2017. Volume 12

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's Decision on Amending Certain Rules and Regulations Released

On November 21, 2017, China Food and Drug Administration (CFDA) released the *CFDA's Decision on Amending Certain Rules and Regulations* (CFDA Order No. 37), which shall come into effect as from the date of promulgation.

CFDA's Decision on Amending Certain Rules and Regulations

To implement the State Council's requirements to deepen the administration streamlining and institute decentralization, integrate power delegation and strong regulation, and optimize public service, CFDA scrutinized certain Rules and Regulations concerning the reform of the administrative review & approval system and the commercial system, and decided to amend certain articles of the *Provisions for Drug Distributing License* (CFDA Order No. 6 issued on February 4, 2004), the *Provisions for Internet Drug Information Service* (CFDA Order No. 9 issued on July 8, 2004), the *Provisions for the Supervision of Drug Manufacturing* (CFDA Order No. 14 issued on August 5, 2004), the *Provisions for the Supervision of Medical Device Manufacturing* (CFDA Order No. 7 issued on July 30, 2014), the *Provisions for the Supervision of Medical Device Distribution* (CFDA Order No. 8 issued on July 30, 2014), the *Administrative Measures for Import and Export of Anabolic Agents and Peptide Hormones* (Order No. 9 of CFDA, General Administration of Customs and General Administration of Sport of China issued on September 28, 2014), the *Administrative Measures for Food Production Licensing* (CFDA Order No. 16 issued on August 31, 2015), and the *Administrative Measures for Food Business Operation Licensing* (CFDA Order No. 17 issued on August 31, 2015). This Decision shall come into effect as of the date of promulgation. According to the Decision, the above rules and regulations are amended and will be re-released.

(November 21, 2017)

《国家食品药品监督管理总局关于修改部分规章的决定》发布

2017年11月21日，国家食品药品监督管理总局发布《国家食品药品监督管理总局关于修改部分规章的决定》（国家食品药品监督管理总局令第37号），决定自公布之日起施行。

国家食品药品监督管理总局关于修改部分规章的决定

为贯彻落实国务院深化简政放权、放管结合、优化服务改革的要求，国家食品药品监督管理总局对涉及行政审批制度改革、商事制度改革等有关规章进行了清理，决定对《药品经营许可证管理办法》（2004年2月4日国家食品药品监督管理局令第6号）（以下简称总局令）、《互联网药品信息服务管理办法》（2004年7月8日总局令第9号）、《药品生产监督管理办法》（2004年8月5日总局令第14号）、《医疗器械生产监督管理办法》（2014年7月30日总局令第7号）、《医疗器械经营监督管理办法》（2014年7月30日总局令第8号）、《蛋白同化制剂和肽类激素进出口管理办法》（2014年9月28日总局、海关总署国家体育总局令第9号）、《食品生产许可管理办法》（2015年8月31日总局令第16号）、《食品经营许可管理办法》（2015年8月31日总局令第17号）的部分条款予以修改。本决定自公布之日起施行。根据本决定，对上述规章作相应修改，重新公布。（2017-11-21）

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

On December 6, 2017, CFDA released the *Announcement on Self-inspection & Verification of Drug Clinical Trial Data for Registration Applications* with the decision made to verify the clinical trial data of 39 newly received registration applications for drugs whose clinical trials have been completed and which are under application for production or importation, and notified the relevant issues.

Annex: List of Registration Applications for 39 Drugs Subject to Self-inspection & Verification of Clinical Trial Data (Omitted)

(December 6, 2017)

国家食品药品监督管理总局发布《关于药物临床试验数据自查核查注册申请情况的公告》

2017年12月6日，国家食品药品监督管理总局发布《关于药物临床试验数据自查核查注册申请情况的公告》，决定对新收到39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，并就有关事宜进行了公告。

附件：39个药物临床试验数据自查核查注册申请清单（略）（2017-12-06）

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

CFDA Released the Guidance for Acceptance & Review of Drug Registration Applications (Interim)

To implement the policies set forth in the *Opinions of the State Council on the Reform of the Review & Approval System for Drugs and Medical Devices* (State Council [2015] No. 44), in alignment with the requirements of the *Announcement on Adjusting the Acceptance Procedures for Drug Registration* (Announcement [2017] No. 134), on November 30, 2017, CFDA organized to formulate the Guidance for Acceptance & Review of Drug Registration Applications (Interim), including:

1. Guidance for Acceptance & Review of Registration Applications for Chemical Drugs (Part I: Registration Categories 1, 2, 3, 5.1) (Interim)
2. Guidance for Acceptance & Review of Registration Applications for Chemical Drugs (Part II, Registration Categories 4, 5.2) (Interim)
3. Guidance for Acceptance & Review of Registration Applications for Therapeutic Biological Products (Interim)
4. Guidance for Acceptance & Review of Registration Applications for Prophylactic Biological Products (Interim)
5. Guidance for Review & Approval, Acceptance & Review of Registration Applications for TCMs and Natural Medicines (Interim)
6. Guidance for Acceptance & Review of Supplementary Applications for Drugs (Interim)
7. Guidance for Examination & Approval, Acceptance & Review of Registration Renewal of Imported Drugs (Interim)
8. Guidance for Acceptance, Review and Issuance of Approval Documents for Imported Crude Drugs (Interim)

(November 30, 2017)

国家食品药品监督管理总局发布药品注册受理审查指南（试行）

为落实《国务院关于改革药品医疗器械审评审批制度的意见》（国发〔2015〕44号），根据《关于调整药品注册受理工作的公告》（2017年第134号）要求，2017年11月30日，国家食品药品监督管理总局组织制定了药品注册受理审查指南（试行），包括：

1. 化学药品注册受理审查指南（第一部分注册分类1、2、3、5.1）（试行）
2. 化学药品注册受理审查指南（第二部分注册分类4、5.2）（试行）
3. 治疗用生物制品注册受理审查指南（试行）
4. 预防用生物制品注册受理审查指南（试行）
5. 中药、天然药物注册审批受理审查指南（试行）
6. 药品补充申请受理审查指南（试行）
7. 进口药品再注册核准受理审查指南（试行）
8. 进口药材批件核发受理审查指南（试行）。

（2017-11-30）

CFDA Released the *Announcement on Adjusting the Review & Approval Items of APIs, Pharmaceutical Excipients and Pharmaceutical Packaging Materials*

To implement the policies set forth in the *Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Review and Approval System Reform and Encouraging the Drug and Medical Device Innovation* (CPC & SC [2017] No. 42) and the *Decision of the State Council on Canceling a Number of Administrative Licensing Items* (State Council [2017] No. 46), the separate review & approval for pharmaceutical excipients and pharmaceutical packaging materials & containers in direct contact with pharmaceuticals (hereinafter referred to as pharmaceutical packaging materials) has been canceled. The review & approval of APIs, pharmaceutical excipients and pharmaceutical packaging materials shall be dealt with concurrently as one item in the application for registration of drug preparations. On November 30, 2017, CFDA released the *Announcement on Adjusting the Review & Approval Items of APIs, Pharmaceutical Excipients and Pharmaceutical Packaging Materials* to notify the following issues:

1. This Announcement shall apply to the APIs for drug preparations classified as 2.2, 2.3, 2.4, 3, 4, and 5 in registration classification, and to pharmaceutical excipients, pharmaceutical packaging materials for all drugs in registration applications filed by any applicant within the territory of the People's Republic of China.
2. As from the promulgation of this Announcement, the food and drug regulatory authorities at all levels shall no longer handle separately the registration

国家食品药品监督管理总局发布《关于调整原料药、药用辅料和药包材审评审批事项的公告》

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）与《国务院关于取消一批行政许可事项的决定》（国发〔2017〕46号），取消药用辅料与直接接触药品的包装材料和容器（以下简称药包材）审批，原料药、药用辅料和药包材在审批药品制剂注册申请时一并审评审批。2017年11月30日，国家食品药品监督管理总局发布《关于调整原料药、药用辅料和药包材审评审批事项的公告》，就有关事项公告如下：

一、药品注册申请人在中华人民共和国境内提出的注册分类2.2、2.3、2.4、3、4、5类药品制剂申请所使用的原料药，以及各类药品注册申请所使用的药用辅料、药包材适用于本公告要求。

二、自本公告发布之日起，各级食品

applications for APIs, pharmaceutical excipients and pharmaceutical packaging materials. The Center for Drug Evaluation, CFDA (hereinafter referred to as CDE) shall establish a registration platform for APIs, pharmaceutical excipients and pharmaceutical packaging materials (hereinafter referred to as the registration platform) and the corresponding database, based on which relevant enterprises or units may submit registration dossiers of APIs, pharmaceutical excipients and pharmaceutical packaging materials as per the requirements of this Announcement, and get a unified registration number for consolidated review once the associated drug preparations are under application for registration.

3. Major contents of the registration dossiers of APIs: basic information, production information, characterization, quality control of APIs, reference substances, pharmaceutical packaging materials, and stability, etc. The specific contents shall comply with the requirements for application dossiers of APIs as stated in the *Announcement on Promulgating the Requirements for Application Dossiers of Chemical Drugs in New Registration Classifications (Interim)* (CFDA Announcement [2016] No. 80).

4. Major contents of the registration dossiers of pharmaceutical excipients: basic information of enterprise, basic information of excipients, production information, characterization, quality control, batch test report, stability study, and pharmacology and toxicology studies, etc. The specific contents shall conform to the requirements for application dossiers of pharmaceutical excipients as stated in the *Announcement on Promulgating the Requirements for Application Dossiers of Pharmaceutical Packaging Materials and Pharmaceutical Excipients (Interim)* (CFDA Announcement [2016] No. 155).

5. Major contents of the registration dossiers of pharmaceutical packaging materials: basic information of enterprise, basic information of pharmaceutical packaging materials, production information, quality control, batch test report, stability study, and safety and compatibility studies, etc. The specific contents shall comply with the requirements for application dossiers of pharmaceutical packaging materials as stated in the CFDA Announcement [2016] No. 155.

6. During the transitional period while establishing the registration platform, CDE shall publicize on its portal website (www.cde.org.cn) in form-format the "Registration Data of APIs", "Registration Data of Pharmaceutical Excipients", and "Registration Data of Pharmaceutical Packaging Materials", the publicized information shall mainly include: registration number, variety name, enterprise name, registered address, domestic drug/imported drug, packaging size, registration date, date of renewal, and review and approval of associated drug preparations, etc.

   Upon completion of the input of product basic information via CDE portal website, enterprises of APIs, pharmaceutical excipients and pharmaceutical packaging materials should submit the registration dossiers (including the registration form, see Annex 1) in CD-ROM to CDE (mailing address: Division of Business Management, Center for Drug Evaluation, No. 1 A, Fuxing Road, Haidian District, Beijing, P. R. China). Within 5 working days after receiving the dossiers, CDE shall review the integrity of the registration dossiers, and inform the applicant in a one-time manner all the items that need to be supplemented where the information is not complete; while conforming dossiers shall be subject to online publicity by CDE.

7. For registration applications for APIs, pharmaceutical excipients and pharmaceutical packaging materials that have been accepted but not yet subject to review & approval, CDE shall generate the corresponding registration numbers and import the application information into the above registration data form for public notification. The applicant shall submit the registration dossiers as required by this Announcement to CDE in CD-ROM. APIs, pharmaceutical excipients

药品监督管理部门不再单独受理原料药、药用辅料和药包材注册申请，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）建立原料药、药用辅料和药包材登记平台（以下简称为登记平台）与数据库，有关企业或者单位可通过登记平台按本公告要求提交原料药、药用辅料和药包材登记资料，获得原料药、药用辅料和药包材登记号，待关联药品制剂提出注册申请后一并审评。

三、原料药登记资料主要内容：基本信息、生产信息、特性鉴定、原料药的质量控制、对照品、药包材、稳定性等。具体内容应当符合《关于发布化学药品新注册分类申报资料要求（试行）的通告》（国家食品药品监督管理总局通告2016年第80号）中原料药药学申报资料要求。

四、药用辅料登记资料主要内容：企业基本信息、辅料基本信息、生产信息、特性鉴定、质量控制、批检验报告、稳定性研究、药理毒理研究等。具体内容应当符合《关于发布药包材药用辅料申报资料要求（试行）的通告》（国家食品药品监督管理总局通告2016年第155号）中药用辅料申报资料要求。

五、药包材登记资料主要内容：企业基本信息、药包材基本信息、生产信息、质量控制、批检验报告、稳定性研究、安全性和相容性研究等。具体内容应当符合2016年第155号通告中药包材申报资料要求。

六、在登记平台建立的过渡期，药审中心在门户网站（网址：www.cde.org.cn）以表格方式对社会公示“原料药登记数据”“药用辅料登记数据”“药包材登记数据”，公示的信息主要包括：登记号、品种名称、企业名称、企业注册地址、国产/进口、包装规格、登记日期、更新日期、关联药品制剂审批情况等。

原料药、药用辅料和药包材企业在药审中心门户网站“申请人之窗”填写品种基本信息后，将登记资料（含登记表，见附件1）以光盘形式提交至药审中心（邮寄地址：北京市海淀区复兴路甲1号药品审评中心业务管理处），药审中心在收到资料后5个工作日内，对登记资料进行完整性审查。资料不齐全的，一次性告知所需补正的登记资料；资料符合要求的，由药审中心进行公示。

七、对已受理未完成审评审批的原料药、药用辅料和药包材注册申请，由药审中心生成原料药、药用辅料和药包材登记号，并将申报信息导入上述登记数据表后对社会公示。申请人应按本公告要求将申报登记资料以光盘形式提交至药审中心。新申报的药

and pharmaceutical packaging materials using existing approval numbers in newly applied drug preparations (including supplementary application for changes of APIs, pharmaceutical excipients and pharmaceutical packaging materials), should also be registered as required.

8. APIs, pharmaceutical excipients and pharmaceutical packaging materials can do without registration if they are intended for self-use by the applicants of pharmaceutical preparations, or exclusive use by specific drug marketing authorization holders, provided that their dossiers (in compliance with this Announcement) have been submitted in sync with the applications for drug preparations.

9. Applicants for drug preparations may select to use the existing APIs, pharmaceutical excipients and pharmaceutical packaging materials with registration numbers for study, and file the application for marketing or application for changes of APIs, pharmaceutical excipients and pharmaceutical packaging materials. Where the applicant for drug preparations and the applicant for APIs, pharmaceutical excipients and pharmaceutical packaging materials are not identical, the former shall provide in the application dossiers a Letter of Authorized Use (Annex 2) by the marketing authorization holder or enterprise of APIs, pharmaceutical excipients and pharmaceutical packaging materials.

10. Enterprises that have obtained the registration numbers of APIs, pharmaceutical excipients and pharmaceutical packaging materials shall conduct their management in strict compliance with the relevant state requirements to ensure the quality of their products, and submit the product quality management reports on an annual basis after obtaining the registration numbers; if the products are subject to change, they should promptly update the relevant information in the registration platform, and take the initiative to inform the applicants who use their products before implementing the changes.

Applicants for drug preparations should be responsible for the quality of the APIs, pharmaceutical excipients and pharmaceutical packaging materials used, whose changes and the accompanying influence on the quality of the products shall be fully studied and evaluated. The studies shall be performed in line with the relevant CFDA's provisions and guidelines, and the application for changes or filing shall be made as required.

11. CFDA shall mark the publicity information on APIs, pharmaceutical excipients and pharmaceutical packaging materials after the drug preparations are approved for marketing, or marketed drug preparations are approved for change of APIs, pharmaceutical excipients and pharmaceutical packaging materials (incl. the changes of suppliers of APIs, the varieties and suppliers of pharmaceutical excipients and pharmaceutical packaging materials). The other requirements for unified review & approval of APIs, pharmaceutical excipients and pharmaceutical packaging materials shall be implemented after the relevant administrative measures of CFDA are promulgated.

The registration requirements for APIs, pharmaceutical excipients and pharmaceutical packaging materials that have obtained approval numbers prior to the release of this Announcement will be notified separately after the registration platform is established.

12. The provincial food and drug regulatory authorities shall be responsible for the daily supervision and administration of manufacturers of APIs, pharmaceutical excipients and pharmaceutical packaging materials within their respective administrative regions. During the review & approval process for drug preparations, CFDA shall organize on-site inspection and test, as necessary, on the related APIs, pharmaceutical excipients and pharmaceutical packaging materials.

13. This Announcement shall come into effect as of the date of promulgation, and shall prevail where inconsistencies arise with former documents related to the associated review & approval of pharmaceutical excipients and pharmaceutical packaging materials.

(November 30, 2017)

品制剂（含变更原料药、药用辅料和药包材的补充申请）中使用已有批准文号的原料药、药用辅料和药包材，该原料药、药用辅料和药包材也应按要求进行登记。

八、药品制剂申请人仅供自用的原料药、药用辅料和药包材，或者专供特定药品上市许可持有人使用的原料药、药用辅料和药包材，可在药品制剂申请中同时提交原料药、药用辅料和药包材资料（资料要求参照本公告执行），不进行登记。

九、药品制剂申请人可选用已有登记号的原料药、药用辅料和药包材进行研究，提出上市申请或者变更原料药、药用辅料和药包材申请。药品制剂与原料药、药用辅料和药包材不是同一申请人的，药品制剂申请人应当在申报资料中提供原料药、药用辅料和药包材上市许可持有人或者企业的授权使用书（附件2）。

十、已获得登记号的原料药、药用辅料和药包材企业，应当严格按照国家有关要求进行管理，保证产品质量，并在获得登记号后按年度提交产品质量管理报告；在产品发生变更时应当及时在登记平台中变更相关信息，并在实施变更前主动告知使用其产品的药品制剂申请人。

药品制剂申请人应当对选用原料药、药用辅料和药包材的质量负责，充分研究和评估原料药、药用辅料和药包材变更对其产品质量的影响，按照国家食品药品监督管理总局有关规定和相关指导原则进行研究，按要求提出变更申请或者进行备案。

十一、药品制剂批准上市后或者已上市药品制剂批准变更原料药、药用辅料和药包材后（含变更原料药供应商，药用辅料和药包材种类和供应商），国家食品药品监督管理总局在原料药、药用辅料和药包材的公示信息予以标识。原料药、药用辅料和药包材与药品制剂一并审评审批的其他要求，待国家食品药品监督管理总局相关管理办法发布后实施。

本公告发布前已获得批准文号的原料药、药用辅料和药包材相关登记要求将在登记平台建立后另行通知。

十二、各省级食品药品监督管理部门负责对本行政区域内的原料药、药用辅料和药包材生产企业的日常监督管理。药品制剂申请审评审批过程中，国家食品药品监督管理总局根据需要组织对涉及的原料药、药用辅料和药包材进行现场检查和检验。

十三、本公告自发布之日起实施，原发布的药用辅料药包材关联审评审批相关文件与本公告不一致的，以本公告为准。 (2017-11-30)

CFDA Issued the *Announcement on Modifying the Package Inserts of Five Varieties Incl. Lipid-soluble Vitamin for Injection (I)*

To further protect drug safety for the public, on November 29, 2017, CFDA decided to modify, in accordance with the results of the adverse drug reaction evaluation, the [Adverse reactions], [Contraindications], [Precautions] and other items of the package inserts of the compound lipid-soluble vitamin injections [including lipid-soluble vitamin for injection (I), lipid-soluble vitamin for injection (II), lipid-soluble vitamin injection (I), lipid-soluble vitamin injection (II), compound vitamin injection (4)].

(November 29, 2017)

国家食品药品监督管理总局发布《关于修订注射用脂溶性维生素（I）等5个品种说明书的公告》

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11月29日，国家食品药品监督管理总局决定对复方脂溶性维生素注射剂〔包括注射用脂溶性维生素（Ⅰ）、注射用脂溶性维生素（Ⅱ）、脂溶性维生素注射液（Ⅰ）、脂溶性维生素注射液（Ⅱ）、复方维生素注射液（4）〕说明书【不良反应】、【禁忌】、【注意事项】等项进行修订。（2017-11-29）

CFDA Released the *Notice on Regulating the Nomenclature for China Approved Drug Names of Marketed Chinese Patent Medicines*

Pursuant to the requirements for regulating the nomenclature of marketed drugs in violation of the naming rules as stated in the *Announcement on Promulgating the Technical Guidelines for Nomenclature of Generic Names of Chinese Patent Medicines* (Announcement [2017] No. 188), on November 28, 2017, CFDA issued a Notice in this regard.

(November 28, 2017)

国家食品药品监督管理总局发布《关于规范已上市中成药通用名称命名的通知》

根据《关于发布中成药通用名称命名技术指导原则的通告》（2017年第188号）中关于对已上市的药品违反命名原则的要进行规范的要求，2017年11月28日，国家食品药品监督管理总局就已上市中成药通用名称命名规范工作发布了通知。（2017-11-28）

CFDA Announcement on Promulgating the *Technical Guidelines for Nomenclature of China Approved Drug Names of Chinese Patent Medicines*

To regulate the nomenclature of Chinese patent medicines and reflect the characteristics of traditional Chinese medicines, CFDA organized to formulate the *Technical Guidelines for Nomenclature of Generic Names of Chinese Patent Medicines* which is issued on November 28, 2017.

(November 28, 2017)

国家食品药品监督管理总局发布《中成药通用名称命名技术指导原则》

为规范中成药命名，体现中医药特色，国家食品药品监督管理总局组织制定了《中成药通用名称命名技术指导原则》，于2017年11月28日发布。（2017-11-28）

CFDA and NHFPC Released the *Announcement on the Second Batch of Stem Cell Clinical Research Institutions Granted for Filing*

In alignment with the *Administrative Measures for Stem Cell Clinical Study (Interim)* (NHFPC Department of Health Science, Technology and Education [2015] No. 48), to regulate and facilitate the clinical study of stem cells, NHFPC and CFDA organized the re-review of the filing materials of the institutions applying for stem cell clinical study, and announced the list of the second batch of stem cell clinical research institutions granted for filing.

(November 28, 2017)

国家卫生和计划生育委员会 国家食品药品监督管理总局发布《关于第二批干细胞临床研究备案机构的公告》

为规范和促进干细胞临床研究，根据《干细胞临床研究管理办法（试行）》（国卫科教发〔2015〕48号），国家卫生计生委和食品药品监管总局组织对申报干细胞临床研究机构备案材料进行复核，公布了第二批干细胞临床研究备案机构。（2017-11-28）

CFDA General Office Released the *Notice on Organizing the Application for Key Laboratories of CFDA*

To promote the construction of key laboratories and meet the strategic needs for the innovation & development and scientific supervision of food and drug industries in China, according to the *Provisions for the Administration of Key Laboratories of CFDA*, on November 27, 2017, CFDA issued a Notice on Organizing the Application of Key Laboratories of CFDA for relevant issues. (November 27, 2017)

国家食品药品监督管理总局办公厅发布《关于组织开展国家食品药品监督管理总局重点实验室申报工作的通知》

为推进重点实验室建设，满足我国食品药品创新发展和科学监管的战略需求，根据《国家食品药品监督管理总局重点实验室管理办法》，2017年11月27日，国家食品药品监督管理总局就组织开展国家食品药品监督管理总局重点实验室申报工作有关事项进行了通知。（2017-11-27）

Medical Devices

CFDA General Office Issued the *Notice on Carrying out Filing of Medical Device Clinical Trial Institutions*

The *Administrative Measures for Qualification and Filing of Medical Device Clinical Trial Institutions* (hereinafter referred to as the Filing Measures) have been promulgated and shall come into force as from January 1, 2018. For better implementation in this regard, CFDA issued a Notice on November 24, 2017 to clarify the relevant issues.

(November 24, 2017)

医疗器械

国家食品药品监督管理总局办公厅发布《关于做好医疗器械临床试验机构备案工作的通知》

《医疗器械临床试验机构条件和备案管理办法》（以下简称《备案办法》）已经发布，自2018年1月1日起施行。为做好医疗器械临床试验机构备案工作，2017年11月24日，国家食品药品监督管理总局办公厅发布通知，就有关工作进行了明确。（2017-11-24）

CFDA Promulgated the *Guidelines for the Division of Medical Device Registration Units*

To strengthen the management and guidance of the registration of medical devices, and further regulate the registration and technical review of medical devices, according to the *Provisions for Medical Device Registration* (CFDA Order No. 4) and the *Provisions for In-vitro Diagnostic Reagent Registration* (CFDA Order No. 5), CFDA organized to formulate the *Guidelines for the Division of Medical Device Registration Units*, which has been promulgated on November 23, 2017.

(November 23, 2017)

国家食品药品监督管理总局发布《医疗器械注册单元划分指导原则》

为加强医疗器械产品注册工作的管理和指导，进一步规范医疗器械注册申报和技术审评工作，根据《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）和《体外诊断试剂注册管理办法》（国家食品药品监督管理总局令第5号）有关要求，国家食品药品监督管理总局组织制定了《医疗器械注册单元划分指导原则》，于2017年11月23日发布。（2017-11-23）

Cosmetics

CFDA Released the *Announcement on Regulating Cosmetics Registration and Filing Applications*

According to the unified arrangements of CFDA, the renewal of the new *Cosmetics Production License* has been completed. To ensure the convergence and conformance of the post-renewal information of cosmetics manufacturing enterprise with product registration and filing information, on December 5, 2017, CFDA released the *Announcement on Regulating Cosmetics Registration and Filing Applications* to clarify relevant issues.

(November 30, 2017)

化妆品

国家食品药品监督管理总局发布《关于规范化妆品注册及备案申报有关事宜的通告》

根据国家食品药品监督管理总局统一部署，新版《化妆品生产许可证》的换发工作业已完成，为保证换证后化妆品生产企业信息与产品注册备案信息的衔接一致，2017年12月5日，国家食品药品监督管理总局发布《关于规范化妆品注册及备案申报有关事宜的通告》，就有关事宜进行了明确。（2017-11-30）

Special Focus

业界专题

Information on Trading of Medical Devices in the First Half of 2017

According to the data statistics of China Customs, the trading amount of medical devices in China in the first half of 2017 has reached USD 19.658 billion, showing 4.19% year-on-year growth and 3.38% year-on-year growth rate. Thereinto, the export amount of medical devices has reached USD 10.208 billion, showing 3.15% year-on-year growth; the import amount of medical devices has reached USD 9.45 billion, showing 5.34% year-on-year growth.

2017年上半年医疗器械贸易情况

根据中国海关数据统计，2017年上半年我国医疗器械贸易额为196.58亿美元，同比增长4.19%，同比增速上升3.38个百分点。其中，出口额102.08亿美元，同比增长3.15%；进口额94.5亿美元，同比增长5.34%。

2017年上半年进出口医疗器械产品结构统计
Structure Statistics for the Imported and Exported Medical Devices in the First Half of 2017

商品名称 Name of product	出口额（亿美元） Export amount (USD 100 million)	同比 Year-on-year growth (%)	进口额（亿美元） Import amount (USD 100 million)	同比 Year-on-year growth (%)
医疗器械类总计 Total amount of medical devices	102.08	3.15	94.5	5.34
医用敷料 Medical dressings	11.67	-2.2	1.79	-2.68
医用耗材 Medical consumables	17	8.16	14.25	8.67
诊疗设备 Diagnosis and treatment equipment	44.34	-0.41	67.72	3.95
保健康复 Devices for health care and rehabilitation	25.39	8.44	7.31	9.7
口腔设材 Dental equipment	3.67	9.18	3.42	16.41

(2017-10-10)

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