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# 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 Issued the *Decision on Adjusting the Registration Administration of Imported Drugs*

On October 10, 2017, CFDA issued the *Decision on Adjusting the Registration Administration of Imported Drugs* (CFDA Order No. 35), the full text of which is as follows:

In accordance with the requirements of the *Decision of the Standing Committee of the National People's Congress on Authorizing the State Council to Perform Marketing Authorization Holder System Pilot and Relevant Matters 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), to encourage the marketing of new drugs and meet clinical demands, several adjustments of the registration administration of imported drugs are made as follows upon decided by CFDA executive meeting through discussion:

I. For the implementation of international multi-center clinical trials of imported drugs in China, allow phase I clinical trial to be conducted simultaneously in China and overseas and remove the requirement that the IND shall have been registered overseas or have entered phase II/phase III clinical trial (excluding biological products for preventive use).

II. Upon completion of the international multi-center clinical trial in China, the applicant can submit NDA directly. Application of NDA shall comply with requirements of the *Provisions for Drug Registration* and relevant documents.

III. For CTA for imported drugs, NDA for imported new chemical drugs, and NDA for imported innovative biological products for therapeutic use, remove the requirement that the product shall have been approved in the country/region of the overseas manufacturer.

IV. If an applicant had applied for clinical trial exemption for an imported product using data generated from MRCTs for support and the application has been accepted by CFDA before the issuance of this Decision, CFDA can directly grant approval if the application comply with the requirements of the *Provisions for Drug Registration* and relevant documents.

The Decision shall be implemented as of the date of release. If there is any discrepancy between the provisions in applicable regulations for imported drugs and this Decision, this Decision shall prevail.

(October 10, 2017)

## 国家食品药品监督管理总局发布《关于调整进口药品注册管理有关事项的决定》

2017年10月10日，国家食品药品监督管理总局发布《关于调整进口药品注册管理有关事项的决定》(国家食品药品监督管理总局令第35号)，全文如下：

根据《全国人民代表大会常务委员会关于授权国务院在部分地方开展药品上市许可持有人制度试点和有关问题的决定》《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，为鼓励新药上市，满足临床需求，经国家食品药品监督管理总局局务会议研究决定，对进口药品注册管理有关事项作如下调整：

一、在中国进行国际多中心药物临床试验，允许同步开展I期临床试验，取消临床试验用药物应当已在境外注册，或者已进入II期或III期临床试验的要求，预防用生物制品除外。

二、在中国进行的国际多中心药物临床试验完成后，申请人可以直接提出药品上市注册申请。提出上市注册申请时，应当执行《药品注册管理办法》及相关文件的要求。

三、对于提出进口药品临床试验申请、进口药品上市申请的化学药品新药以及治疗用生物制品创新药，取消应当获得境外制药厂商所在生产国家或者地区的上市许可的要求。

四、对于本决定发布前已受理、以国际多中心临床试验数据提出免做进口药品临床试验的注册申请，符合《药品注册管理办法》及相关文件要求的，可以直接批准进口。

本决定自发布之日起实施。药品监管相关规章中有关规定与本决定不一致的，按照本决定执行。

(2017-10-10)

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

## The General Office of the CPC Central Committee and the General Office of the State Council Printed and Issued the *Opinions on Deepening the Reform of Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices*

On October 8, 2017, the General Office of the CPC Central Committee and the General Office of the State Council printed and issued the *Opinions on Deepening the Reform of Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices*.

The Opinions include 36 items in six sections.

**I. Reform of clinical trial management**

(1) The qualification accreditation of clinical trial institutions is subject to filing management.

(2) Support clinical trial institutions and personnel to carry out clinical trials.

(3) Improve the mechanism of the ethics committee.

(4) Improve the efficiency of ethical review.

(5) Optimize clinical trial review and approval procedures.

(6) Accept the overseas clinical trial data.

(7) Support expanded clinical trials.

(8) Seriously investigate and punish the deceptive behaviors of data.

**II. Accelerate the review and approval for marketing application**

(9) Accelerate the review and approval of the pharmaceuticals and medical devices urgently needed in clinical settings.

(10) Support the research and development of the pharmaceuticals and medical devices for rare diseases.

(11) Conduct review and approval of drug injections in a strict manner.

(12) Implement the associated review and approval of the pharmaceuticals with the pharmaceutical raw materials and excipients and packaging materials.

(13) Support the inheritance and innovation of traditional Chinese medicines.

(14) Establish the priority review and approval system for the drugs with patent compulsory license.

**III. Promote drug innovation and the development of generic drugs**

(15) Establish a list of marketed drugs.

(16) Explore to establish the pharmaceutical patent linkage system.

(17) Carry out the pilot implementation of drug patent period compensation system.

(18) Improve and implement the drug trial data protection system.

(19) Promote the production of generic drugs.

(20) Give a play of the role of enterprises as the main body of innovation.

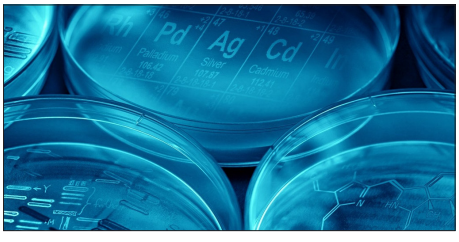
(21) Support the clinical application of new pharmaceuticals.

**IV. Strengthen the life cycle management of pharmaceuticals and medical devices**

(22) Promote the full implementation of the Marketing Authorization Holder (MAH) System.

(23) Implement the legal liabilities of marketing authorization holders.

(24) Establish the direct adverse reaction and adverse event reporting system of




## 中共中央办公厅国务院办公厅印发《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》

2017年10月8日，中共中央办公厅、国务院办公厅印发了《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》。

《意见》共6项36条。

**一、改革临床试验管理**

（一）临床试验机构资格认定实行备案管理。

（二）支持临床试验机构和人员开展临床试验。

（三）完善伦理委员会机制。

（四）提高伦理审查效率。

（五）优化临床试验审批程序。

（六）接受境外临床试验数据。

（七）支持拓展性临床试验。

（八）严肃查处数据造假行为。

**二、加快上市审评审批**

（九）加快临床急需药品医疗器械审评审批。

（十）支持罕见病治疗药品医疗器械研发。

（十一）严格药品注射剂审评审批。

（十二）实行药品与药用原辅料和包装材料关联审批。

（十三）支持中药传承和创新。

（十四）建立专利强制许可药品优先审评审批制度。

**三、促进药品创新和仿制药发展**

（十五）建立上市药品目录集。

（十六）探索建立药品专利链接制度。

（十七）开展药品专利期限补偿制度试点。

（十八）完善和落实药品试验数据保护制度。

（十九）促进药品仿制生产。

（二十）发挥企业的创新主体作用。

（二十一）支持新药临床应用。

**四、加强药品医疗器械全生命周期管理**

（二十二）推动上市许可持有人制度全面实施。

（二十三）落实上市许可持有人法律责任。

（二十四）建立上市许可持有人直接报告不良反应和不良事件制度。

（二十五）开展药品注射剂再评价。

marketing authorization holders.

(25) Carry out re-evaluation of the drug injections.

(26) Improve medical device re-evaluation system.

(27) Regulate the academic promotion of drugs.

**V. Improve technical support capacity**

(28) Improve the technical review system.

(29) Implement the responsibilities of relevant staff for confidentiality.

(30) Strengthen the construction of review and inspection capacity.

(31) Implement the inspection responsibilities for the whole process.

(32) Construct a professional inspector team.

(33) Strengthen international cooperation.

**VI. Strengthen the organization of implementation**

(34) Strengthen the organization and leadership.

(35) Strengthen collaboration and coordination.

(36) Carry out propaganda and interpretation. (October 8, 2017)

（二十六）完善医疗器械再评价制度。

（二十七）规范药品学术推广行为。

**五、提升技术支撑能力**

（二十八）完善技术审评制度。

（二十九）落实相关工作人员保密责任。

（三十）加强审评检查能力建设。

（三十一）落实全过程检查责任。

（三十二）建设职业化检查员队伍。

（三十三）加强国际合作。

**六、加强组织实施**

（三十四）加强组织领导。

（三十五）强化协作配合。

（三十六）做好宣传解释。

（2017-10-08）

## CFDA Issued the *Announcement on Modifying the Package Inserts of Sodium Prasterone Sulfate for Injection*

In accordance with the results of ADR evaluation, in order to further ensure drug safety for the public, on September 27, 2017, CFDA decided to add warnings on the package inserts of sodium prasterone sulfate for injection and to modify such items as [Adverse Reactions], and [Precautions].

(September 27, 2017)

## 国家食品药品监督管理总局发布《关于修订注射用硫酸普拉睾酮钠说明书的公告》

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9月27日，国家食品药品监督管理总局决定对注射用硫酸普拉睾酮钠说明书增加警示语，并对【不良反应】、【注意事项】等项进行修订。

（2017-09-27）

## CFDA Issued the *Guidelines for Acceptance and Review of Conformance Evaluation of the Quality and Efficacy of Generic Drugs (to which Such Evaluation is Compulsory)* and the *Guidelines for Acceptance and Review of Conformance Evaluation of the Quality and Efficacy of Generic Drugs (that are Produced in the Same Line in China and Marketed in Europe, US and Japan)*

To implement the policies set forth in the *Opinions of the State Council General Office on Carrying out Conformance Evaluation of the Quality and Efficacy of Generic Drugs* (State Council General Office [2016] No. 8), according to the requirements set forth in the *Announcement on Matters concerning the Conformance Evaluation of the Quality and Efficacy of Generic Drugs* (CFDA Announcement [2017] No. 100) and other documents, CFDA organized the development of the *Guidelines for Acceptance and Review of Conformance Evaluation of the Quality and Efficacy of Generic Drugs* (to which Such Evaluation is Compulsory) and the *Guidelines for Acceptance and Review of Conformance Evaluation of the Quality and Efficacy of Generic Drugs (that are Produced in the Same Line in China and Marketed in Europe, US and Japan)* and related documents, which have been released on September 5, 2017.

(September 5, 2017)

## 国家食品药品监督管理总局发布《仿制药质量和疗效一致性评价受理审查指南（需一致性评价品种）》《仿制药质量和疗效一致性评价受理审查指南（境内共线生产并在欧美日上市品种）》

为落实《国务院办公厅关于开展仿制药质量和疗效一致性评价的意见》（国办发〔2016〕8号）文件精神，根据《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理总局公告2017年第100号）等文件要求，国家食品药品监督管理总局组织制定了《仿制药质量和疗效一致性评价受理审查指南（需一致性评价品种）》《仿制药质量和疗效一致性评价受理审查指南（境内共线生产并在欧美日上市品种）》及相关单据，于2017年9月5日发布。

（2017-09-05）

## CFDA and NHFPC Issued the *Notice on Further Strengthening Vaccine Circulation & Supervision to Promote Vaccine Supply*

To further implement the newly revised *Regulations on Management of Vaccine Circulation and Inoculation*, standardize the cold chain storage and transportation management for Class II vaccines (hereinafter referred to as vaccines), solve the practical problems in the process of vaccine delivery, and ensure the availability of the vaccine supply, on September 1, 2017, the CFDA and the National Health and Family Planning Commission (NHFPC) issued the *Notice on Further Strengthening Vaccine Circulation & Supervision to Promote Vaccine Supply*, which requires to standardize the vaccine storage and transportation management, improve the efficiency of vaccine delivery; actively promote the construction of full course traceability system for the vaccines; strengthen the management of the validity period of vaccine; further improve the centralized procurement of vaccines; and reinforce the supervision and inspection of vaccine circulation.

(September 1, 2017)

## 国家食品药品监督管理总局国家卫生计生委发布《关于进一步加强疫苗流通监管促进疫苗供应工作的通知》

为进一步贯彻落实新修订的《疫苗流通和预防接种管理条例》，规范第二类疫苗（以下称疫苗）冷链储存运输管理，解决疫苗配送过程中的实际问题，保证疫苗供应的可及性，2017年9月1日，国家食品药品监管总局国家卫生计生委发布《关于进一步加强疫苗流通监管促进疫苗供应工作的通知》。通知要求，规范疫苗储运管理，提高疫苗配送效率；积极推动疫苗全程追溯体系建设；加强疫苗有效期管理；进一步完善疫苗集中采购工作；加强疫苗流通监督检查。

（2017-09-01）

## CFDA Released the *Technical Guidelines for Studies on the Production Process Alterations of Post-marketed Traditional Chinese Medicine*

To guide the applicants to study the production process alterations of post-marketed TCM, CFDA organized the formulation of and released on August 31, 2017 the *Technical Guidelines for Studies on the Production Process Alterations of Post-marketed Traditional Chinese Medicine*.

( August 31, 2017)

## 国家食品药品监督管理总局发布已上市中药生产工艺变更研究技术指导原则

为指导申请人对已上市中药拟变更生产工艺开展研究，国家食品药品监督管理总局组织制定了《已上市中药生产工艺变更研究技术指导原则》，于2017年8月31日发布。

（2017-08-31）

## CFDA Released *Technical Guidelines for Studies on the Production Process Alterations of Post-marketed Chemicals*

To standardize and guide the study on the production process alterations of post-marketed chemicals, CFDA organized the formulation of and released on August 28, 2017 the *Technical Guidelines for Studies on the Production Process Alterations of Post-marketed Chemicals*. Alterations not covered in the said Technical Guidelines shall be subject to studies in accordance with the original *Technical Guidelines for Studies on the Production Process Alterations of Post-marketed Chemicals (I)*.

(August 29, 2017)

## 国家食品药品监督管理总局发布已上市化学药品生产工艺变更研究技术指导原则

为规范和指导已上市化学药品的生产工艺变更研究，国家食品药品监督管理总局组织制定了《已上市化学药品生产工艺变更研究技术指导原则》，于 2017年8月28日发布。本指导原则中未涉及的变更事项，仍按照《已上市化学药品变更研究的技术指导原则（一）》开展变更研究。

（2017-08-29）

## CFDA issued the *Announcement on Establishing the 11th Chinese Pharmacopoeia Commission*

On August 28, 2017, CFDA issued the *Announcement on Establishing the 11th Chinese Pharmacopoeia Commission*. As per the decision of CFDA, the said Pharmacopoeia Commission shall consist of an Executive Committee and 26 Specialized Committees, with 405 members whose name list is to be announced.

(August 28, 2017)

## 国家食品药品监督管理总局发布《关于成立第十一届药典委员会的公告》

2017年8月28日　国家食品药品监督管理总局发布《关于成立第十一届药典委员会的公告》，决定成立第十一届药典委员会。本届药典委员会由405名委员组成，设执行委员会和26个专业委员会，并将第十一届药典委员会组成人员予以公告。

（2017-08-28）

## CFDA issued *Announcement on Matters concerning the Conformance Evaluation of the Quality and Efficacy of Generic Drugs*

For better conformance evaluation of the quality and efficacy of generic drugs (hereinafter referred to as the conformance evaluation), on August 25, 2017, CFDA issued the *Announcement on Matters concerning the Conformance Evaluation of the Quality and Efficacy of Generic Drugs*, which clarifies relevant matters encompassing the enterprises' selection and information disclosure of reference preparations; the filing management of bioequivalence testing institutions; the differentiation with the originators manufactured and marketed in China; the acceptance and filing review of application materials, and the use of the *Conformance Evaluation Passed* logo, etc.

(August 25, 2017)

## 国家食品药品监督管理总局发布《关于仿制药质量和疗效一致性评价工作有关事项的公告》

为做好仿制药质量和疗效一致性评价工作（以下简称一致性评价），2017年8月25日，国家食品药品监督管理总局发布《关于仿制药质量和疗效一致性评价工作有关事项的公告》。公告就企业选择参比制剂、参比制剂信息公开、对生物等效性试验机构实行备案制管理、原研企业在中国境内生产上市的品种的区分、对申报资料的受理和立卷审查、“通过一致性评价”标识的使用等事宜进行了明确。

（2017-08-25）

Medical Devices

## CFDA Issued Five Guidelines for Technical Review Including the Guidelines for Technical Review of Microplate Reader Registration

With a view to strengthening the supervision and guidance over medical device registration and further improving the quality of registration review, CFDA organized to formulate the *Guidelines for Technical Review of Microplate Reader Registration*, the *Guidelines for Technical Review of Disposable ECG Electrode Registration*, the *Guidelines for Technical Review of Ambulatory Blood Pressure Monitor Registration*, the *Guidelines for Technical Review of Electrocardiograph Registration* (2017 Revision) and the *Guidelines for Technical Review of Patient Care Product (Class II) Registration (2017 Revision)*, which were promulgated on October 9, 2017.

(October 9, 2017)

医疗器械

## 国家食品药品监督管理总局发布酶标仪等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《酶标仪注册技术审查指导原则》《一次性使用心电电极注册技术审查指导原则》《动态血压测量仪注册技术审查指导原则》《心电图机注册技术审查指导原则（2017年修订版）》《病人监护产品（第二类）注册技术审查指导原则（2017年修订版）》，于2017年10月9日发布。

（2017-10-09）

## The General Office of CFDA Issued the *Notice on Regulating the Work Related to Classification of Medical Devices*

The General Office of CFDA issued the *Notice on Regulating the Work Related to Classification of Medical Devices* to regulate the work related to medical device classification among food and drug regulatory authorities of all provinces, autonomous regions and municipalities directly under the central government on September 26, 2017, which specified the working procedure for classification definition, other situations involving classification determination, and adjustment of classification catalogue, etc.

(September 28, 2017)

## 国家食品药品监督管理总局办公厅发布《关于规范医疗器械产品分类有关工作的通知》

2017年9月26日，国家食品药品监督管理总局办公厅就规范医疗器械产品分类有关工作，向各省、自治区、直辖市食品药品监督管理局，各有关单位发布《关于规范医疗器械产品分类有关工作的通知》。通知明确了分类界定工作程序、涉及类别确认的其他情况、分类目录调整等事项。（2017-09-28）

## CFDA Approved the Release of Seven Medical Device Industry Standards Including YY/T 0661-2017 *Semi-crystalline Polylactide Polymer and Copolymer Resins for Surgical Implants*

CFDA approved the release of seven medical device industry standards including YY/T 0661-2017 *Semi-crystalline Polylactide Polymer and Copolymer Resins for Surgical Implants* on September 28, 2017, which shall be implemented on October 1, 2018.

(September 28, 2017)

## 国家食品药品监督管理总局批准发布YY/T 0661-2017《外科植入物半结晶型聚丙交酯聚合物和共聚物树脂》等7项医疗器械行业标准

2017年9月28日，国家食品药品监督管理总局批准发布YY/T 0661—2017《外科植入物半结晶型聚丙交酯聚合物和共聚物树脂》等7项医疗器械行业标准，标准自2018年10月1日起实施。（2017-09-28）

## CFDA General Office Issued the *Notice on Issues pertaining to the Implementation of GMP in Manufacturers of Class I & II Medical Devices*

To promote the orderly implementation of the *Good Manufacturing Practice for Medical Devices* (hereinafter referred to as the GMP) and the relevant laws and regulations, CFDA issued in 2014 the *Announcement on Relevant Issues of Medical Device GMP Implementation* (Announcement [2014] No. 15, hereinafter referred to as the Announcement), and in accordance with the principles of risk management, classified and in-depth implementation, the specific time limits are set for manufacturers of different classes of medical device to implement the GMP. In accordance with the requirements of the Announcement, as of January 1, 2018, all medical device manufacturers should meet the GMP requirements. To ensure the full implementation of the GMP within the time limits, in particular, the implementation of GMP in Class I & Class II medical device manufacturers, on September 1, 2017, CFDA General Office issued the *Notice on Issues pertaining to the Implementation of GMP in Manufacturers of Class I & II Medical Devices*.

The Notice requires all areas to strengthen organization, leadership, and overall planning; intensify publicity and training, and create a favorable environment for GMP; reinforce supervision and inspection, and investigate in strict accordance with the regulations. (September 1, 2017)

## 国家食品药品监管总局办公厅发布《关于第一类、第二类医疗器械生产企业实施医疗器械生产质量管理规范有关工作的通知》

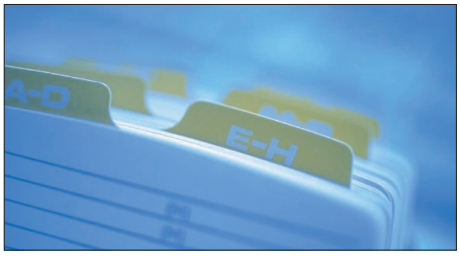
为有序推进《医疗器械生产质量管理规范》（以下简称《规范》）及相关法规的实施，2014年，国家食品药品监督管理总局发布了《关于医疗器械生产质量管理规范执行有关事宜的通告》（2014年第15号，以下简称《通告》），按照风险管理、分类推进的原则，确定了不同类型医疗器械生产企业实施《规范》的具体时限要求。按照《通告》要求，自2018年1月1日起，所有医疗器械生产企业均应当符合《规范》要求。为确保《规范》按时限全面落实到位，特别是推进第一类、第二类医疗器械生产企业实施《规范》，2017年9月1日，国家食品药品监管办公厅发布《关于第一类、第二类医疗器械生产企业实施医疗器械生产质量管理规范有关工作的通知》。

通知要求，各地要加强组织领导，做好统筹规划：强化宣传培训，营造良好氛围；加强监督检查，严格依规查处。（2017-09-01）

## CFDA issued the *Announcement on the Classification Catalogue for Medical Devices*

To implement the requirements of the *Regulations for the Supervision and Administration of Medical Devices 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), CFDA has revised and released on August 31, 2017 the Classification Catalogue for Medical Devices, which shall come into effect as of August 1, 2018.

According to the technical and clinical use characteristics of medical devices, the new Classification Catalogue is divided into 22 sub-catalogs, each of which consists of Class I and Class II product catalog, product description, intended use, exemplary brands and management category. The new Classification Catalogue features in: 1. a more scientific structure that is more in line with clinical practice. Based on the clinical use-oriented classification system in the United States, the 43 sub-catalogs of the current Catalogue are reduced to 22 sub-catalogs by referring to the structure of the *EU Notified Body Framework Catalogue*, and the 260 product categories are refined to 206 Class-I product categories and 1,157 Class-II product categories, forming a three-level directory hierarchy; 2. wider covering, and more instructive and operational catalogue. More than 2,000 products' intended uses and product descriptions are added, and the current 1,008 exemplary brands in the Classification Catalogue are expanded into 6,609 brands; 3. reasonable adjustment of the product management category, which has enhanced the adaptability of the status quo to the actual regulation, and provided a basis for optimizing the allocation of regulatory resources. According to the degree of product risk and regulatory practice, the management category has been reduced for 40 medical devices with long-term marketing, high product maturity and controllable risk.

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(August 31, 2017)

## 国家食品药品监督管理总局发布《医疗器械分类目录的公告》

为贯彻实施《医疗器械监督管理条例》和《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）的要求，国家食品药品监督管理总局组织修订了《医疗器械分类目录》，于2017年8月31日发布。目录自2018年8月1日起施行。

新《分类目录》按照医疗器械技术专业和临床使用特点分为22个子目录，子目录由一级产品类别、二级产品类别、产品描述、预期用途、品名举例和管理类别组成。新《分类目录》主要特点有：一是架构更具科学性，更切合临床实际。借鉴美国以临床使用为导向的分类体系，参考《欧盟公告机构用框架目录》的结构，将现行《分类目录》的43个子目录整合精简为22个子目录，将260个产品类别细化调整为206个一级产品类别和1157个二级产品类别，形成三级目录层级结构。二是覆盖面更广泛，更具指导性和操作性。增加2000余项产品预期用途和产品描述，将现行《分类目录》1008个产品名称举例扩充到6609个。三是合理调整产品管理类别，提升了产业现状与监管实际的适应性，为优化监管资源配置提供了依据。根据产品风险程度和监管实际，对上市时间长、产品成熟度高及风险可控的40种医疗器械产品降低管理类别。

**目 录**



（2017-08-31）

## CFDA Issued the Announcement on Issues pertaining to the Implementation of the *Classification Catalogue for Medical Devices*

To implement the *Regulations for the Supervision and Administration of Medical Devices 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), CFDA has issued on August 31, 2017 the *Classification Catalogue for Medical Devices* (hereinafter referred to as the new Classification Catalogue), which shall come into effect as of August 1, 2018. For better implementation of the new Classification Catalogue, on August 31, 2017, CFDA issued an Announcement on Issues pertaining to the Implementation of the *Classification Catalogue for Medical Devices* to provide a general description of the new Classification Catalogue, and elaborate the relevant policies for medical device registration, filing management, and licensing of production and distribution of medical devices.

(August 31, 2017)

## 国家食品药品监督管理总局发布关于实施《医疗器械分类目录》有关事项的通告

为贯彻落实《医疗器械监督管理条例》和《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），国家食品药品监督管理总局于2017年8月31日发布《医疗器械分类目录》（以下简称新《分类目录》），自2018年8月1日起施行。为做好新《分类目录》实施工作，2017年8月31日，国家食品药品监督管理总局发布关于实施《医疗器械分类目录》有关事项的通告。通告对新《分类目录》进行了总体说明，明确了医疗器械注册和备案管理有关政策和医疗器械生产经营许可有关政策。（2017-08-31）

## CFDA Approved the Promulgation of YY/T 1574-2017 *Tissue Engineering Medical Device Products: Guidelines for Immobilization or Microencapsulation of Alginate Gel* and Other 3 Medical Device Industry Standards

The YY/T 1574-2017 *Tissue Engineering Medical Device Products: Guidelines for Immobilization or Microencapsulation of Alginate Gel, Tissue Engineering Medical Device Products: Guidelines for Evaluation of Bone Formation Activity of Bone Tissue Implants for Repair and Replacement, Tissue Engineering Medical Device Products: Absorbable Material Implantation Test, and Tissue Engineering Medical Device Products: Guidelines for Evaluation of Polymer Stent Microstructure*, as well as their Standard Numbers and scope of application, have been adopted and promulgated on August 28, 2017, and shall enter into force as of September 1, 2018.

(August 28, 2017)

## 国家食品药品监督管理总局批准发布YY/T 1574—2017《组织工程医疗器械产品海藻酸盐凝胶固定或微囊化指南》等4项医疗器械行业标准

YY/T 1574—2017《组织工程医疗器械产品海藻酸盐凝胶固定或微囊化指南》《组织工程医疗器械产品修复和替代骨组织植入物骨形成活性的评价指南》《组织工程医疗器械产品可吸收材料植入试验》《组织工程医疗器械产品聚合物支架微结构评价指南》标准编号及适用范围等4项医疗器械行业标准已经审定通过，国家食品药品监督管理总局予以公布。标准自2018年9月1日起实施。（2017-08-28）

**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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