决定、国产第三类医疗器械和进口医疗器械许可事项变更审批决定、国产第三类医疗器械和进口医疗器械延续注册审批决定，由总局医疗器械技术审评中心以总局名义作出，审批决定由总局医疗器械技术审评中心负责人签发。

（2017-04-06）

CFDA issued the *Guiding Opinions on the Classification of Drug Varieties in Consistency Evaluation of the Quality and Efficacy of Generic Drugs*

To regulate the consistency evaluation of the quality and efficacy of generic drugs, CFDA organized to formulate the *Guiding Opinions on the Classification of Drug Varieties in Consistency Evaluation of the Quality and Efficacy of Generic Drugs*, which were issued on April 5, 2017.

Guiding Opinions on the Classification of Drug Varieties in Consistency Evaluation of the Quality and Efficacy of Generic Drugs

To further promote the consistency evaluation of the quality and efficacy of generic drugs (hereinafter referred to as consistency evaluation), the following guiding opinions are hereby given for the classification of drug varieties:

I. Imported originators which have been marketed. After the review, confirmation and release by CFDA, these drugs may be chosen as reference preparations without the need for consistency evaluation.

II. Varieties produced and marketed in China by the enterprises of originators. These varieties may be chosen as reference preparations after the review, confirmation and release by CFDA.

III. Imported generic drugs.

(A) For those imported generic drugs applied for registration and reviewed before marketing as per the principles consistent with the quality and efficacy of originators, Center for Administrative Service, Complaint & Reporting, CFDA shall accept the applicants' application dossiers, and Center for Drug Evaluation, CFDA shall review and provide comments, and report to CFDA for issuance.

(B) For those imported generic drugs not applied for registration and reviewed before marketing as per the principles consistent with the quality and efficacy of originators, the consistency evaluation shall be performed according to the relevant provisions.

IV. Domestic generic drugs. For those applied for registration and reviewed before marketing as per the principles consistent with the quality and efficacy of originators, the procedures of III- (A) stated above shall apply; otherwise the consistency evaluation shall be performed according to the relevant provisions.

V. For generic drugs with altered strength, dosage forms, and bases, the consistency evaluation shall be performed as per the *General Consideration of Generic Drug Quality & Efficacy Consistency Evaluation of Drugs (Oral Solid Preparations) with Alterations of Strength*, the *General Consideration of Generic Drug Quality & Efficacy Consistency Evaluation of Drugs (Oral Solid Preparations) with Alterations of Dosage Forms*, and the *General Consideration of Generic Drug Quality & Efficacy Consistency Evaluation of Drugs with Alterations of Bases*.

VI. For domestic unique drugs, the enterprise may opt to re-conduct a clinical trial to prove the safety and efficacy of a drug, and submit an application by referring to the *Requirements for Application Dossiers of Quality & Efficacy Consistency Evaluation for*

国家食品药品监督管理总局发布《仿制药质量和疗效一致性评价品种分类指导意见》

为规范仿制药质量和疗效一致性评价工作，国家食品药品监督管理总局组织制定了《仿制药质量和疗效一致性评价品种分类指导意见》，于2017年4月5日发布。

仿制药质量和疗效一致性评价品种分类指导意见

为进一步推动仿制药质量和疗效一致性评价（以下简称一致性评价）工作的开展，现对品种的分类情况提出如下指导意见：

一、原研进口上市品种。无需开展一致性评价，经国家食品药品监督管理总局审核确定发布后，可选择为参比制剂。

二、原研企业在中国境内生产上市的品种。原研企业在中国境内生产上市的品种，经国家食品药品监督管理总局审核确定发布后，可选择为参比制剂。

三、进口仿制品种。

（一）上市前按照与原研药品质量和疗效一致原则申报和审评的，由企业提交申请，国家食品药品监督管理总局行政事项受理服务和投诉举报中心接收资料，国家食品药品监督管理总局药品审评中心审核并提出意见，报国家食品药品监督管理总局发布。

（二）上市前未按照与原研药品质量和疗效一致原则申报和审评的，需按有关规定开展一致性评价。

四、国内仿制品种。上市前按照与原研药品质量和疗效一致原则申报和审评的，按照上述第三条第一款规定的程序执行；未按照与原研药品质量和疗效一致原则申报和审评的，需按照有关规定开展一致性评价。

五、改规格、改剂型、改盐基的仿制品种。需按照国家食品药品监督管理总局发布的《仿制药质量和疗效一致性评价工作中改规格药品（口服固体制剂）评价一般考虑》《仿制药质量和疗效一致性评价工作中改剂型药品（口服固体制剂）评价一般考虑》《仿制药质量和疗效一致性评价工作中改盐基药品评价一般考虑》等指导原则开展一致性评价。

六、国内特有品种。由企业选择可重新开展临床试验证明其安全有效性，并参照《化学药品仿制药口服固体制剂质量和疗效一致性评价申报资料要求（试行）》提交申

Oral Solid Preparations of Chemical Drugs and Generic Drugs (Interim), if the application is approved in follow-up review, the consistency evaluation may be deemed as approved; where the enterprise did not opt to re-conduct a clinical trial, CFDA shall announce its lack of valid data, and the unique drug is not recommended for use.

VII. In the event of major technical issues and differences, an expert committee conference shall be held for discussion and demonstration. (April 5, 2017)

请，后续审核通过后视同通过一致性评价；企业未选择重新开展临床试验的，国家食品药品监督管理总局对外公布其缺乏有效性数据，不建议使用。

七、遇有重大技术性问题和分歧意见，召开专家委员会论证。（2017-04-05）

CFDA issued the *Announcement on the Suspension of Drug Protection Fees, Certification Fees, and Import and Export License Fees for Narcotic Drugs and Psychotropic Substances*

On March 31, 2017, CFDA issued the *Announcement on the Suspension of Drug Protection Fees, Certification Fees, and Import and Export License Fees for Narcotic Drugs and Psychotropic Substances* (Announcement No. 187), which reads as follows:

According to the requirements of the *Notice on Several Policies on the Cleanup and Standardization of Administrative and Institutional Fees of the Ministry of Finance and the National Development and Reform Commission* (CS [2017] No. 20), since April 1, 2017, the drug protection fees, certification fees, test fees (excluding commissioned test fees), and import and export license fees for narcotic drugs and psychotropic substances shall be suspended.

For suspended fee-charging items, if a notice of payment has been issued before April 1, they shall be levied in full and the proceeds received shall be turned over to the state treasury in full through the channels stipulated by the Ministry of Finance.

For suspended fee-charging items, if the relevant administrative counterpart has made advance payment for related costs, such administrative counterpart shall be allowed to apply for the refund of the relevant expenses with specific reference to the refund procedures in the CFDA Announcement No. 53.

(March 31, 2017)

国家食品药品监督管理总局发布《关于停征药品保护费、认证费和麻醉、精神药品进出口许可证费的公告》

2017年3月31日，国家食品药品监督管理总局发布《关于停征药品保护费、认证费和麻醉、精神药品进出口许可证费的公告》（公告第187号），内容如下：

根据《财政部　国家发展改革委关于清理规范一批行政事业性收费有关政策的通知》（财税〔2017〕20号）要求，自2017年4月1日起，停征药品保护费、认证费、检验费（不含委托检验费）和麻醉、精神药品进出口许可证费。

属于停征收费项目，并已于4月1日前发出缴费通知书的，应当足额征收，所收款项按照财政部门规定的渠道全额上缴国库。

属于停征收费项目，行政相对人预缴相关费用的，允许行政相对人申请退还相关费用，具体参照国家食品药品监督管理总局2015年第53号公告中的退费程序执行。

（2017-03-31）

CFDA Issued the *Announcement on Modifying the Package Inserts of Mycophenolic Drugs*

According to the results of adverse drug reactions assessment, to further protect the safety of public drug use, on March 28, 2017, CFDA issued the *Announcement on Modifying the Package Inserts of Mycophenolic Drugs*, and decided to add black box warning and modify the [adverse reactions], [contraindications] and other items of the package inserts of mycophenolic drugs (including: mycophenolate mofetil preparations (tablets, dispersible tablets, capsules, dry suspensions, injections), mycophenolate sodium enteric-coated tablets). (March 28, 2017)

国家食品药品监督管理总局发布《关于修订麦考酚类药品说明书的公告》

根据药品不良反应评估结果，为进一步保障公众用药安全，2017年3月28日，国家食品药品监督管理总局发布《关于修订麦考酚类药品说明书的公告》，决定对麦考酚类药品〔包括：吗替麦考酚酯制剂（包括片、分散片、胶囊、干混悬剂、注射剂）、麦考酚钠肠溶片〕说明书增加黑框警告、并对【不良反应】、【禁忌】等项进行修订。

（2017-03-28）

Food

CFDA Issued the Several Regulations on the Establishment of a Food Safety Traceability System for Food Manufacturers and Distributors

According to the *Food Safety Law of the People's Republic of China*, *the Opinions of the General Office of the State Council on Accelerating the Construction of Traceability System for Important Products* (GBF [2015] No. 95)and the *CFDA Opinions on Urging Food and Drug Manufacturers and Distributors to Improve the Traceability System* (SYJK [2016] No. 122)and other provisions, CFDA researched and developed the *Several Regulations on the Establishment of a Food Safety Traceability System for Food Manufacturers and Distributors*, which was issued on April 1, 2017.

(April 1, 2017)

General Office of CFDA issued the *Technical Specifications for Evaluation of Food Rapid Detection Methods*

To ensure the scientific and normative evaluation of the rapid detection methods of foods, CFDA organized to formulate the *Technical Specifications for Evaluation of Food Rapid Detection Methods*, which were issued on March 28, 2017.

(March 31, 2017)

Medical Devices

CFDA issued the Guidelines for Technical Review of Fetal Chromosomal Aneuploidy (T21, T18, and T13) Test Kit (High-throughput Sequencing) Registration

To strengthen the supervision and guidance of the registration of medical devices, and further improve the quality of registration review, CFDA organized to formulate the Guidelines for Technical Review of Fetal Chromosomal Aneuploidy (T21, T18, T13) Test Kit (High-Throughput Sequencing) Registration, which were issued on April 1, 2017. (April 1, 2017)

CFDA Issued 40 Industry Standards for Medical Devices Including the *Biological Evaluation of Oral Medical Devices Part 7: Dental Pulp Dentin Application Test*

Forty industry standards for medical devices including YY/T 0217.7-2017 *Biological Evaluation of Oral Medical Devices Part 7: Dental Pulp Dentin Application Test*, which have been deliberated and adopted, were issued on April 1, 2017. The standards shall come into effective as from April 1, 2018.

(April 1, 2017)

食品

国家食品药品监督管理总局发布食品生产经营企业建立食品安全追溯体系若干规定

根据《中华人民共和国食品安全法》《国务院办公厅关于加快推进重要产品追溯体系建设的意见》（国办发〔2015〕95号）和《食品药品监管总局关于推动食品药品生产经营者完善追溯体系的意见》（食药监科〔2016〕122号）等规定，国家食品药品监督管理总局研究制定了《关于食品生产经营企业建立食品安全追溯体系的若干规定》，于2017年4月1日发布。 (2017-04-01)

国家食品药品监督管理总局办公厅印发《食品快速检测方法评价技术规范》

为保证食品快速检测方法评价工作的科学性和规范性，国家食品药品监管总局组织制定了《食品快速检测方法评价技术规范》，于2017年3月28日印发。 (2017-03-31)

医疗器械

国家食品药品监督管理总局发布胎儿染色体非整倍体（T21、T18、T13）检测试剂盒（高通量测序法）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胎儿染色体非整倍体（T21、T18、T13）检测试剂盒（高通量测序法）注册技术审查指导原则，于2017年4月1日发布。 (2017-04-01)

国家食品药品监督管理总局发布《口腔医疗器械生物学评价第7部分：牙髓牙本质应用试验》等40项医疗器械行业标准

YY/T 0217.7—2017《口腔医疗器械生物学评价第7部分：牙髓牙本质应用试验》等40项医疗器械行业标准已经审定通过，于2017年4月1日予以公布。标准自2018年4月1日起实施。 (2017-04-01)

CFDA Issued the Provisions for the Administration of Expert *Advisory Committee on Medical Device Technical Review*

To further improve the quality and efficiency of the medical device technical review as per the *Opinions of the State Council on the Reform of the Review & Approval System for Drugs and Medical Devices*, CFDA organized to formulate the *Provisions for the Administration of Expert Advisory Committee on Medical Device Technical Review*, which were issued on March 21, 2017, and shall come into force since the date of promulgation.

(March 28, 2017)

国家食品药品监督管理总局发布《医疗器械技术审评专家咨询委员会管理办法》

为贯彻《国务院关于改革药品医疗器械审评审批制度的意见》，进一步提高医疗器械技术审评的质量和效率，国家食品药品监督管理总局组织制定《医疗器械技术审评专家咨询委员会管理办法》，于2017年3月21日发布，自发布之日起施行。（2017-03-28）

Annual Report

2016 Annual Report for Medical Device Registration Released

In 2016, China Food and Drug Administration (hereinafter referred to as CFDA) has implemented the *Regulations for the Supervision and Administration of Medical Devices, and, in accordance with the Opinions of the State Council on the Reform of the Review & Approval System for Drugs and Medical Devices* (GF [2015] No. 44), further promoted the medical device review and approval system reform, and strengthened the supervision and administration over national medical device registration, escalated on-site verification and authenticity sampling inspection, and constantly improved the quality and efficiency of medical device registration review and approval.

On March 27, 2017, CFDA issued the *2016 Annual Report for Medical Device Registration*, which contains 5 parts: Medical device registration, Acceptance of medical device registration applications, Medical device registration review and approval, Review and approval of innovative medical devices and other products, Other registration management status.

In 2016, CFDA received a total of 8,920 applications for medical device registration, registration renewal and change of licensed items, down by 5.1% as compared with that of 2015.

In 2016, CFDA has approved a total of 8,653 applications for medical device registration, registration renewal and change of licensed items. Compared with 2015, the total number of registration applications approved increased by 14.9%.

(March 27, 2017)

年报

《2016年度医疗器械注册工作报告》发布

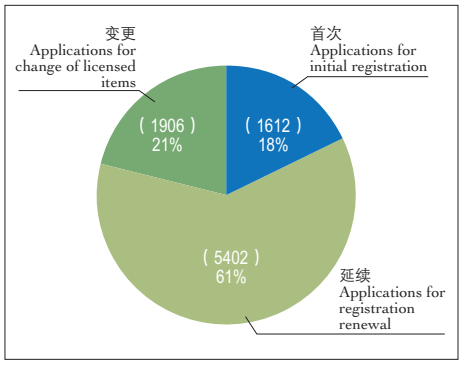
2016年，国家食品药品监督管理总局（以下简称食品药品监管总局）贯彻落实《医疗器械监督管理条例》，按照《国务院关于改革药品医疗器械审评审批制度的意见》(国发〔2015〕44号)，持续深入推进医疗器械审评审批制度改革工作，进一步加强对全国医疗器械注册工作监督和管理，加大现场核查和真实性抽查力度，不断提升医疗器械注册审评审批的质量与效率。

2017年3月27日，国家食品药品监督管理总局发布《2016年度医疗器械注册工作报告》。报告共分医疗器械注册工作情况、医疗器械注册申请受理情况、医疗器械注册审评审批情况、创新医疗器械等产品审评审批情况、其他注册管理情况五部分内容。

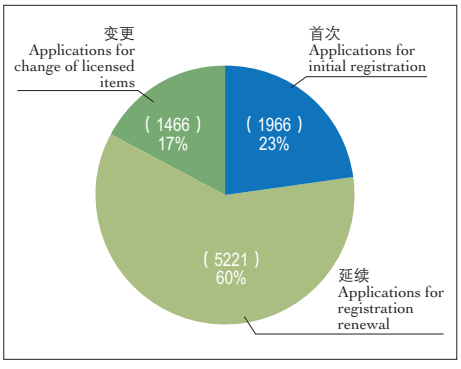
2016年共受理医疗器械注册、延续注册和许可事项变更申请8920项，与2015年相比注册受理项目减少5.1%。

2016年共批准医疗器械注册、延续注册和许可事项变更注册8653项。与2015年相比注册批准总数量增长14.9%。（2017-03-27）

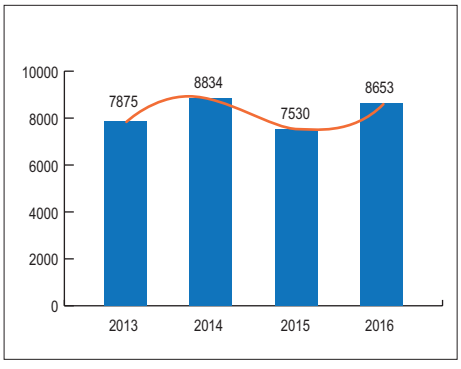
2016年注册受理形式比例图
2016 Proportion Chart for Registration Forms



2016年注册批准形式比例图
2016 Proportion Chart for Registration Forms



2013—2016年度注册批准数据图
CFDA Approvals for Medical Devices 2013-2016



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.ccfdie.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。
- 电子版Newsletter阅览请登录网站http://www.ccfdie.org

China Center for Food and Drug International Exchange (CCFDIE)
中国食品药品国际交流中心

Address: Room 1106, 11th Floor, Office Building B, Maples International Center, No. 32, Xizhimen North Street, Haidian District, Beijing, 100082, P.R.C.
中国北京市海淀区西直门北大街32号枫蓝国际中心B座写字楼11层1106室
邮编：100082

Tel: 010-8221 2866 Fax: 010-8221 2857
Email: ccfdie@ccfdie.org
Website: www.ccfdie.org

Servier (Tianjin) Pharmaceutical Co., Ltd.
施维雅（天津）制药有限公司

Address: 6 Floor, West Building, World Financial Center, No.1, East 3rd Ring Middle Road, Chaoyang District, 100020 Beijing, China
北京市朝阳区东三环中路1号环球金融中心西楼6层
邮政编码：100020

Tel: 010-6561 0341
Fax: 010-6561 0348
Website: www.servier.com.cn