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 Legislative Plan 2018 Released

To implement the policies set forth in the 19th CPC National Congress, China Food and Drug Administration (CFDA) has formulated and promulgated on February 13, 2018 the CFDA Legislative Plan 2018 pursuant to the *Administrative Rules of China Food and Drug Administration on Legislative Procedure* (CFDA Order No. 1), aiming to basically establish as of 2020 a scientific and complete food & drug safety supervision legal system with clear orientation, overall service planning, highlighted priorities, and coordinated action.

The Plan covers 36 legislative projects, encompassing: 3 Laws: 1. the furtherance of the amendment of the *Drug Administration Law of the People's Republic of China*; 2. the furtherance of the introduction of the *Decision of the National People's Congress Standing Committee on Authorizing the Pilot Project of Patent-Term Compensation System for Certain Drugs and Exploring the Establishment of a Pharmaceutical Patent Linkage System; 3. the formulation of the revision of the Drug Administration Law of the People's Republic of China (Draft for Review)*, which shall reported to the State Council for deliberation as scheduled.

3 Regulations: 1. the furtherance of amending the *Regulation on the Implementation of the Food Safety Law of the People's Republic of China*; 2. accelerate the revision of the *Regulations for the Supervision and Administration of Medical Devices*, efforts shall be made to ensure the submission of the draft amendment to the State Council in the first quarter of 2018; 3. the promulgation of the *Regulation for the Supervision and Administration of Cosmetics* ASAP.

31 Departmental Rules subject to development and revision: 1. 12 food supporting rules as per the *Food Safety Law*; 2. 15 Rules on drugs and medical devices in accordance with the requirements for deepening the drug and medical device review and approval system reform; 3. 4 General Rules for acceleration of the construction of the rule of law pertaining food and drugs. (February 12, 2018)

《国家食品药品监督管理总局2018年立法计划》发布

为贯彻落实党的十九大精神，国家食品药品监督管理总局坚持围绕中心、服务大局、突出重点、协调推进，以2020年基本建成科学完备的食品药品安全法律制度体系为目标，根据《国家食品药品监督管理总局立法程序规定》（总局令第1号），制定了2018年立法计划，于2018年2月13日公布。

2018年立法项目共36部，其中，法律3部：一是继续推动《中华人民共和国药品管理法》修正案出台；二是继续推动《全国人大常委会授权开展部分药品专利期补偿制度试点和探索建立药品专利链接制度的决定》出台；三是形成《中华人民共和国药品管理法》修改草案送审稿，按程序报请国务院审议。

法规3部：一是推动完成《中华人民共和国食品安全法实施条例》修订；二是加快《医疗器械监督管理条例》修改进程，力争第一季度向国务院报送修正案草案；三是继续推动《化妆品监督管理条例》尽快出台。

规章31部：一是围绕食品安全法，制修订食品类配套规章12部；二是按照深化药品医疗器械审评审批制度改革要求，制修订药品医疗器械类规章15部；三是为加快食品药品法治建设，制修订综合类规章4部。（2018-02-12）

CFDA Issued the *Information Guide for Pharmaceutical Research in Phase III Clinical Trials of Innovative Drugs (Chemical Drugs)*

As per the State Council's *Opinions on the Reform of the Review & Approval System for Drugs and Medical Devices* (SC [2015] No. 44) and the *Opinions on Deepening the Review & Approval System and Encouraging the Drug and Medical Device Innovation* (CPC Central Committee & SC [2017] No. 42) issued by the General Office of the CPC Central Committee and the General Office of the State Council, to encourage the R&D of new drugs, speed up the establishment of a standard system for innovative drug pharmacy research and guidelines for technical review, and improve the quality and efficiency of R&D and review, CFDA organized to formulate the *Information Guide for Pharmaceutical Research in Phase III Clinical Trials of Innovative Drugs* (*Chemical Drugs*) which was promulgated on March 16, 2018. (March 16, 2018)

国家食品药品监督管理总局发布《创新药（化学药）Ⅲ期临床试验药学研究信息指南》

为贯彻落实国务院《关于改革药品医疗器械审评审批制度的意见》（国发〔2015〕44号）及中共中央办公厅、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），鼓励研究和创制新药，加快创新药药学研发和审评技术指南标准体系的建立，提高研发和审评质量及效率，国家食品药品监督管理总局组织制定了《创新药（化学药）Ⅲ期临床试验药学研究信息指南》，于2018年3月16日发布。（2018-03-16）

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

CFDA Issued the *Technical Guidelines for Drug Genotoxicity Study*

To guide and regulate the research on the genetic toxicity of drugs, CFDA has organized the revision of the *Technical Guidelines for Drug Genotoxicity Study*, which was promulgated on March 15, 2018, and simultaneously abolished the *Technical Guidelines for Drug Genotoxicity Study* issued by the former State Food and Drug Administration in 2007.

(March 15, 2018)

国家食品药品监督管理总局发布《药物遗传毒性研究技术指导原则》

为指导和规范药物遗传毒性研究，国家食品药品监督管理总局组织修订了《药物遗传毒性研究技术指导原则》，于2018年3月15日发布。原国家食品药品监督管理局2007年发布的《药物遗传毒性研究技术指导原则》废止。（2018-03-15）

CFDA Issued the *Technical Guidelines for Clinical Trials of Antidepressants*

To guide and regulate the clinical trials of new antidepressants, CFDA organized the formulation of the *Technical Guidelines for Clinical Trials of Antidepressants* which was promulgated on February 27, 2018.

(February 27, 2018)

国家食品药品监督管理总局发布《抗抑郁药的药物临床试验技术指导原则》

为指导和规范抗抑郁新药的药物临床试验，国家食品药品监督管理总局组织制定了《抗抑郁药的药物临床试验技术指导原则》，于2018年2月27日发布。（2018-02-27）

CFDA Issued the *Announcement on the Implementation of Filing Management over TCM Formulations Prepared by Medical Institutions Using Traditional Processes*

Pursuant to the Law of the People's Republic of China on Traditional Chinese Medicine (hereinafter referred to as the TCM Law) and the Drug Administration Law of the People's Republic of China, to effectively perform the filing management over TCM formulations prepared by medical institutions using traditional processes, and promote their healthy and orderly development, on February 12, 2018, CFDA issued the Announcement on the Implementation of Filing Management over TCM Formulations Prepared by Medical Institutions Using Traditional Processes to clarify the relevant issues.

(February 12, 2018)

国家食品药品监督管理总局发布《关于对医疗机构应用传统工艺配制中药制剂实施备案管理的公告》

为贯彻实施《中华人民共和国中医药法》和《中华人民共和国药品管理法》，做好对医疗机构应用传统工艺配制中药制剂的备案管理工作，促进其健康、有序发展，2018年2月12日，国家食品药品监督管理总局发布《关于对医疗机构应用传统工艺配制中药制剂实施备案管理的公告》，就有关事宜进行了明确。

（2018-02-12）

CFDA Issued the *Information Release of the Third Batch of Over-duplicated Drug Varieties*

To scientifically guide enterprises and R&D institutions in orderly research and development, optimize the allocation of R&D resources, and promote the sound and healthy development of the pharmaceutical industry, in accordance with the *Opinions of the State Council*

国家食品药品监督管理总局发布《第三批过度重复药品提示信息》

为科学引导企业及研发机构有序研发、优化研发资源配置，促进医药行业良性、健康发展，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）和《关于药品注册审评审批若干政策的公告》（国家食品药品监督管理总局公告2015年第230号）要求，国家食品药品监督

on the Reform of the Review & Approval System for Drugs and Medical Devices (SC [2015] No. 44) and the *Announcement on Policies Pertaining to the Review & Approval of Drug Registration* (CFDA Announcement [2015] No. 230), CFDA commissioned the China Pharmaceutical Association to monitor and analyze the situation of drugs marketed in 2017, and selected a total of 298 varieties via Generic-Name Screening as per the criterion of "≥20 enterprises with approval numbers for a single variety", covering 13 categories and 59 subcategories in clinical pharmacology and therapeutics classification. On February 8,2018, CFDA Issued the *Information Release of the Third Batch of Over-duplicated Drug Varieties*.

CFDA reminds relevant drug manufacturers and R&D institutions that they must fully understand the market supply and demand situation, scientifically assess the risks of drug R&D, and make prudent investment business decisions. The food and drug regulatory authorities of all provinces, autonomous regions, and municipalities directly under the central government shall strengthen the acceptance & review of applications for registration of related drugs, the R&D site verification, as well as the production site inspection; and shall actively publicize the listed Over-duplicated Drug Varieties to guide enterprises in rational R&D and registration application. (February 8, 2018)

管理总局委托中国药学会对2017年市场在售药品情况进行监测分析，按照符合已有批准文号企业数≥20家的条件进行通用名品种筛选，共遴选出298个品种，涉及临床药理学和治疗学分类的13个大类、59个亚类。2018年2月8日，发布了《第三批过度重复药品提示信息》。

国家食品药品监督管理总局提醒相关药品生产企业和研发机构，要充分了解市场供需状况，科学评估药品研发风险，慎重进行投资经营决策。各省、自治区、直辖市食品药品监督管理部门要加强对相关药品注册申请的受理审查、研制现场核查和生产现场检查，对已经公布的过度重复药品品种，主动做好宣传工作，引导企业理性研发和申报。（2018-02-08）

CFDA Issued the *Announcement on the Conversion of 3 Prescription Drugs Incl. Huoxiang Zhengqi Liquid to Non-prescription Drugs and the Modification of Corresponding OTC Package Inserts*

To protect the public's drug safety, according to the *Regulations for the Classification Management of Prescription and Non-prescription Drugs* (*Interim*) (formerly SFDA Order No. 10), CFDA organized an argumentation and examination, and canceled the double-span (Prescription + Non-prescription) category of Huoxiang Zhengqi Liquid, Huoxiang Zhengqi Oral Liquid, Huoxiang Zhengqi Soft Capsule, which are converted to a single category of non-prescription drugs. CFDA modified as well the non-prescription drug package inserts of the above-mentioned three categories of drugs along with those of Huoxiang Zhengqi Dripping Pills and Compound Fresh Bamboo Juice, and released an Announcement on these issues on February 6, 2018. (February 6, 2018)

国家食品药品监督管理总局发布《关于藿香正气水等3种药品转换为非处方药并修订非处方药说明书的公告》

为保障公众用药安全，根据《处方药与非处方药分类管理办法（试行）》（原国家药品监督管理局令第10号）的规定，经国家食品药品监督管理总局组织论证和审定，将藿香正气水、藿香正气口服液、藿香正气软胶囊取消双跨类别，转换为非处方药，并对上述3种药品及藿香正气滴丸、复方鲜竹沥液的非处方药说明书进行修订，于2018年2月6日发布有关修事项的公告。（2018-02-06）

CFDA Modified the Package Inserts of 4 Drug Varieties Incl. Jingwu Capsules

To protect the public's drug safety, according to the *Regulations for the Classification Management of Prescription and Non-prescription Drugs (Interim)* (formerly SFDA Order No. 10), CFDA organized an argumentation and examination, and transferred Jingwu Capsules out of the OTC drug list to prescription drug list; and modified the category of Bailemian Capsules from OTC Category-B to OTC Category-A. At the same time, the package inserts of the above two drugs and Qibao Meiran Pills, Xinyuan Capsules were modified. The relevant information was released in an Announcement on February 5, 2018. (February 5, 2018)

国家食品药品监督管理总局修订精乌胶囊等4个品种药品说明书

为保障公众用药安全，根据《处方药与非处方药分类管理办法（试行）》（原国家药品监督管理局令第10号）的规定，经国家食品药品监督管理总局组织论证和审定，将精乌胶囊调出非处方药目录，按处方药管理，百乐眠胶囊由乙类非处方药调整为甲类非处方药，同时对上述2种药品及七宝美髯丸、心元胶囊的说明书进行修订，2018年2月5日发布了有关修订事宜的公告。（2018-2-05）

CFDA issued the *Announcement on Modifying the Package Inserts of Lysine Acetylsalicylate for Injection*

In accordance with the results of the ADR evaluation, to further protect drug safety for the people, on January 31, 2018, CFDA issued the *Announcement on Modifying the Package Inserts of Lysine Acetylsalicylate for Injection*, with decisions made to add warnings to its package inserts and modifying the corresponding items such as [Indications], [Adverse Reactions], [Precautions], and [Pediatric Use].

(January 31, 2018)

国家食品药品监督管理总局发布《关于修订注射用赖氨匹林说明书的公告》

根据药品不良反应评估结果，为进一步保障公众用药安全，2018年1月31日，国家食品药品监督管理总局发布《关于修订注射用赖氨匹林说明书的公告》，决定对注射用赖氨匹林说明书增加警示语，并对【适应症】【不良反应】【注意事项】【儿童用药】等项进行修订。（2018-01-31）

CFDA Issued the *Technical Guidelines for Application of Phase I Clinical Trials for New Drugs*

As per the *Opinions on Deepening the Review & Approval System Reform and Encouraging the Drug and Medical Device Innovation* (CPC Central Committee & SC [2017] No. 42) issued by the General Office of the CPC Central Committee and the General Office of the State Council, to help applicants for new drug registration to apply for Phase I clinical trials and improve new drug R&D and review efficiency as well as the quality of application dossiers for Phase I clinical trials, CFDA organized to formulate the *Technical Guidelines for Application of Phase I Clinical Trials for New Drugs* which was released on January 25, 2018. (January 25, 2018)

国家食品药品监督管理总局发布《新药Ⅰ期临床试验申请技术指南》

根据中共中央办公厅、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），为帮助新药注册申请人规范申请Ⅰ期临床试验，提高新药研发与审评效率，提高Ⅰ期临床试验申报资料的质量，国家食品药品监督管理总局组织制定了《新药Ⅰ期临床试验申请技术指南》，于2018年1月25日发布。（2018-01-25）

CFDA Issued the *Announcement on Applying the ICH Secondary Guidelines*

On January 25, 2018, CFDA issued the Announcement on Applying the ICH Secondary Guidelines ([2018] No. 10), which reads as follows:

Pursuant to the *Opinions on Deepening the Review & Approval System Reform and Encouraging the Drug and Medical Device Innovation* (CPC Central Committee & SC [2017] No. 42) issued by the General Office of the CPC Central Committee and the General Office of the State Council, to encourage drug innovation, promote drug registration gearing to international technical standards, accelerate drug review & approval, and strengthen the management over the full life cycle of drugs, CFDA decided to apply five ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) Secondary Guidelines, namely: *M4: Common Technical Document for the Registration of Pharmaceuticals for Human Use (CTD); E2A: Clinical Safety*

国家食品药品监督管理总局发布《关于适用国际人用药品注册技术协调会二级指导原则的公告》

2018年1月25日，国家食品药品监督管理总局发布《关于适用国际人用药品注册技术协调会二级指导原则的公告》（2018年第10号），内容如下：

为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）精神，鼓励药品创新，推动药品注册技术标准国际接轨，加快药品审评审批，加强药品全生命周期管理，食品药品监管总局决定适用《M4：人用药物注册申请通用技术文档（CTD）》《E2A：临床安全数据的管理：快速报告的定义和标准》《E2D：上市后安全数据的管理：快速报告的定义和标准》《M1：监管活动医学词典（MedDRA）》和《E2B（R3）：临床安全数据的管理：个例安全报告传输的数据元素》五个国际人用药品注册技术协调会（ICH）二级指导原

Data Management: Definitions and Standards for Expedited Reporting; E2D: Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting; M1: Medical Dictionary for Regulatory Activities (MedDRA) and E2B (R3): Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports. The relevant matters are announced as follows.

1. As from February 1, 2018, M4 shall be applied to the registration applications for Class 1, Class 5.1 chemical drugs, Class 1 therapeutic biological products and Class 1 preventive biological products. M4 is further subdivided into the following modules: *M4 (R4): Organization of CTD; CTD: Administrative Information; M4Q (R1): Quality Section of the CTD: Pharmaceutical Section; M4S (R2): CTD: Safety Section and M4E (R2): CTD: Efficacy Section*.
2. As from May 1, 2018, E2A, M1, and E2B (R3) shall be applied to the reporting of serious and unexpected adverse drug reactions during clinical study of drugs.
3. As from July 1, 2018, E2D shall be applied to the reporting of post-market adverse drug reactions.
4. As from July 1, 2019, M1 and E2B (R3) shall be applied to the reporting of post-market adverse drug reactions. As from July 1, 2022, all of the above technical guidelines shall be applied to the reporting of post-market adverse drug reactions.
5. The relevant technical guidelines may be accessed on the website of the Center for Drug Evaluation of CFDA. The Center for Drug Evaluation of CFDA shall be responsible for effective technical guidance in relation to the implementation of this Announcement.

(January 25, 2018)

则。现就有关事项公告如下。

一、自2018年2月1日起，化学药品注册分类1类、5.1类以及治疗用生物制品1类和预防用生物制品1类注册申请适用《M4：人用药物注册申请通用技术文档（CTD）》。其中，《M4：人用药物注册申请通用技术文档（CTD）》包括《M4（R4）：人用药物注册申请通用技术文档的组织》《人用药物注册通用技术文档：行政管理信息》《M4Q（R1）：人用药物注册通用技术文档：药学部分》《M4S（R2）：人用药物注册通用技术文档：安全性部分》和《M4E（R2）：人用药物注册通用技术文档：有效性部分》。

二、自2018年5月1日起，药物临床研究期间报告严重且非预期的药品不良反应适用《E2A：临床安全数据的管理：快速报告的定义和标准》《M1：监管活动医学词典（MedDRA）》和《E2B（R3）：临床安全数据的管理：个例安全报告传输的数据元素》。

三、自2018年7月1日起，报告上市后药品不良反应适用《E2D：上市后安全数据的管理：快速报告的定义和标准》。

四、自2019年7月1日起，报告上市后药品不良反应可适用《M1：监管活动医学词典（MedDRA）》和《E2B（R3）：临床安全数据的管理：个例安全报告传输的数据元素》的要求。自2022年7月1日起，报告上市后药品不良反应适用以上技术指导原则。

五、相关技术指导原则可在国家食品药品监督管理总局药品审评中心网站查询。国家食品药品监督管理总局药品审评中心做好本公告实施过程中的相关技术指导工作。

（2018-01-25）

Medical Devices

CFDA Issued the *Guidelines for Technical Review of Ophthalmic Optical Coherence Tomography Scanner Registration*

To strengthen the supervision and guidance of the registration of medical devices and further improve the quality of registration review, CFDA organized the formulation of the *Guidelines for Technical Review of Ophthalmic Optical Coherence Tomography Scanner Registration* which was promulgated on March 2, 2018.

(March 2, 2018)

医疗器械

国家食品药品监督管理总局发布《眼科光学相干断层扫描仪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《眼科光学相干断层扫描仪注册技术审查指导原则》，于2018年3月2日发布。（2018-03-02）

CFDA General Office Issues the *Notice on Implementing the Provisions for the Supervision and Administration of Network Sales of Medical Devices*

The *Provisions for the Supervision and Administration of Network Sales of Medical Devices* (CFDA Order No. 38) (hereinafter referred to as the Provisions) have been issued and shall be put into effect as from March 1, 2018. For effective implementation of the Provisions, on February 27, 2018, the General Office of CFDA issued the Notice on Implementing the *Provisions for the Supervision and Administration of Network Sales of Medical Devices*. The Notice requires more input into the publicity and implementation of the Provisions and relevant training for effectively supervision and management of medical device network sales, and clarifies the filing work for medical device network sales and third-party platforms for network trading service. (February 27, 2018)

国家食品药品监督管理总局办公厅发布关于实施《医疗器械网络销售监督管理办法》有关事项的通知

《医疗器械网络销售监督管理办法》（国家食品药品监督管理总局令第38号）（以下简称《办法》）已发布，自2018年3月1日起施行。为贯彻落实《办法》的有关要求，2018年2月27日，国家食品药品监督管理总局办公厅就实施《医疗器械网络销售监督管理办法》有关事项发布通知。通知要求大力做好《办法》宣传贯彻和培训工作、切实做好医疗器械网络销售监督管理工作，并就医疗器械网络销售和医疗器械网络交易服务第三方平台备案工作进行了明确。 （2018-02-27）

CFDA Issued the *Guidelines for Technical Review of Ultrasonic Soft Tissue Cutting and Hemostatic System Registration*

To strengthen the supervision and guidance of the registration of medical devices and further improve the quality of registration review, CFDA organized the formulation of the *Guidelines for Technical Review of Ultrasonic Soft Tissue Cutting and Hemostatic System Registration* which was promulgated on February 24, 2018.

(February 24, 2018)

国家食品药品监督管理总局发布《超声软组织切割止血系统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《超声软组织切割止血系统注册技术审查指导原则》，于2018年2月24日发布。 （2018-02-24）

CFDA Issued Four Guidelines for Technical Review of Registration Incl. Guidelines for Technical Review of Human Epidermal Growth Factor Receptor (EGFR) Mutation Gene Detection Reagent Registration

To strengthen the supervision and guidance of the registration of medical devices and further improve the quality of registration review, CFDA organized the formulation of the *Guidelines for Technical Review of Human Epidermal Growth Factor Receptor (EGFR) Mutation Gene Detection Reagent Registration (PCR Method)*, the *Guidelines for Technical Review of Helicobacter Pylori Antigen/Antibody Detection Reagent Registration*, the *Guidelines for Technical Review of Anti-human Globulin Detection Reagent Registration*, and the *Guidelines for Technical Review of Intestinal Virus Nucleic Acid Detection Reagent Registration*, which were promulgated on February 24, 2018.

(February 24, 2018)

国家食品药品监督管理总局发布人表皮生长因子受体（EGFR）突变基因检测试剂等4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《人表皮生长因子受体（EGFR）突变基因检测试剂（PCR法）注册技术审查指导原则》《幽门螺杆菌抗原/抗体检测试剂注册技术审查指导原则》《抗人球蛋白检测试剂注册技术审查指导原则》《肠道病毒核酸检测试剂注册技术审查指导原则》，于2018年2月24日发布。

（2018-02-24）

CFDA Issued the *Planning for the Development of Medical Device Standards (2018-2020)*

Pursuant to the *Guiding Opinions of the CPC Central Committee and the State Council on Carrying out Quality Improvement Actions* (CPC Central Committee [2017] No. 24) and the *Opinions on Deepening the Review & Approval System Reform and Encouraging the Drug and Medical Device Innovation* (CPC Central Committee & SC [2017] No. 42) issued by the General Office of the CPC Central Committee and the General Office of the State Council, as well as the relevant requirements set forth in the *Provisions for Medical Device Standards and the Management Practice for the Development and Revision of Medical Device Standards, CFDA organized the formulation of the Planning for the Development of Medical Device Standards* (2018-2020), which has been issued on January 29, 2018, with a view to improving the levels of medical device standards, strengthening the supervisory inspection on the implementation of standards, and promoting the innovative development of medical devices.

(January 29, 2018)

国家食品药品监督管理总局发布《医疗器械标准规划（2018—2020年）》

为深入贯彻《中共中央国务院关于开展质量提升行动的指导意见》（中发〔2017〕24号）和中共中央办公厅、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），提高医疗器械标准水平，加强标准实施的监督检查，助推医疗器械创新发展，按照《医疗器械标准管理办法》和《医疗器械标准制修订工作管理规范》有关要求，国家食品药品监督管理总局组织制定了《医疗器械标准规划（2018—2020年）》，于2018年1月29日印发。 (2018-01-29)

CFDA Issued Three Guidelines for Technical Review of Registration Incl. Guidelines for Technical Review of Apolipoprotein A1 Assay Reagent 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 Apolipoprotein A1 Assay Reagent Registration,* the *Guidelines for Technical Review of Apolipoprotein B Assay Reagent Registration*, and the *Guidelines for Technical Review of D-Dimer Assay Reagent (Immunoturbidimetry) Registration*, which were promulgated on January 16, 2018.

(January 16, 2018)

国家食品药品监督管理总局发布载脂蛋白A1测定试剂等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，国家食品药品监督管理总局组织制定了《载脂蛋白A1测定试剂注册技术审查指导原则》《载脂蛋白B测定试剂注册技术审查指导原则》《D-二聚体测定试剂（免疫比浊法）注册技术审查指导原则》，于2018年1月16日发布。 (2018-01-16)

CFDA Issued Five Guidelines for Technical Review of Registration Incl. Guidelines for Technical Review of Alanine Aminotransferase Assay Reagent Registration

To strengthen the supervision and guidance of the registration of medical devices and further improve the quality of registration review, CFDA organized the formulation of the *Guidelines for Technical Review of Alanine Aminotransferase Assay Reagent Registration*, the *Guidelines for Technical Review of Urinalysis Test Strip Registration*, the *Guidelines for Technical Review of Homocysteine Assay Reagent Registration*, the *Guidelines for Technical Review of Insulin Assay Reagent Registration*, and the *Guidelines for Technical Review of C-Peptide Assay Reagent Registration*, which were promulgated on January 16, 2018.

(January 16, 2018)

国家食品药品监督管理总局发布丙氨酸氨基转移酶测定试剂等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《丙氨酸氨基转移酶测定试剂注册技术审查指导原则》《尿液分析试纸条注册技术审查指导原则》《同型半胱氨酸测定试剂注册技术审查指导原则》《胰岛素测定试剂注册技术审查指导原则》《C-肽测定试剂注册技术审查指导原则》，于2018年1月16日发布。 (2018-01-16)

CFDA Issued the *Guidelines for Design of Medical Device Clinical Trials*

To implement the policies set forth in the *Opinions on Deepening the Review & Approval System Reform and Encouraging the Drug and Medical Device Innovation* (CPC Central Committee & SC [2017] No. 42) issued by the General Office of the CPC Central Committee and the General Office of the State Council, strength the management of medical device registration, further improve the quality of registration review, and encourage R&D and innovation in medical devices, CFDA organized the development of the *Guidelines for Design of Medical Device Clinical Trials*, which was promulgated on January 8, 2018.

(January 8, 2018)

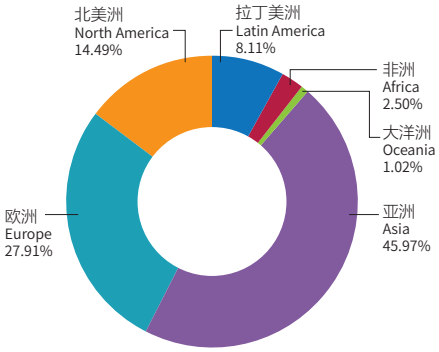
国家食品药品监督管理总局发布《医疗器械临床试验设计指导原则》

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），加强医疗器械产品注册工作的管理，进一步提高注册审查质量，鼓励医疗器械研发创新，国家食品药品监督管理总局组织制定了医疗器械临床试验设计指导原则，于2018年1月8日发布。（2018-01-08）

Special Focus 业界专题

China's Import and Export Volume of APIs Hit a New Ceiling in 2017

In 2017, China's APIs import and export re-appeared a rapid boom. The import and export volume reached a record high of US$37.84 billion, with an increase of 13.84% YOY. Among them, the export volume was up by 13.71% YOY to 29.117 billion U.S. dollars. The imports amounted to US$8.723 billion, up by 14.3% YOY.



(Source: China Pharmaceutical News, March 6, 2018)

2017年我国原料药进出口额再创新高

2017年，我国原料药产品进出口贸易重现较快增长，进出口额再创新高，达到378.4亿美元，同比增长13.84%。其中，出口额同比增长13.71%，达到291.17亿美元。进口额为87.23亿美元，同比增长14.3%。

（摘自：中国医药报 2018-03-06）

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

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