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中国食品药品国际交流中心
SERVIER
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CNDA Announcement on the Issuance of the Technical Guidelines for Accepting Overseas Clinical Trial Data of Drugs

To implement the *Opinions on Deepening the Review and Approval System Reform and Encouraging the Drug and Medical Device Innovation* issued by the General Office of the CPC Central Committee and the General Office of the State Council (CPCCC & SC General Office [2017] No. 42), strengthen the guidance and regulation of the acceptance of overseas clinical trial data of drugs, CNDA organized to formulate the *Technical Guidelines for Accepting Overseas Clinical Trial Data of Drugs* which was released on July 10, 2018.

Technical Guidelines for Accepting Overseas Clinical Trial Data of Drugs

I. Scope

The Guidelines are applicable to guiding the acceptance of the applicants' use of overseas clinical trial data as clinical evaluation data while applying for drug registration within the territory of the People's Republic of China.

The data of overseas clinical trials covered by the Guidelines include, but are not limited to, the applicant's clinical trial data obtained overseas through simultaneous R&D of innovative drugs at home and abroad. Fully evaluable bioequivalence data for the R&D of generic drugs outside China can also be used for registration applications.

II. Basic principles for accepting overseas clinical trial data

Applicants shall ensure the authenticity, integrity, accuracy and traceability of data from overseas clinical trials.

The process of generating overseas clinical trial data shall comply with the relevant requirements of the Good Clinical Practice (GCP) of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Applicants shall ensure the scientific design of overseas clinical trials, the compliance of clinical trial quality management system with the requirements, and the accuracy and integrity of statistical analysis of data.

To ensure that the clinical trial design and statistical analysis of the data are scientific and reasonable, for the drugs with simultaneous R&D at home and abroad and forthcoming clinical trials in China, the applicants can, prior to implementing key clinical trials, contact the Center for Drug Evaluation of CNDA (CDE) to ensure the compliance of their design with the essential technical requirements for drug registration in China.

III. Requirements for data integrity while accepting overseas clinical trial data

For overseas clinical trials used for drug registration applications in China, the overseas clinical trial data shall be provided in whole, not selectively in part. Ensuring the integrity of clinical trial data is a basic requirement for accepting registration applications.

For existing early phase clinical trials abroad, if the follow-up clinical R&D is to be carried out in China, the drug registration applicant shall evaluate the early phase clinical trial data and communicate with CDE for its use in supporting subsequent clinical trials provided that the data integrity is confirmed.

国家药品监督管理局发布关于接受药品境外临床试验数据的技术指导原则的通告

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），加强对接受药品境外临床试验数据工作的指导和规范，国家药品监督管理局组织制定了《接受药品境外临床试验数据的技术指导原则》，于2018年7月10日发布。

接受药品境外临床试验数据的技术指导原则

一、范围

本指导原则适用于指导药品在中华人民共和国境内申报注册时，接受申请人采用境外临床试验数据作为临床评价资料的工作。

本指导原则所涉及的境外临床试验数据，包括但不限于申请人通过创新药的境内外同步研发在境外获得的临床试验数据。在境外开展仿制药研发，具备完整可评价的生物等效性数据的，也可用于注册申请。

二、接受境外临床试验数据的基本原则

申请人应确保境外临床试验数据真实性、完整性、准确性和可溯源性。

境外临床试验数据的产生过程，应符合人用药品注册技术国际协调会议（ICH）临床试验质量管理规范（GCP）的相关要求。

申请人应确保境外临床试验设计科学，临床试验质量管理体系符合要求，数据统计分析准确、完整。

为确保临床试验设计和数据统计分析科学合理，对于境内外同步研发的且将在中国开展临床试验的药物，申请人在实施关键临床试验之前，可与国家食品药品监督管理总局药品审评中心（以下简称药审中心）进行沟通，确保关键临床试验的设计符合中国药品注册的基本技术要求。

三、接受境外临床试验数据的完整性要求

境外临床试验用于中国药品注册申请的，应提供境外所有临床试验数据，不得选择性提供临床试验数据。保证临床试验数据的完整性是接受注册申请的基本要求。

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

For the drug whose clinical trials that have been completed overseas but not yet marketed, a complete overseas clinical trial data packet shall be provided; if already marketed, the safety and effectiveness update data shall also be provided before it can be used for registration application in China.

IV. The submission of overseas clinical trial data and basic technical requirements

For domestic and foreign synchronous clinical R&D, while submitting a drug registration application, the applicant shall collect and summarize all kinds of clinical trials at home and abroad as per the requirements for application dossiers set forth in the *Provisions for Drug Registration*, so that a complete clinical trial data packet can be formed before it can be used for drug registration application in China.

For overseas clinical trial data submitted for drug registration application in China, the application dossiers shall encompass biopharmaceutical, clinical pharmacology, effectiveness and safety data. Applicants for drug registration are encouraged to submit dossiers in the Common Technical Document (CTD) format.

Biopharmaceutical data shall include important in vitro or in vivo data and results related to bioavailability and bioequivalence, providing support and data linkage for dosage form determination and optimization of preparation processes during clinical R&D.

Clinical pharmacology data shall include pharmacokinetic and pharmacodynamic study data. Drug registration applicant shall conduct racial sensitivity analysis from multiple perspectives such as region and ethnicity, to support the application of overseas clinical trial data to the Chinese population, and the drug effectiveness and safety assessment.

The effectiveness data, mainly including the key clinical trial data from abroad and that from China, shall not only confirm the effectiveness of the investigational drug as a whole, but the consistency of the Chinese subgroup with the general world population.

The safety data, including all domestic and foreign data for safety assessments, shall analyze not only the overall safety but the consistency of the Chinese subgroup with the general world population.

The data of overseas clinical trials shall support the evaluation of effectiveness and safety. Applicants for drug registration shall consider complying with the requirements for drug registration management in China. Based on the analysis of the complete clinical trial data packet, the key clinical trial data shall be evaluated to confirm the effectiveness of the investigational drug. Following the ICH requirements for ethnical influence factors (E5) while accepting clinical data from abroad, the consistency of the Chinese subgroup with the general world population shall be analyzed to support the extrapolation of overseas clinical trial results to the Chinese population.

V. Acceptability of overseas clinical trial data

In alignment with the quality of clinical trial data, the acceptability of clinical trial data can be divided into fully acceptable, partially acceptable and not acceptable.

Fully acceptable. The data of overseas clinical trials are authentic and reliable and in line with ICH GCP and drug registration inspection requirements; overseas clinical study data can support the effectiveness and safety evaluation of target indications; and the absence of racial sensitivity factors that affect effectiveness and safety.

Partially acceptable. The data of overseas clinical trials are authentic and reliable and in line with ICH GCP and drug registration inspection requirements; overseas clinical study data can support the effectiveness

对于已有境外早期临床试验，后续在境内进行临床研发的，药品注册申请人应对早期临床试验数据进行评价，具备完整临床试验数据的，经与药审中心沟通交流后，可用于支持后续临床试验。

对于所有临床试验已在境外完成尚未上市的，应提供完整的境外临床试验数据包；已上市的，还应提供安全性、有效性更新数据，方可用于在中国的注册申请。

四、境外临床试验数据的提交情况及基本技术要求

对于境内外同步临床研发的，提交药品注册申请时，应按照《药品注册管理办法》的申报资料要求整理汇总境内外各类临床试验，形成完整的临床试验数据包，方可用于在中国的药品注册申请。

提交境外临床试验数据用于中国药品注册申请的资料，应包括生物药剂学、临床药理学、有效性和安全性资料数据。鼓励药品注册申请人采用通用技术文件格式（CTD）提交。

生物药剂学数据，应提供生物利用度和生物等效性相关的重要体外或体内数据和结果，为剂型确定和临床研发过程中制剂工艺优化提供支持依据和数据衔接。

临床药理学数据，主要包括药代动力学和药效学研究数据。药品注册申请人应从区域和人种等多角度进行种族敏感性分析，为境外临床试验数据适用于中国人群，及其有效性和安全性评价提供支持。

有效性数据，主要包括境外关键临床试验数据和在中国开展的临床试验数据，既要从整体上确证研究药物的有效性，还要分析中国亚组与总体人群的一致性。

安全性数据，包括境内外所有的用于安全性评价的数据，既要分析总体安全性，还要分析中国亚组与总体人群的一致性。

境外临床试验数据应支持有效性和安全性评价，药品注册申请人应考虑符合中国药品注册管理要求，在对完整临床试验数据包分析的基础上，对关键临床试验数据进行评价，以确证研究药物的有效性；遵循ICH关于接受国外临床资料的种族影响因素（E5）要求，分析中国亚组与总体人群的一致性，以支持境外临床试验结果外推至中国人群。

五、境外临床试验数据的可接受性

依据临床试验数据的质量，对临床试验数据接受分为完全接受、部分接受与不接受。

完全接受。境外临床试验数据真实可靠，符合 ICH GCP和药品注册检查要求；境外临床研究数据支持目标适应症的有效性和

and safety evaluation of target indications; but there are racial sensitivity factors that affect effectiveness and/or safety. There is considerable uncertainty in the evaluation of the effectiveness and safety of extrapolated data from overseas clinical trials to the Chinese population. Drug registration applicants shall analyze the situation in line with the influencing factors, and communicate with CDE to conduct targeted clinical trials.

Not acceptable. The data of overseas clinical trials have significant problems in terms of authenticity, integrity, accuracy and traceability; and cannot fully support the effectiveness and safety evaluation of target indications. To provide support for drug registration applications in China, the applicants shall thus follow the innovative drug R&D protocol to conduct well-directed systematic clinical trials in China.

For registration applications of drugs for critical illness, orphan diseases, and pediatrics, etc., which are in lack of effective treatment, if the overseas clinical trial data is evaluated as "partially acceptable", conditional acceptance of clinical trial data may be taken to collect the post-marketing drug effectiveness and safety data for further evaluation. (July 10, 2018)

安全性评价；不存在影响有效性和安全性的种族敏感性因素。

部分接受。境外临床试验数据真实可靠，符合ICH GCP和药品注册检查要求；境外临床研究数据支持目标适应症的有效性和安全性评价，但存在影响有效性和/或安全性的种族敏感性因素。境外临床试验数据外推至中国人群的有效性和安全性评价存在较大的不确定性。药品注册申请人应根据影响因素分析情况，与药审中心进行沟通交流后，有针对性地开展相应临床试验。

不接受。境外临床试验数据在真实性、完整性、准确性和可溯源性方面存在重大问题，境外临床试验数据不能充分支持目标适应症的有效性和安全性评价，药品注册申请人应按照创新药研发思路，在中国开展系统临床试验，以支持在中国的药品注册申请。

对于用于危重疾病、罕见病、儿科且缺乏有效治疗手段的药品注册申请，经评估其境外临床试验数据属于"部分接受"情形的，可采用有条件接受临床试验数据方式，在药品上市后收集进一步的有效性和安全性数据用于评价。（2018-07-10）

CNDA Announcement on the Issuance and Implementation of the First Supplement to the 2015 Edition of the *Pharmacopoeia of the People's Republic of China*

On July 5, 2018, China National Drug Administration (CNDA) issued an Announcement on the Issuance and Implementation of the First Supplement to the 2015 Edition of the *Pharmacopoeia of the People's Republic of China*, which reads as follows: The first supplement of the 2015 edition of the *Pharmacopoeia of the People's Republic of China* has been completed and is hereby released for implementation as from January 1, 2019.

(July 5, 2018)

国家药品监督管理局发布关于实施《中华人民共和国药典》2015年版第一增补本的公告

2018年7月5日，国家药品监督管理局发布关于实施《中华人民共和国药典》2015年版第一增补本的公告。内容为：《中华人民共和国药典》2015年版第一增补本已编制完成，现予发布，自2019年1月1日起施行。

（2018-07-05）

CNDA Issued the *Technical Guidelines for Clinical Evaluation of TCM-induced Hepatic Injury*

To control the safety risks of traditional Chinese medicines, promote the R&D of new TCMs, and promote the healthy development of the TCM industry, CNDA organized to formulate the *Technical Guidelines for Clinical Evaluation of TCM-induced Hepatic Injury* which was released on June 19, 2018.

(June 19, 2018)

国家药品监督管理局发布《中药药源性肝损伤临床评价技术指导原则》

为控制中药用药的安全风险，推动中药新药研发，促进中药产业健康发展，国家药品监督管理局组织制定了《中药药源性肝损伤临床评价技术指导原则》，于2018年6月19日发布。（2018-06-19）

CNDA Elected as a Member of the ICH Management Committee

On the afternoon of June 7, at the 1st ICH Conference, held in Kobe, Japan, in 2018, CNDA was elected as a member of the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) Management Committee (MC).

(June 7, 2018)

国家药品监督管理局当选为国际人用药品注册技术协调会管理委员会成员

2018年6月7日下午，在日本神户举行的国际人用药品注册技术协调会（ICH）2018年第一次大会上，国家药品监督管理局当选为ICH管理委员会成员。（2018-06-07）

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

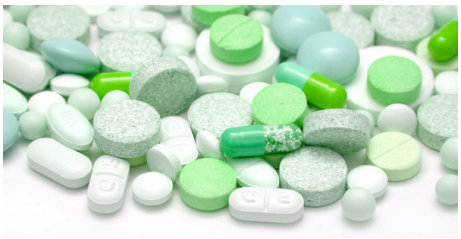
On June 6, 2018, CNDA decided to conduct clinical trial data verification for newly received registration applications of 192 drugs whose clinical trials have been completed and which are applying for production or import. The relevant matters are hereby announced:

I. If the drug registration applicants found inauthenticity of clinical trial data before CNDA verification, they shall take the initiative to apply for withdrawal of registration application, and CNDA shall announce the list of withdrawals without affixing accountability.

II. Center for Food and Drug Inspection of CNDA shall publicize on its website and inform the drug registration applicants and the local competent provincial food and drug regulatory authorities of the on-site verification plan. The Center shall, 10 working days after the public notification, inform the date for on-site verification and no longer accept the applicants' withdrawal of drug registration applications.

III. Pursuant to the law, CNDA shall severely punish the applicants, responsible persons and managers of drug clinical trials and responsible persons of CROs found with frauds in clinical trial data on-site verification.

(June 6, 2018)



国家药品监督管理局发布《关于药物临床试验数据自查核查注册申请情况的公告》

2018年6月6日，国家药品监督管理局决定对新收到的192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，并将有关事宜公告如下：

一、在国家药品监督管理局组织核查前，药品注册申请人自查发现药物临床试验数据存在真实性问题的，应主动撤回注册申请，国家药品监督管理局公布其名单，不追究其责任。

二、国家食品药品监督管理总局食品药品审核查验中心将在其网站公示现场核查计划，并通知药品注册申请人及其所在地省级食品药品监管部门，公示10个工作日后该中心将通知现场核查日期，不再接受药品注册申请人的撤回申请。

三、对药物临床试验数据现场核查中发现数据造假的申请人、药物临床试验责任人和管理人、合同研究组织责任人，国家药品监督管理局将依法严肃处理。

（2018-06-06）

CNDA Issued the *Announcement on the Regulations for Simplified Registration Review and Approval of TCM Compound Preparations with Ancient Classical Prescriptions*

To inherit and develop the traditional Chinese medicine (TCM) industry as per the Law of the *People's Republic of China on Traditional Chinese Medicine* and the Opinions of the State Council on the *Reform of the Review & Approval System for Drugs and Medical Devices* (State Council [2015] No. 44), CNDA and the State Administration of Traditional Chinese Medicine organized to formulate the *Regulations for Simplified Registration Review and Approval of TCM Compound Preparations with Ancient Classical Prescriptions*, which was released on June 1, 2018 and shall take effect thereafter.

(June 1, 2018)

国家药品监督管理局发布《古代经典名方中药复方制剂简化注册审批管理规定的公告》

为贯彻落实《中华人民共和国中医药法》《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），传承发展中医药事业，国家药品监督管理局会同国家中医药管理局组织制定了《古代经典名方中药复方制剂简化注册审批管理规定》，于2018年6月1日发布，自发布之日起执行。（2018-06-01）

CNDA Issued the *Technical Guidelines for the Compilation of Package Inserts of Antibacterial Drugs*

To establish a technical system for the study of antibacterial drugs in China and guide the work related to the compilation of package inserts of antibacterial drugs, CNDA organized to formulate the *Technical Guidelines for the Compilation of Package Inserts of Antibacterial Drugs* which was released on May 31, 2018. (May 31, 2018)

国家药品监督管理局发布《抗菌药物说明书撰写技术指导原则》

为建立我国抗菌药物研究的技术体系，指导抗菌药物说明书撰写相关工作，国家药品监督管理局组织制定了《抗菌药物说明书撰写技术指导原则》，于2018年5月31日发布。（2018-05-31）

CNDA Issued the *Announcement on Drug Varieties Subject to Exempted or Simplified Human Bioequivalence (BE) Test*

To fulfill the requirements of the *Announcement on Matters Concerning the Consistency Evaluation of the Quality and Efficacy of Generic Drugs* (CFDA Announcement [2017] No. 100), after research, investigation and solicitation for comments, the Office for Quality & Efficacy Consistency Evaluation of Generic Drugs has determined and issued on May 31, 2018 the Drug Varieties Subject to Exempted or Simplified Human Bioequivalence (BE) Test in the list of generic drugs that are required to complete consistency evaluation before the end of 2018. (May 31, 2018)

国家药品监督管理局发布《可豁免或简化人体生物等效性（BE）试验品种的通告》

为落实《关于仿制药质量和疗效一致性评价工作有关事项的公告》（国家食品药品监督管总局公告2017年第100号）的要求，仿制药质量和疗效一致性评价办公室经调研论证和征求意见，确定了2018年底前需完成仿制药一致性评价品种目录中可豁免或简化人体生物等效性（BE）试验品种，于2018年5月31日发布。（2018-05-31）

CNDA Issued the *Technical Guidelines for the Study of Antimicrobial Drug Breakpoint*

To establish a technical system for the study of antibacterial drugs in China and guide the work related to antibacterial drug study, CNDA organized to formulate the *Technical Guidelines for the Study of Antimicrobial Drug Breakpoints* which was released on May 31, 2018. (May 31, 2018)

国家药品监督管理局发布《抗菌药物折点研究技术指导原则》

为建立我国抗菌药物研究的技术体系，指导抗菌药物研究相关工作，国家药品监督管理局组织制定了《抗菌药物折点研究技术指导原则》，于2018年5月31日发布。（2018-05-31）

Medical Devices

CNDA Issued Two Guidelines for Clinical Trials of Rigid Gas Permeable Contact Lenses for Orthokeratology and Soft Contact Lenses

To strengthen the supervision and management of medical device clinical trials and further improve the quality of registration review, CNDA organized to formulate the *Guidelines for Clinical Trial of Rigid Gas Permeable Contact Lenses for Orthokeratology* and the *Guidelines for Clinical Trial of Soft Contact Lenses* which was released on July 5, 2018. (June 5, 2018)

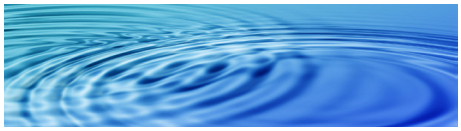
医疗器械

国家药品监督管理局发布角膜塑形用硬性透气接触镜及软性接触镜2项临床试验指导原则

为加强医疗器械临床试验监督管理，进一步提高注册审查质量，国家药品监督管理局组织制定了《角膜塑形用硬性透气接触镜临床试验指导原则》《软性接触镜临床试验指导原则》，于2018年7月5日发布。（2018-07-05）

CNDA Issued the *Guidelines for Compiling Application Dossiers for Review & Approval of Clinical Trials for Passive Implantable Medical Devices*

As per the *Opinions on Deepening the Review and Approval System Reform and Encouraging the Drug and Medical Device Innovation* issued by the General Office of the CPC Central Committee and the General Office of the State Council (CPCCC & SC General Office [2017] No. 42), to strengthen the supervision and management of medical device clinical trials, and further improve the quality of registration review, according to the *Announcement on Issuing the Requirements for Medical Device Registration Application Dossiers and the Format of Approval Documents* (CFDA Announcement [2014] No. 43), CNDA organized to formulate the *Guidelines for Compiling Application Dossiers for Review & Approval of Clinical Trials for Passive Implantable Medical Devices* which was released on June 4, 2018. (June 7, 2018)



国家药品监督管理局发布《无源植入性医疗器械临床试验审批申报资料编写指导原则》

为贯彻实施中共中央办公厅 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），加强医疗器械临床试验监督管理，进一步提高注册审查质量，根据《关于公布医疗器械注册申报资料要求和批准证明文件格式的公告》（国家食品药品监督管理总局公告2014年第43号）要求，国家药品监督管理局组织制定了《无源植入性医疗器械临床试验审批申报资料编写指导原则》，于2018年6月4日发布。

（2018-06-07）

CNDA Issued Three Guidelines for Technical Review of Registration Including the Guidelines for Technical Review of Anaesthetic Laryngoscope Registration

To strengthen the supervision and guidance over the medical device registration and further improve the registration review quality, CNDA organized to formulate the *Guidelines for Technical Review of Anaesthetic Laryngoscope Registration, the Guidelines for Technical Review of Endoscope Washer-Disinfector Registration, and the Guidelines for Technical Review of Sleep Apnea Monitoring System Registration* which were released on May 31, 2018.

(May 31, 2018)

国家药品监督管理局发布麻醉咽喉镜等3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，国家药品监督管理局组织制定了《麻醉咽喉镜注册技术审查指导原则》《内镜清洗消毒机注册技术审查指导原则》《睡眠呼吸监测产品注册技术审查指导原则》，于2018年5月31日发布。

（2018-05-31）

CNDA General Office Issued the *Notice on the Management Specifications for the Development and Revision of the Guidelines for Technical Review of Medical Device Registration*

To strengthen the standardized management of medical device registration and the development and revision of the guidelines for technical review of medical device registration, CNDA organized to formulate the *Management Specifications for the Development and Revision of the Guidelines for Technical Review of Medical Device Registration* which was released on May 28, 2018 and effective thenceforward.

(May 28, 2018)

国家药品监督管理局办公室印发《医疗器械注册技术审查指导原则制修订工作管理规范的通知》

为加强医疗器械注册管理和医疗器械注册技术审查指导原则制修订工作的规范化管理，国家药品监督管理局组织制定了《医疗器械注册技术审查指导原则制修订工作管理规范》，于2018年5月28日发布，自发布之日起实施。（2018-05-28）

CNDA General Office Issued the *Notice on the Notice on the Classification and Definition of Intense Pulsed Light Hair Removal Products*

To strengthen the supervision and management of medical devices, CNDA has further defined the management attributes and management categories of

国家药品监督管理局办公室发布《关于强脉冲光脱毛类产品分类界定的通知》

为加强医疗器械监督管理，国家药品监督管理局组织对强脉冲光脱毛类产品的管理

intense pulsed light (IPL) hair removal products. On May 25, 2018, a Notice was issued on related issues and it underscores that enterprises of IPL hair removal products shall effectively implement their subject responsibilities for product quality and safety, and ensure the safety and effectiveness of marketed products. From the date of publication of this Notice, an application for registration may be submitted according to the *Provisions for Medical Device Registration* (CFDA Order No. 4). As from January 1, 2023, IPL hair removal products without legally obtained registration certificates shall not be manufactured, imported, and sold.

(May 31, 2018)

属性及管理类别进行了界定。2018年5月25日，就有关事项发布通知，并强调，强脉冲光脱毛类产品相关企业应当切实落实产品质量安全主体责任，确保上市产品的安全有效。自本通知发布之日起，可按《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）的规定申请注册。自2023年1月1日起，强脉冲光脱毛类产品未依法取得医疗器械注册证不得生产、进口和销售。 （2018-05-31）

Annual Reports

CNDA Issued *2017 Annual Report of Drug Inspection*

To further strengthen the disclosure of drug inspection information and improve its transparency, CNDA has summarized, computed and analyzed pre-approval inspection, GMP follow-up inspection, unannounced inspection, overseas inspection, GSP unannounced inspection, and observation of international inspection, and released *2017 Annual Report of Drug Inspection* (Chinese & English versions) on June 8, 2018.

2017 Annual Report of Drug Inspection (Excerpt)

In 2017, the former China Food and Drug Administration organized a total of 751 inspections including pre-approval inspection, on-site inspection of generic drug consistency evaluation, GMP follow-up inspection, unannounced inspection, overseas inspection, GSP unannounced inspection and observation of international inspection.

In 2017, the former China Food and Drug Administration dispatched a total of 148 inspectors in 41 inspectorates to complete the inspection of overseas production sites of 51 imported drugs.

2017年完成各类药品检查任务一览表
Overview of the Inspections in 2017

检查工作 Inspections	检查企业数／品种数Amount of inspected enterprises/ varieties	派出组数 Amount of inspectorates	派出人次 Amount of inspectors
药品注册生产现场检查 Pre-approval inspection	52	47	168
仿制药一致性评价检查 Inspection of generic drug consistency evaluation	12	8	38
药品GMP跟踪检查 GMP follow-up inspection	428	296	1,234
药品飞行检查 Unannounced inspection	57	55	183
进口药品境外生产现场检查 Overseas inspection	51	41	148
药品流通检查 GSP unannounced inspection	67	62	202
国际观察检查 Observation of international inspection	84	84	92
合计 Total	751	593	2,065

(June 8, 2018)

年报

国家药品监督管理局发布《2017年度药品检查报告》

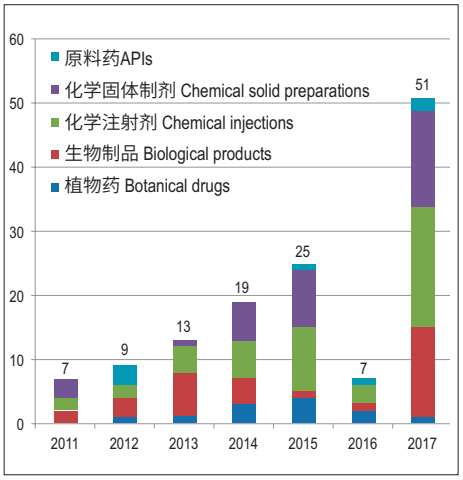
为进一步加强药品检查信息公开，提高检查工作透明度，国家药品监督管理局对2017年国家开展的药品注册生产现场检查、药品GMP跟踪检查、药品飞行检查、进口药品境外生产现场检查、药品流通检查、国际药品GMP观察检查等工作情况进行汇总、统计和分析，2018年6月8日发布《2017年度药品检查报告》（中文版、英文版）。

2017年度药品检查报告（节选）

2017年原国家食品药品监督管理总局组织开展药品注册生产现场检查、仿制药一致性评价现场检查、药品GMP跟踪检查、飞行检查、进口药品境外生产现场检查、流通检查及国际观察检查共计751项。

2017年原国家食品药品监督管理总局共派出41个检查组148名检查员完成了51个品种的进口药品境外生产现场检查任务。

2011—2017年境外检查执行数量
Numbers of overseas inspections performed in 2011-2017



(2018-06-08)

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

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