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中国食品药品国际交流中心
SERVIER
施维雅（天津）制药有限公司

National Work Conference on Food and Drug Supervision and Administration Convened in Beijing

From July 24 to 25, 2017, the National Work Conference on Food and Drug Supervision and Administration was held in Beijing. The Conference mainly aims to carry out the decision-making and deployments of the CPC Central Committee and the State Council; implement the Thirteenth Five-Year Plan for Food and Drugs, the arrangements for food safety priorities, and the opinions of the NPC Standing Committee on Drug Administration; further promote the reform of the review & approval system for drugs and medical devices, comprehensively investigate food and drug safety risks, to ensure food and drug safety, and create a favorable environment for the successful convening of the 19th National Congress of the CPC. CFDA Secretary of the Party Committee, Minister Bi Jingquan presided over the Conference and delivered a speech.

Bi pointed out that, in the first half of 2017, the whole system adhered to the principle of "seeking improvement in stability"; followed the "Four Strictest (standards, regulation, punishment and accountability)" requirements; strengthened the "Four Haves (having duties, posts, personnel, and means) and Two Responsibilities (for routine supervision and sampling inspection)"; and actively carried forward the nine tasks deployed earlier this year to lay the foundation, strengthen primary health care, seek long-term goals, and promote the reforms. Positive progress has been achieved in all aspects, contributing to the stable status of food and drug administration.

Bi stressed that, in the second half of 2017, the 19th National Congress of the CPC will be convened, it is of special significance for the protection of food and drug safety. We should earnestly study and implement the series of important instructions of General Secretary Xi Jinping on food and drug safety, and strengthen the whole process supervision and administration "from farm to table" and "from laboratory to hospital", to ensure the safety of the masses "on the tip of tongue". We should make overall plan and good use of four regulatory approaches: inspection, testing, handling and information disclosure; work hard to improve the source control of food quality and safety; continue to rectify the prominent issues of general concern to the masses; promote the creation of "safe meat and vegetable" supermarkets; deepen the reform of the review & approval system; encourage innovation in drugs & medical devices; and speed up the construction of professional inspector team, to welcome the successful convocation of the 19th National Congress of the CPC with an ideal morale and excellent results.

CFDA leaders: Wu Zhen, Jiao Hong, Sun Xianze, Sun Meijun respectively summed up and deployed the work tasks within their respective jurisdiction. Ma Ben, Chief of CCDI-accredited Discipline Inspection Group of the National Health and Family Planning Commission, attended the Conference. The attendees also include leaders of food and drug regulatory authorities of all provinces (autonomous regions and municipalities) and the Xinjiang Production and Construction Corps; the Health Bureau, Logistics Support Department of Central Military Commission; as well as CFDA departments, bureaus and directly-affiliated units.

(July 25, 2017)

全国食品药品监督管理工作座谈会在京召开

2017年7月24至25日，全国食品药品监督管理工作座谈会在北京召开。会议的主要任务是，贯彻党中央国务院决策部署，落实食品和药品“十三五”规划、食品安全重点工作安排以及全国人大常委会关于药品管理工作的意见，深入推进药品医疗器械审评审批制度改革，全面排查食品药品安全风险，保障食品药品安全，为十九大胜利召开营造良好环境。国家食品药品监督管理总局党组书记、局长毕井泉主持会议并讲话。

毕井泉指出，今年上半年，全系统坚持“稳中求进”，遵循“四个最严”，强化“四有两责”，积极推进年初部署的九大任务，打基础、强基层、谋长远、促改革，各项工作都取得了积极进展，食品药品安全形势总体稳定。

毕井泉强调，下半年将召开党的十九大，保障食品药品安全具有特殊重要意义。要认真学习贯彻习近平总书记关于食品药品安全工作的一系列重要指示批示精神，加强“从农田到餐桌”“从实验室到医院”的全过程监管，确保广大人民群众“舌尖上的安全”。要统筹用好检查、检验、办案和信息公开四个监管手段，在推进食品安全源头治理上下功夫，继续整治群众普遍关心的突出问题，推进“放心肉菜”超市创建，深化审评审批制度改革，鼓励药品医疗器械创新，加快职业化检查员队伍建设，以良好的精神状态和优异的成绩迎接党的十九大胜利召开。

总局领导吴浈、焦红、孙咸泽、孙梅君分别总结和部署了分管领域工作，中央纪委派驻卫生计生委纪检组组长马奔出席会议，各省（区、市）及新疆生产建设兵团食品药品监管部门负责人，中央军委后勤保障部卫生局负责人，总局机关各司局及直属单位负责人参加会议。

（2017-07-25）

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With Basic Elimination of the Backlog of Drug Registration Applications, China's Reform of Drug Review and Approval System Takes Effect

On June 22, CFDA Minister Bi Jingquan expressed, while reporting to the NPC Standing Committee as commissioned by the State Council on drug administration, that China has now basically eliminated the backlog of drug registration applications, wherein the peak of 22,000 applications pending for review in 2015 has shrunk to 6,000 to date. The review for clinical trial applications of chemical drugs and vaccines and registration applications of various TCMs has all been achieved within the prescribed time limit.

In August 2015, the State Council issued the *Opinions on the Reform of the Review & Approval System for Drugs and Medical Devices*, to address the legacy problems of the backlog of drug registration, the procrastinated marketing of new drugs, the low-level repetitive construction in the pharmaceutical industry, and the lack of innovation capacity. Since then, the reform has progressed smoothly, Bi introduced that:

- A number of new drugs are given priority to be marketed. With the establishment of the priority review system, a number of "new global" drugs are granted with entry into clinical trials, such as the recombinant Ebola virus vaccine, the third-generation Avitinib maleate tablet for drug-resistant mutant small cell lung cancer; and a number of innovative drugs and drugs urgently needed in clinical settings are approved for marketing, such as Nemonoxacin malate capsules, Osimertinib tablets, Inactivated Poliomyelitis Vaccine (IPV) and EV71 vaccines.

- The consistency evaluation of the quality and efficacy of generic drugs has been performed. In February 2016, the General Office of the State Council issued the *Opinions on Carrying out Consistency Evaluation of the Quality and Efficacy of Generic Drugs*, which clarified the target tasks and favorable policies for conducting consistency evaluation of marketed oral preparations of generic drugs as per the criteria of consistency of the quality and efficacy of generic drugs and originators. At present, 19 supportive documents have been published for consistency evaluation, and 5,111 filing cases have been accepted for reference preparations of generic drugs.

- The quality of drug clinical study has been improved. The verification on clinical trial data, dated back to July 2015, has been conducted and on-site inspections for 203 registered drug varieties and 463 clinical trial institutions have been carried out, wherein 27 drug varieties, 11 clinical trial institutions and contract research organizations (CRO) suspected of data fraud were subjected to investigation; and 1,323 registration applications were either voluntarily withdrawn by enterprises after their self-inspection, or disapproved outright in the verification. Through verification, the purpose of "crack down a very few, educate the vast majority" has been achieved for purification of drug R&D and ecological environment.

- The transparency of review and approval has been improved. Comprehensive disclosure of drug registration acceptance, technical review, product testing and on-site inspection criteria and related technical requirements, and open information relative to the acceptance & approval can guide the applicant for orderly research and development. CFDA has issued 11 Announcements on Approved Drugs for Marketing. Since October 2016, the comprehensive review reports for new drugs have been made public to accept social supervision.

基本消除药品注册申请积压 我国药品审评审批制度改革显成效

2017年6月22日，国家食品药品监督管理总局局长毕井泉受国务院委托，向全国人大常委会报告药品管理工作情况时表示，我国目前基本消除了药品注册申请积压，等待审评的药品注册申请已由2015年高峰时的22000件降至6000件。化学药和疫苗临床试验申请、中药各类注册申请已实现按时限审评。

毕井泉介绍，为解决长期以来形成的药品注册积压、新药上市慢、制药行业低水平重复、创新能力不足等突出问题，2015年8月国务院印发《关于改革药品医疗器械审评审批制度的意见》，改革进展顺利：

——我国一批新药优先获准上市。建立优先审评制度，一批"全球新"药物获准进入临床，如重组埃博拉病毒疫苗、治疗耐药突变小细胞肺癌的第三代药物马来酸艾维替尼片等；一批创新药物和临床急需药物获准上市，如苹果酸奈诺沙星胶囊、奥希替尼片、脊髓灰质炎灭活疫苗、EV71疫苗等。

——开展仿制药质量和疗效一致性评价。2016年2月国务院办公厅印发《关于开展仿制药质量和疗效一致性评价的意见》，明确了按照与原研药质量和疗效一致的标准，对已上市仿制药口服制剂开展一致性评价的目标任务和鼓励政策。目前已发布一致性评价配套文件19个，受理仿制药参比制剂备案5111个。

——提高药物临床研究质量。2015年7月开始组织临床试验数据核查，对203个注册品种、463家临床试验机构开展现场检查，对其中涉嫌数据造假的27个品种、11个临床试验机构及合同研究组织（CRO）予以立案调查，企业自查主动撤回和核查不予批准的注册申请1323个。通过核查，达到了严惩极少数、教育大多数的目的，净化了药物研发生态环境。

——提高审评审批透明度。全面公开药品注册的受理、技术审评、产品检验和现场检查标准与相关技术要求，公开受理和审批的相关信息，引导申请人有序研发。已发布11期批准上市药品公告。2016年10月起公开新药综合审评报告，接受社会监督。

——开展药品上市许可持有人制度试

- The pilot projects of the Marketing Authorization Holder (MAH) system have been conducted. In November 2015, the NPC Standing Committee authorized the State Council to conduct pilot projects of the MAH system in 10 provinces and cities, which has greatly mobilized the enthusiasm of scientific research units and researchers, further clarified the subject responsibilities of MAHs for drug R&D, manufacture, distribution, use and adverse reaction reporting. All sectors of society have responded positively, and all areas are expecting a nationwide roll-out of the MAH system with the least delay.

(June 22, 2017)

点。2015年11月，全国人大常委会授权国务院在十省市开展药品上市许可持有人制度试点，极大调动科研单位和科研人员的积极性。进一步明确上市许可持有人对药品研发、制造、经销、使用、不良反应报告的主体责任。社会各界反映积极，各地希望尽快在全国实施。（2017-06-22）

CFDA Issued the *Announcement on Enabling the Online Reservation & Acceptance System of CFDA Administrative Service Center*

To deepen the reform of "Decentralization, Administration and Service"; speed up the pace of "Internet + Government Service"; and improve the quality and efficiency of the reform of food and drug administrative acceptance, and provide more efficient and convenient service for administrative counterparts, the Online Reservation & Acceptance System of CFDA Administrative Service Center (hereinafter referred to as the Center) will be on-line in the near future. On July 13, 2017, CFDA issued the *Announcement on Enabling the Online Reservation & Acceptance System of CFDA Administrative Service Center* (No. 192), to announce the relevant matters as follows.

I. Scope of reservation (appointment): the acceptance, on-site consultation and issuance of approval letters for drugs, medical devices, special food, cosmetics, safety supervision and administration and so forth as within the jurisdiction of CFDA.

II. On-line time. The system will be officially launched on September 1, 2017.

III. Registration method. From July 20, 2017 onwards, the applicant may visit the sub-website (http://www.cfda.gov.cn/WS01/CL0025/) of "Acceptance Service of Administrative Items" on CFDA portal for registration in advance (for detail, see the schematic diagram for users). Enterprises may apply for online reservation only after passing the registration review.

IV. Reservation method. Registered enterprises may log on the sub-website of "Acceptance Service of Administrative Items" on CFDA portal to make an appointment. A registered enterprise may register up to 10 staff for business at most, for each business category, only one appointment can be made within a day. After successful appointment, the registration staff must hold their own valid ID cards and the Power of Attorney at the appointed time for receipt of appointment number and handling of relevant business.

V. Restrictions for breaking an appointment. After successful appointment, the applicant can cancel the appointment 4 natural days prior to the appointed date. A breaking of appointment is deemed should the applicant fail to show up at the appointed date without such a cancellation in advance. With such no-show for more than 3 times, the enterprise's registered account shall be frozen for 30 natural days. During this period, the applicant can only handle the business by on-site application for service numbers in the Center. After the frozen period, the restriction shall be automatically removed, the enterprise's registration account can continue to be used, while

国家食品药品监督管理总局发布《关于启用总局行政受理服务大厅网上预约受理系统的公告》

为了深化“放管服”改革，加快“互联网+政务服务”工作步伐，推动食品药品行政受理改革提质增效，为行政相对人提供更加高效便捷的服务，国家食品药品监督管理总局行政受理服务大厅（下称大厅）网上预约受理系统将于近期上线运行。2017年7月13日，国家食品药品监督管理总局发布《关于启用总局行政受理服务大厅网上预约受理系统的公告》（第192号），就有关事项公告如下。

一、预约范围。国家食品药品监督管理总局依法承担的药品、医疗器械、特殊食品、化妆品、安全监管等行政许可事项的受理、现场咨询、批件领取。

二、上线时间。2017年9月1日起正式上线运行。

三、注册方式。2017年7月20日起，申请人可登陆国家食品药品监督管理总局门户网站“行政事项受理服务”子网站（http://www.cfda.gov.cn/WS01/CL0025/）提前注册（详见用户操作示意图）。注册审核通过后，企业方可办理网上预约业务。

四、预约方式。注册企业登陆国家食品药品监督管理总局门户网站“行政事项受理服务”子网站进行预约。一个注册企业最多可注册10个业务办理人，每个业务类别一个工作日只能预约一次。预约成功后，注册办理人须在约定时间持本人有效身份证和委托书到大厅领取预约号，办理相关业务。

五、爽约限制。预约成功后，申请人可在约定时间的办理日的4个自然日之前取消预约。未取消预约且未按预约时间前来办理业务的，视为爽约。爽约次数超过3次，企业注册账户冻结30个自然日。期间，申请人只能通过大厅现场取号办理业务。冻结期过后限制自动解除，企业注册账户可继续使

the number of no-show times shall be accumulated again.

VI. Prioritized reservation. The applicants are encouraged to make appointment for various businesses via the online reservation system. As from the operation of the on-line system, service-number-taking in the Center shall remain unchanged, while applications with prior appointment shall be handled with priority. The Center shall, depending on changes in the number of applications, timely adjust the number of online reservations. (July 14, 2017)

用，爽约次数重新累计。

六、预约优先。鼓励申请人通过网上预约系统预约办理各项业务。该系统上线运行后，大厅现场取号方式不变，持预约号的申请事项优先予以办理。大厅将视各申请事项数量变化情况，适时调整网上预约数量。

（2017-07-14）

CFDA Issued the List of Reference Preparations for Generic Drugs (Seventh Batch) and the List of Reference Preparations for Generic Drugs (Eighth Batch)

On July 19, 2017, the List of Reference Preparations for Generic Drugs (Seventh Batch) (Announcement [2017] No. 115) and the List of Reference Preparations for Generic Drugs (Eighth Batch) (Announcement [2017] No. 116) were issued, upon review and confirmation by the CFDA Committee of Experts on Consistency Evaluation of the Quality and Efficacy of Generic Drugs.

(July 19, 2017)

国家食品药品监督管理总局发布仿制药参比制剂目录（第七批）和仿制药参比制剂目录（第八批）

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，2017年7月19日，仿制药参比制剂目录（第七批）（2017年第115号通告）和仿制药参比制剂目录（第八批）（2017年第116号通告）发布。（2017-07-19）

CFDA Issued the *Announcement on 135 Drug Registration Applications Withdrawn by 106 Enterprises*

CFDA issued the *Announcement on Carrying out Self-inspection & Verification of Drug Clinical Trial Data* ([2015] No. 117) and *Announcements on Self-inspection & Verification of Drug Clinical Trial Data for Registration Applications* ([2016] No. 81, No. 142, No. 171, No. 202 and [2017] No. 42, No. 59) and required drug registration applicants to conduct self-inspection & verification of drug clinical trial data of the drugs pending for review and approval of production or importation. After self-inspection is conducted by the drug registration applicants, 106 enterprises took initiative to withdraw 135 drug registration applications.

(June 29, 2017)

国家食品药品监督管理总局发布《关于106家企业撤回135个药品注册申请的公告》

国家食品药品监督管理总局发布了《关于开展药物临床试验数据自查核查的公告》（2015年第117号）和《关于药物临床试验数据自查核查注册申请情况的公告》（2016年第81号、第142号、第171号、第202号和2017年第42号、第59号），要求药品注册申请人对已申报生产或进口的待审药品注册申请进行药物临床试验数据自查核查。经药品注册申请人自查后，106家企业提出主动撤回135个药品注册申请。（2017-06-29）

CFDA Issued the *Announcement on the Results of Attribute Definition of the Third Batch of Drug-device Combination Products*

To guide the applicant to apply for registration in a reasonable manner, on June 27, 2017, CFDA announced the Results of Attribute Definition of the Third Batch of Drug-device Combination Products.

Annex: Summary of Results of Attribute Definition of the Third Batch of Drug-device Combination Products (Omitted) (June 27, 2017)

国家食品药品监督管理总局发布《关于第三批药械组合产品属性界定结果的公告》

为引导申请人合理申报，2017年6月27日，国家食品药品监督管理总局将第三批药械组合产品属性界定结果予以公布。

附件：第三批药械组合产品属性界定结果汇总（略）

（2017-06-27）

Medical Devices

CFDA Issued the *Announcement on Implementing the Decision of the State Council on Revising the Regulations for the Supervision and Administration of Medical Devices*

On June 22, CFDA issued the Announcement on Implementing the *Decision of the State Council on Revising the Regulations for the Supervision and Administration of Medical Devices* ([2017] No. 78), which includes the following content:

The *Decision of the State Council on Revising the Regulations for the Supervision and Administration of Medical Devices* (State Council Decree No. 680, hereinafter referred to as the Decision) has been issued and put into force as of May 4, 2017. The matters related to the implementation of the Decision are hereby announced as follows:

According to the *Decision*, the qualification accreditation of medical device clinical trial institutions was changed into filing management. CFDA is pressing ahead with formulating the provisions for the administration of conditions and filing of medical device clinical trial institutions together with NHFPC. Before the issuance of relevant provisions, in case of any medical device clinical trial, the sponsor should select the drug clinical trial institution recognized by CFDA and NHFPC; among which the IVD reagent clinical trial should be conducted in accordance with relevant regulations in the *CFDA Notice on Implementing the Provisions for Medical Device Registration and the Provisions for In-vitro Diagnostic Reagent Registration* (SYJXG [2014] No. 144).

(June 22, 2017)

医疗器械

国家食品药品监督管理总局发布关于贯彻实施《国务院关于修改〈医疗器械监督管理条例〉的决定》有关事项的公告

2017年6月22日，国家食品药品监督管理总局发布关于贯彻实施《国务院关于修改〈医疗器械监督管理条例〉的决定》有关事项的公告（2017年第78号），内容如下：

《国务院关于修改〈医疗器械监督管理条例〉的决定》（国务院令第680号，以下简称《决定》）已于2017年5月4日公布施行。现就贯彻实施《决定》有关事项公告如下：

根据《决定》，医疗器械临床试验机构由资质认定改为备案管理。食品药品监管总局正在会同国家卫生计生委抓紧制定医疗器械临床试验机构的条件及备案管理办法。相关管理办法出台前，开展医疗器械临床试验的，申办者应当选择经食品药品监管总局会同国家卫生计生委认定的药物临床试验机构；其中，开展体外诊断试剂临床试验的，按照《食品药品监管总局关于实施〈医疗器械注册管理办法〉和〈体外诊断试剂注册管理办法〉有关事项的通知》（食药监械管〔2014〕144号）中的有关规定执行。

（2017-06-22）

CFDA Announcement on Approving the Issuance of Eight Medical Device Industry Standards Including *Intravascular Catheters - Sterile and Single-use Catheters - Part 1: General Requirements* and One Amendment

Eight medical device industry standards including YY 0285.1 - 2017 *Intravascular Catheters - Sterile and Single-use Catheters - Part 1: General Requirements* and No. 1 Amendment of YY 0669 - 2008 *Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Infant Phototherapy Equipment*, have been deliberated and adopted, and published on July 17, 2017.

(July 18, 2017)

国家食品药品监督管理总局批准发布《血管内导管 一次性使用无菌导管 第1部分：通用要求》等8项医疗器械行业标准和1项修改单的公告

YY 0285.1—2017《血管内导管一次性使用无菌导管第1部分：通用要求》等8项医疗器械行业标准和YY 0669—2008《医用电气设备第2部分：婴儿光治疗设备安全专用要求》第1号修改单已经审定通过，2017年7月17日，国家食品药品监督管理总局批准发布。

（2017-07-18）

CFDA Issued the *Announcement on Abolishing 21 Medical Device Industry Standards Including YY 0097-1992: Magnetic Health Care Cup*

In accordance with the *Notice of the State Council on the Issuance of the Scheme for Deepening Standardization Reform* (State Council [2015] No. 13), CFDA issued on July 12, 2017, after streamlining & integration and centralized re-review of the medical device industry standards, the *Announcement on Abolishing 21 Medical Device Industry Standards Including YY 0097-1992: Magnetic Health Care Cup*, with decisions made to abolish such standards. (July 12, 2017)

国家食品药品监督管理总局发布《关于废止YY 0097—1992《磁疗保健杯》等21项医疗器械行业标准的公告》

按照《国务院关于印发深化标准化工作改革方案的通知》（国发〔2015〕13号）有关要求，经对医疗器械行业标准进行整合精简和集中复审，2017年月12日，国家食品药品监督管理总局发布《关于废止YY 0097—1992《磁疗保健杯》等21项医疗器械行业标准的公告》，决定废止YY 0097—1992《磁疗保健杯》等21项医疗器械行业标准。

(2017-07-12)

CFDA Issued the *Announcement on Carrying out Supervisory Sampling Inspection on Medical Device Clinical Trials* in 2017

To implement the requirements in the *Regulations for the Supervision and Administration of Medical Devices 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 strengthen the supervision and management on the clinical trials of medical devices, CFDA, based on the established work schedule of 2017, carry out supervisory inspection as per the principle of "Double Randomization and One Public Release" to verify the authenticity and compliance of the clinical trial data included in the medical device registration applications that are under review, investigate and deal with any illegal acts arising from conducting clinical trials and release the information of supervisory inspection and handling results to the public. On July 10, 2017, CFDA issued the *Announcement on Carrying out Supervisory Sampling Inspection on Medical Device Clinical Trials in 2017* (2017 [No. 103]) and announced relevant items. (July 10, 2017)

国家食品药品监督管理总局发布《关于开展2017年医疗器械临床试验监督抽查工作的通告》

为贯彻实施《医疗器械监督管理条例》，落实《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）要求，加强对医疗器械临床试验的监督管理，根据2017年重点工作安排，国家食品药品监管总局按照"双随机一公开"的原则，组织开展在审医疗器械注册申请中的临床试验数据真实性、合规性监督检查，查处临床试验违法违规行为，并将监督检查情况和处理结果向社会公布。2017年7月10日，国家食品药品监督管理总局发布《关于开展2017年医疗器械临床试验监督抽查工作的通告》（2017年第103号），就有关事项进行通知。 (2017-07-10)

Annual Report

Phase Report of Drug Clinical Trial Data Verification Released

On July 21, 2017, Center for Food and Drug Inspection of CFDA (hereinafter referred to as CFDI) issued a *Phase Report of Drug Clinical Trial Data Verification* (hereinafter referred to as the Report), which summarized and reviewed drug clinical trial data verification at its second anniversary. The Report shows that, in two years since the debut of drug clinical trial data verification, CFDA has sent a total of 185 inspection teams to perform on-site verification over 313 drug registration applications, and rectified non-standardized behaviors in the field of drug R&D, created a scientific and

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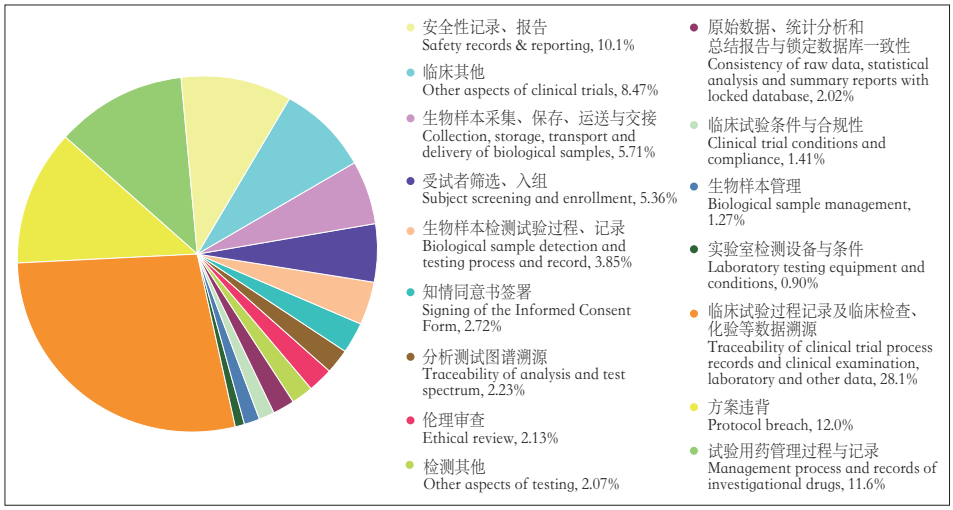
《药物临床试验数据核查阶段性报告》发布

2017年7月21日，国家食品药品监督管理总局审核查验中心（以下简称核查中心）发布《药物临床试验数据核查阶段性报告》（以下简称报告），总结回顾开展药物临床试验数据核查两周年的历程。

图. 核查缺陷分布情况
Figure . Distribution of Verified Defect Items



fair environment for innovation and R&D, and successfully fulfilled its periodic task as promised to the country and the people.

Of the 313 drug registration applications that have been verified, clinical trial data for 38 registration applications (16 for new drugs, 17 for generic drugs, and 5 for imported drugs) are suspected of fraud. CFDA has issued Announcements with decisions made to disapprove 30 registration applications, to investigate 11 clinical trial institutions and contract research organizations (CROs) in which the data were suspected of fraud. The verification information for the remaining 8 registration applications are being handled on a case-by-case basis.

Through analysis of the on-site verification reports of 313 drug registration applications, it was found that there are a total of 5,111 defect items, 4,583 of which are from clinical trial part (on average, each clinical trial institution was found with 6 defect items); 528 of which are from bio-analysis part (on average, each biological sample analysis unit is found with 4.4 defect items). The classification of defect items as per the *Key Points for On-site Verification of Drug Clinical Trial Data* reveals the aspects accounting for the most defect items (3,161, accounting for 61.8% of the total), in descending order, as follows: traceability of clinical trial process records and clinical examination, laboratory and other data (28.1%), protocol breach (12.0%), management process and records of investigational drugs (11.6%), safety records & reporting (10.1%).

(July 21, 2017)

报告显示，国家食品药品监督管理总局开展药物临床试验数据核查两年来，共派出185个检查组，对313个药品注册申请进行现场核查，整肃了我国药品研发领域不规范行为，营造出科学、公平的创新研发环境，圆满完成了总局向国家和人民承诺的阶段性任务。

在已核查的313个药品注册申请中，有38个注册申请的临 床试验数据涉嫌数据造假，其中新药注册申请16个，仿制药注册申请17个，进口药注册申请5个。总局已发布公告，对其中30个注册申请作出不予批准的决定，并对其中涉嫌数据造假的11个临床试验机构及合同研究组织（CRO）予以立案调查。其余8个注册申请的核查资料正在按程序处理。

经对313个药品注册申请的现场核查报告进行分析，共发现5111条缺陷项。其中临床部分4583条，平均每个临床试验机构发现问题6条；生物分析部分528条，平均每个生物样本分析单位发现问题4.4条。依据《药物临床试验数据现场核查要点》对 缺陷进行分类，发现缺陷条款数量最多的部分依次为：临床试验过程记录及临床检查、化验等数据溯源方面（占28.1%）、方案违背方面（占12.0%）、试验用药品管理过程与记录方面（占11.6%）和安全性记录、报告方面（占10.1%），共发现缺陷3161项，占61.8%。

（2017-07-21）

2016 Annual Report for Lot Release of Biological Products Issued

On July 4, 2017, CFDA issued the *2016 Annual Report for Lot Release of Biological Products*. The Report shows that the lot release system has been continuously improved and perfected since its implementation. In recent years, China's production of biological products subject to lot release has been well regulated and the product quality is stable and controllable. In 2016, we've released 3,949 batches of vaccines for about 646 million persons; 4,025 batches (about 59.278 million bottles) of blood products and 836 batches of reagents for blood screening for about 878 million persons. (July 4, 2017)

《2016年生物制品批签发年报》发布

2017年7月4日，国家食品药品监督管理总局发布《2016年生物制品批签发年报》。

报告显示，自我国实施批签发制度以来，批签发体系持续改进、不断完善。近年来，我国批签发制品的生产规范性较好、质量稳定可控。2016年，签发疫苗3949批、约计6.46亿人份；血液制品4025批，约计5927.80万瓶和血筛试剂836批，约计8.78亿人份。（2017-07-04）

2016 Work Report for Test at Port Released

On July 4, 2017, CFDA issued the *2016 Work Report for Test at Port* which shows that in recent years, CFDA has actively promoted the establishment of drug ports, and effectuated the most stringent criteria for the test of pharmaceuticals, consequently the batches and amount of imported pharmaceuticals tested at port saw an upswing year by year, while the nonconformance rate of products in the test at port has remained low.

In 2016, China's pharmaceutical imports showed a steady growth trend, 19 port drug testing institutions completed test for a total of 40,882 batches of imported drugs involving 412 importers, with CIF value beyond 25.8 billion US dollars.

(July 4, 2017)

《2016年度口岸检验工作报告》发布

2017年7月4日，国家食品药品监督管理总局发布《2016年度口岸检验工作报告》。报告显示，近些年，国家食品药品监督管理总局积极推进药品口岸设置，药品注册检验实行最严谨的标准，进口药品口岸检验批次和金额逐年上升，口岸检验不合格率持续保持低位水平。

2016年度我国药品进口呈稳定增长趋势，19个口岸药品检验机构共完成40882批次进口药品的口岸检验工作，涉及412家进口单位，到岸货值超过258亿美元。

(2017-07-04)

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

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