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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

Promulgation of the *Regulations on Supervision and Administration of Cosmetics*

On June 29, 2020, the *Regulations on Supervision and Administration of Cosmetics* (Decree No.727 of the State Council of the People's Republic of China) (hereinafter referred to as the *Regulations*), was promulgated, and shall take effect as from January 1, 2021.

It is the first comprehensive revision of the administrative regulations for supervision and administration of cosmetics since 1989. The Regulations fully implement the new requirements of the CPC Central Committee and the State Council for supervision and administration of cosmetics, to fully serve the people's new expectations for a better life, solidify the fruition of reforms in the cosmetics field in recent years into regulations, and open a new chapter in supervision and administration of cosmetics across-the-board. (June 29, 2020)

《化妆品监督管理条例》颁布

2020年6月29日，《化妆品监督管理条例》（中华人民共和国国务院令第727号）（以下简称《条例》）颁布，自2021年1月1日起施行。

这是自1989年以来，化妆品监管行政法规的首次全面修改。《条例》全面贯彻落实党中央、国务院对化妆品监督管理的新要求，全力服务人民群众对美好生活的新期待，将近年来化妆品领域改革成果固化为法规，全面开启化妆品监管新篇章。（2020-06-29）

NMPA Issues Announcement on *Requirements for the Management of Drug Records and Data (Interim)*

To implement the relevant provisions of the *Drug Administration Law and the Vaccine Administration Law*, strengthen the management of records and data of drug R&D, manufacture, distribution and use, and ensure that the relevant information is true, accurate, complete and traceable, NMPA has organized to formulate the *Requirements for the Management of Drug Records and Data (Interim)*, which has been issued on June 24, 2020 and shall take effect as from December 1, 2020. (July 1, 2020)

国家药品监督管理局发布《药品记录与数据管理要求（试行）》的公告

为贯彻落实《药品管理法》《疫苗管理法》有关规定，加强药品研制、生产、经营、使用活动的记录和数据管理，确保有关信息真实、准确、完整和可追溯。国家药监局组织制定了《药品记录与数据管理要求（试行）》，于2020年6月24日发布，自2020年12月1日起施行。（2020-07-01）

NMPA Issues *Charging Standards for Drug Registration and Rules for Implementing Drug Registration Charges*

According to the *Provisions for Drug Registration* (Decree No.27 of SAMR), *Notice on Re-issuing Administrative Charging Items of Food and Drug Administration under the Central Management and Notice on Printing and Issuing the Administrative Measures for Charging Standards for Drug* and *Medical Device Registration, NMPA has formulated the Charging Standards for Drug Registration and Rules for Implementing Drug Registration Charges,* which shall take effect as from July 1, 2020. (June 30, 2020)

国家药品监督管理局发布《药品注册收费标准》《药品注册收费实施细则》

根据《药品注册管理办法》（国家市场监督管理总局令 第27号）、《关于重新发布中央管理的食品药品监督管理部门行政事业性收费项目的通知》（财税〔2015〕2号）和《关于印发〈药品、医疗器械产品注册收费标准管理办法〉的通知》（发改价格〔2015〕1006号），国家药品监督管理局制定了《药品注册收费标准》《药品注册收费实施细则》，于2020年6月30日公布，自2020年7月1日起施行。（2020-06-30）

NMPA Issues *Requirements for Registration Classification and Application Dossiers of Chemical Drugs*

To support the implementation of the *Provisions for Drug Registration, NMPA has organized to formulate the Requirements for Registration Classification and Application Dossiers of Chemical Drugs*, which has been issued on June 29, 2020. The requirements for registration classification of chemical drugs shall take effect as from July 1, 2020. The requirements for application dossiers of chemical drugs shall take effect as from

国家药品监督管理局发布《化学药品注册分类及申报资料要求》

为配合《药品注册管理办法》实施，国家药品监督管理局组织制定了《化学药品注册分类及申报资料要求》，于2020年6月29日发布。化学药品注册分类，自2020年7月1日起实施。化学药品注册申报资料要求，自2020年10月1日起实施。在2020年9月30日前，可按原要求提交申报资料。

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Servier (Tianjin) Pharmaceutical Co., Ltd.

October 1, 2020. Before September 30, 2020, the application dossiers can be submitted according to the former requirements.

Requirements for Registration Classification and Application Dossiers of Chemical Drugs

I. Registration classification of chemical drugs

The registration classification of chemical drugs covers innovative drugs, modified new drugs, generic drugs and chemical drugs marketed overseas but not in China, which fall into the following 5 categories:

Class 1: Innovative drugs that have not been marketed in China or overseas. They refer to drugs that contain new compounds with clear structures and pharmacological effects, and have clinical values.

Class 2: Modified new drugs that have not been marketed in China or overseas. They refer to drugs that have their structure, dosage form, formulation and process, route of administration and indications optimized on the basis of known active ingredients and have significant clinical advantages.

2.1 Drugs that contain an optical isomer of known active ingredients obtained by resolution or synthesis, or esterification of known active ingredients, or salification of known active ingredients (including salt containing hydrogen bonds or coordination bonds), or change in acid group, basic group, or metallic element of known active ingredients of salt, or formation of other non-covalent bond derivatives (e.g., complex, chelate or clathrate), and have significant clinical advantages.

2.2 Drugs that contain known active ingredients with new dosage form (including new drug delivery system), new formulation process or new route of administration, and have significant clinical advantages.

2.3 New compound preparations that contain known active ingredients and have significant clinical advantages.

2.4 Drugs for new indications that contain known active ingredients.

Class 3: Drugs manufactured by domestic applicants by imitating the original drugs that have been marketed overseas but not yet in China. Such drugs shall have the quality and efficacy consistent with the reference listed drug.

Class 4: Drugs manufactured by domestic applicants by imitating the original drugs that have been marketed in China. Such drugs shall have the quality and efficacy consistent with the reference formulations.

Class 5: Drugs that have been marketed overseas and are under application for being marketed in China.

5.1 Original drugs and modified drugs that have been marketed overseas and are under application for being marketed in China. Modified drugs shall have obvious clinical advantages,

5.2 Generic drugs that have been marketed overseas and are under application for being marketed in China.

Original drugs refer to drugs that have been firstly approved to be marketed in China and overseas and have complete and sufficient safety and effectiveness data as the basis for being marketed.

Reference listed drugs refer to the reference drugs used in the R&D of generic drugs that have been evaluated and confirmed by NMPA. The selection and promulgation of reference listed drugs shall be performed according to the relevant regulations of NMPA.

II. Relevant registration management requirements

(1) Class 1 chemical drugs are innovative drugs that contain new compounds with clear structures and pharmacological effects and have clinical values. Class 2.1 drugs in modified new drugs are not included. New compound preparations containing new compounds with clear structures and pharmacological effects shall be applied in accordance with Class 1 chemical drugs.

(2) Class 2 chemical drugs, being modified new drugs, are optimized on the basis of known active ingredients, and shall have obvious clinical advantages over

化学药品注册分类及申报资料要求

一、化学药品注册分类

化学药品注册分类分为创新药、改良型新药、仿制药、境外已上市境内未上市化学药品，分为以下5个类别：

1类：境内外均未上市的创新药。指含有新的结构明确的、具有药理作用的化合物，且具有临床价值的药品。

2类：境内外均未上市的改良型新药。指在已知活性成份的基础上，对其结构、剂型、处方工艺、给药途径、适应症等进行优化，且具有明显临床优势的药品。

2.1 含有用拆分或者合成等方法制得的已知活性成份的光学异构体，或者对已知活性成份成酯，或者对已知活性成份成盐（包括含有氢键或配位键的盐），或者改变已知盐类活性成份的酸根、碱基或金属元素，或者形成其他非共价键衍生物（如络合物、螯合物或包合物），且具有明显临床优势的药品。

2.2 含有已知活性成份的新剂型（包括新的给药系统）、新处方工艺、新给药途径，且具有明显临床优势的药品。

2.3 含有已知活性成份的新复方制剂，且具有明显临床优势。

2.4含有已知活性成份的新适应症的药品。

3类：境内申请人仿制境外上市但境内未上市原研药品的药品。该类药品应与参比制剂的质量和疗效一致。

4类：境内申请人仿制已在境内上市原研药品的药品。该类药品应与参比制剂的质量和疗效一致。

5类：境外上市的药品申请在境内上市。

5.1 境外上市的原研药品和改良型药品申请在境内上市。改良型药品应具有明显临床优势。

5.2 境外上市的仿制药申请在境内上市。

原研药品是指境内外首个获准上市，且具有完整和充分的安全性、有效性数据作为上市依据的药品。

参比制剂是指经国家药品监管部门评估确认的仿制药研制使用的对照药品。参比制剂的遴选与公布按照国家药品监管部门相关规定执行。

二、相关注册管理要求

（一）化学药品1类为创新药，应含有新的结构明确的、具有药理作用的化合物，且具有临床价值，不包括改良型新药中2.1类的药品。含有新的结构明确的、具有药理作用的化合物的新复方制剂，应按照化学药品1类申报。

（二）化学药品2类为改良型新药，在

those before modification. Known active ingredients refer to the active ingredients of drugs that have been marketed in China or overseas. If such drugs meet the requirements of multiple conditions at the same time, such conditions shall be described at application.

(3) Class 3 chemical drugs are drugs manufactured by domestic applicants by imitating the original drugs that have been marketed overseas but not yet in China. They have identical active ingredients, dosage forms, specifications, indications, routes of administration, usage and dosage with those of the reference formulations, and have proven consistency of quality and efficacy with those of the reference formulations.

With sufficient research data to prove the rationality, the specifications, usage and dosage may be inconsistent with those of the reference formulations.

(4) Class 4 chemical drugs are drugs manufactured by domestic applicants by imitating the original drugs that have been marketed in China. They have identical active ingredients, dosage forms, specifications, indications, routes of administration, usage and dosage with those of the reference formulations, and have proven consistency of quality and efficacy with those of the reference formulations.

(5) Class 5 chemical drugs are drugs that have been marketed overseas and are under application for being marketed in China. Drugs manufactured in China and overseas are included. Among them, Class 5.1 chemical drugs are original drugs and modified drugs, and the latter are optimized on the basis of known active ingredients, and shall have obvious clinical advantages over those before modification. Class 5.2 chemical drugs are generic drugs, whose quality and efficacy shall be proven to be consistent with those of the reference formulations, and whose technical requirements are the same as those of Class 3 and Class 4 chemical drugs. Generic drugs developed simultaneously at home and abroad but produced overseas shall be applied in accordance with Class 5.2 chemical drugs. If clinical trials for such drugs are applied, the supporting documents for approval of marketing and sales can be exempted.

(6) The application for registration of additional indications approved abroad but not yet in China shall be handled in accordance with the application channels for drug clinical trial and marketing authorization.

(7) During the review and approval of the drug marketing application, the drug registration classification and technical requirements shall not be changed because the preparation with the same active ingredients is approved to be marketed at home and abroad. Drug registration classification shall be determined when marketing authorization is applied.

III. Requirements for application dossiers

(1) While applying for drug clinical trials, drug marketing registration and chemical APIs, the applicants shall carry out the study in accordance with the requirements of relevant technical guidances promulgated by NMPA, collate and submit the application dossiers as per the format number and item order of the current version of *M4: Common Technical Document for the Registration Application of Pharmaceuticals for Human Use* (hereinafter referred to as CTD). If some items are not applicable, they can be missing, but "not applicable" shall be indicated and the reasons shall be specified. (Non-applicable items can be left default but "not applicable" shall be indicated and reasons shall be specified.)

(2) While applying for drug marketing registration upon completion of the clinical trial, the applicant shall submit the electronic clinical trial database on the basis of CTD. For specific requirements such as database format and related documents, please refer to the relevant guidances for clinical trial data submission.

(3) According to the needs of drug evaluation and the status of revision of the ICH technical guidance, the Center for Drug Evaluation of NMPA will update the CTD on a timely manner on its website.

(June 30, 2020)

已知活性成份基础上进行优化，应比改良前具有明显临床优势。已知活性成份指境内或境外已上市药品的活性成份。该类药品同时符合多个情形要求的，须在申报时一并予以说明。

（三）化学药品3类为境内生产的仿制境外已上市境内未上市原研药品的药品，具有与参比制剂相同的活性成份、剂型、规格、适应症、给药途径和用法用量，并证明质量和疗效与参比制剂一致。

有充分研究数据证明合理性的情况下，规格和用法用量可以与参比制剂不一致。

（四）化学药品4类为境内生产的仿制境内已上市原研药品的药品，具有与参比制剂相同的活性成份、剂型、规格、适应症、给药途径和用法用量，并证明质量和疗效与参比制剂一致。

（五）化学药品5类为境外上市的药品申请在境内上市，包括境内外生产的药品。其中化学药品5.1类为原研药品和改良型药品，改良型药品在已知活性成份基础上进行优化，应比改良前具有明显临床优势；化学药品5.2类为仿制药，应证明与参比制剂质量和疗效一致，技术要求与化学药品3类、4类相同。境内外同步研发的境外生产仿制药，应按照化学药品5.2类申报，如申报临床试验，不要求提供允许药品上市销售证明文件。

（六）已上市药品增加境外已批准境内未批准的适应症按照药物临床试验和上市许可申请通道进行申报。

（七）药品上市申请审评审批期间，药品注册分类和技术要求不因相同活性成份的制剂在境内外获准上市而发生变化。药品注册分类在提出上市申请时确定。

三、申报资料要求

（一）申请人提出药物临床试验、药品上市注册及化学原料药申请，应按照国家药品监管部门公布的相关技术指导原则的有关要求开展研究，并按照现行版《M4：人用药物注册申请通用技术文档（CTD）》（以下简称CTD）格式编号及项目顺序整理并提交申报资料。不适用的项目可合理缺项，但应标明不适用并说明理由。

（二）申请人在完成临床试验提出药品上市注册申请时，应在CTD基础上提交电子临床试验数据库。数据库格式以及相关文件等具体要求见临床试验数据递交相关指导原则。

（三）国家药监局药审中心将根据药品审评工作需要，结合ICH技术指导原则修订情况，及时更新CTD文件并在中心网站发布。

（2020-06-30）

NMPA Issues the *Requirements for Registration Classification and Application Dossiers of Biological Products*

To support the implementation of the *Provisions for Drug Registration, NMPA has organized to formulate the Requirements for Registration Classification and Application Dossiers of Biological Products*, which has been issued on June 29, 2020. The requirements for registration classification of biological products shall take effect as from July 1, 2020. The requirements for application dossiers of biological products shall take effect as from October 1, 2020. Before September 30, 2020, the application dossiers can be submitted according to the former requirements.

(June 30, 2020)

国家药品监督管理局发布《生物制品注册分类及申报资料要求》

为配合《药品注册管理办法》实施，国家药品监督管理局组织制定了《生物制品注册分类及申报资料要求》，于2020年6月29日发布。生物制品注册分类，自2020年7月1日起实施。生物制品申报资料要求，自2020年10月1日起实施。在2020年9月30日前，可按原要求提交申报资料。（2020-06-30）

NMPA Issues the *Announcement on Upgrading Related Systems for Drug Registration*

To support the implementation of the newly revised Provisions for Drug Registration, NMPA is currently stepping up the upgrade of related systems for drug registration. On June 11, 2020, the related issues were announced as follows:

I. On June 24, 2020, the government website of NMPA has released a new version of drug registration application software for applicants.

II. From June 28 to June 30, in order to carry out the switching and joint testing of the new and old system, NMPA and Medical Products Administration of all provinces (autonomous regions and municipalities) shall suspend the use of existing systems related to drug registration, and the corresponding drug registration acceptance and certificate issuance & delivery services will also be suspended. For emergent circumstances during this period, please contact the relevant department of NMPA.

III. From July 1, 2020, NMPA will enable a new version of related system for drug registration. Drug registrants are advised to download the latest version of the application software, and submit registration application as required. (June 17, 2020)

国家药品监督管理局发布《关于药品注册相关系统升级改造的公告》

为保障新修订《药品注册管理办法》顺利实施，目前国家药监局正在抓紧对药品注册相关系统进行升级改造。2020年6月11日，国家药监局就相关事宜公告如下：

一、2020年6月24日，国家药监局政府网站将发布供申请人使用的新版药品注册申报软件。

二、6月28日至6月30日，为开展新旧系统切换及联调测试，国家药监局及各省（区、市）药监局将暂停使用现有药品注册相关系统，相应的药品注册受理和制证送达业务也将暂停。期间遇有紧急情况，请与国家药监局相关工作部门联系。

三、2020年7月1日起，国家药监局将启用新版药品注册相关系统，请药品注册申请人注意下载最新版申报软件，按要求提交注册申请。（2020-06-17）

NMPA Issues Announcement on Revising Package Insert of Sodium Thiosulfate Injection

To further protect drug safety for the people, on June 11, 2020, NMPA issued an Announcement with decisions made to revise the [adverse reactions], [precautions], etc. in the package insert of Sodium Thiosulfate Injection.

(June 11, 2020)

国家药品监督管理局发布关于修订硫代硫酸钠注射剂说明书的公告

为进一步保障公众用药安全，国家药品监督管理局于2020年6月11日发布公告，决定对硫代硫酸钠注射剂说明书【不良反应】、【注意事项】等项进行修订。（2020-06-11）

NMPA Issues Announcement on Revising Package Insert of Vitamin B2 Injection

To further protect drug safety for the people, on June 11, 2020, NMPA issued an Announcement with decisions made to revise the [adverse reactions], [contraindications], etc. in the package insert of Vitamin B2 Injection.

(June 11, 2020)

国家药品监督管理局发布关于修订维生素B2注射剂说明书的公告

为进一步保障公众用药安全，国家药品监督管理局于2020年6月11日发布公告，决定对维生素B2注射剂说明书【不良反应】、【禁忌】等项进行修订。（2020-06-11）

NMPA Issues Announcement on Revising Package Inserts of Chuanbei Pipa Preparations

In accordance with the results of ADR evaluation, to further protect drug safety for the people, NMPA issued an Announcement on June 9, 2020, with decisions made to uniformly revise the [adverse reactions], [contraindications] and [precautions] in the package inserts of Chuanbei Pipa Preparations (including syrups, ointments, granules, tablets and capsules).

(June 9, 2020)

国家药品监督管理局发布关于修订川贝枇杷制剂说明书的公告

根据药品不良反应评估结果，为进一步保障公众用药安全，国家药品监督管理局于2020年6月9日发布公告，决定对川贝枇杷制剂（包括糖浆剂、膏剂、颗粒剂、片剂、胶囊剂）说明书【不良反应】【禁忌】和【注意事项】项进行统一修订。（2020-06-09）

NMPA Issues Announcement on Revising Package Insert of Posterior Pituitary Injection

To further protect drug safety for the people, on June 9, 2020, NMPA issued an Announcement with decisions made to revise the [adverse reactions], [precautions], etc. in the package insert of Posterior Pituitary Injection.

(June 9, 2020)

国家药品监督管理局发布关于修订垂体后叶注射液说明书的公告

为进一步保障公众用药安全，国家药品监督管理局于2020年6月9日发布公告，决定对垂体后叶注射液说明书【不良反应】、【注意事项】等项进行修订。（2020-06-09）

NMPA Issues *Guidance for the Preservation of Essential Documents for Drug Clinical Trials*

To guide and regulate the preservation of essential documents for drug clinical trials, in accordance with the relevant regulations such as the *Drug Administration Law, the Vaccine Administration Law*, and the *Good Clinical Practice,* NMPA organized the formulation of the *Guidance for the Preservation of Essential Documents for Drug Clinical Trials*, which has been released on June 8, 2020 and shall come into effect as from July 1, 2020.

(June 8, 2020)

国家药品监督管理局发布《药物临床试验必备文件保存指导原则》

为指导和规范药物临床试验必备文件的保存，根据《药品管理法》《疫苗管理法》《药物临床试验质量管理规范》等相关法规要求，国家药品监督管理局组织制定了《药物临床试验必备文件保存指导原则》，于2020年6月8日发布，自2020年7月1日起施行。

（2020-06-08）

NMPA Revises Package Insert of Docusate Sodium and Dantron Capsules

To further protect drug safety for the people, on May 22, 2020, NMPA issued an Announcement with decisions made to revise the [adverse reactions], [precautions], etc. in the package insert of Docusate Sodium and Dantron Capsules.

(May 22, 2020)

国家药品监督管理局修订多库酯钠丹蒽醌胶囊说明书

为进一步保障公众用药安全，2020年5月22日，国家药品监督管理局发布公告，决定对多库酯钠丹蒽醌胶囊说明书【不良反应】【注意事项】等项进行修订。（2020-05-22）

NMPA Issues *Announcement on Performing Consistency Evaluation of the Quality and Efficacy of Generic Chemical Injections*

According to the *Opinions of the State Council on the Reform of the Review and Approval System for Drugs and Medical Devices* (State Council [2015] No.44), *Opinions of the State Council on Performing Consistency Evaluation of the Quality and Efficacy of Generic Drugs* (State Council General Office [2016] No.8), *Announcement on Matters Concerning the Consistency Evaluation of the Quality and Efficacy of Generic Drugs* ([2018] No.102) and other relevant regulations, in order to speed up consistency evaluation of generic drugs, NMPA released an Announcement on May 14, 2020, with decisions made to perform consistency evaluation of the quality and efficacy of generic chemical injections (hereinafter referred to as the consistency evaluation of injections), relevant issues are announced as follows:

1. For marketed generic chemical injections, all the varieties that have not been approved as per the principle of consistency with the quality and efficacy of brand-name drugs must be evaluated for consistency. MAHs shall select reference formulations in accordance with the *Catalogue for Reference Formulations of Generic Drugs* issued by NMPA, and apply for R&D of consistency evaluation.

2. While conducting the research on the consistency evaluation of injections, MAHs shall follow relevant technical guidances such as the *Technical Requirements for Consistency Evaluation of the Quality and Efficacy of Generic Chemical Injections*, and the *Technical Requirements for Consistency Evaluation of the Quality and Efficacy of Chemical Injections (Special Injections)*. While applying for consistency evaluation of injections, MAHs shall follow the *Requirements for Application Dossiers for Consistency Evaluation of the Quality and Efficacy of Generic Chemical Injections* to compile the application dossiers, which shall be submitted to the Center for Drug Evaluation, NMPA (hereinafter referred to as CDE) in the form of supplementary application.

3. CDE conducts technical reviews in accordance with relevant regulations and technical guidances, and initiates the testing and inspection based on the review need. CDE summarizes the review, testing and inspection and forms a comprehensive review opinion. If the comprehensive review is passed, CDE will issue an approval document for drug supplementary application.

4. Other relevant issues not covered in this Announcement shall be implemented in accordance with the relevant provisions of the *Announcement on Matters Concerning the Consistency Evaluation of the Quality and Efficacy of Generic Drugs* ([2017] No.100). This Announcement shall come into force as from the date of issuance. (May 14, 2020))

国家药品监督管理局发布《关于开展化学药品注射剂仿制药质量和疗效一致性评价工作的公告》

根据《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）、《关于仿制药质量和疗效一致性评价有关事项的公告》（2018年第102号）等有关规定，为加快推进仿制药一致性评价工作，国家药品监督管理局决定开展化学药品注射剂仿制药质量和疗效一致性评价工作（以下简称注射剂一致性评价），于2020年5月14日发布公告，将有关事项公告如下：

一、已上市的化学药品注射剂仿制药，未按照与原研药品质量和疗效一致原则审批的品种均需开展一致性评价。药品上市许可持有人应当依据国家药品监督管理局发布的《仿制药参比制剂目录》选择参比制剂，并开展一致性评价研发申报。

二、药品上市许可持有人应当按照《化学药品注射剂仿制药质量和疗效一致性评价技术要求》、《化学药品注射剂（特殊注射剂）仿制药质量和疗效一致性评价技术要求》等相关技术指导原则开展注射剂一致性评价研究；按照《化学药品注射剂仿制药质量和疗效一致性评价申报资料要求》撰写申报资料，并以药品补充申请的形式向国家药品监督管理局药品审评中心（以下简称药审中心）提出注射剂一致性评价申请。

三、药审中心依据相关法规及技术指导原则开展技术审评，基于审评需要发起检查检验。药审中心汇总审评、检查和检验情况并形成综合审评意见。综合审评通过的，药审中心核发药品补充申请批件。

四、本公告未涉及的其他有关事项参照《关于仿制药质量和疗效一致性评价工作有关事项的公告》（2017年第100号）相关规定执行。本公告自发布之日起实施。（2020-05-14）

Medical devices

NMPA Issues Three Guidances including the Guidance for Nomenclature for Generic Names of Medical Imaging Devices

To further standardize the generic names of medical devices and strengthen the whole life cycle management for them, NMPA has organized to formulate the *Guidance for Nomenclature for Generic Names of Medical Imaging Devices, Guidance for Nomenclature for Generic Names of Active Implanted Devices and Guidance for Nomenclature for Generic Names of Dental Instruments*, which are issued on June 22, 2020.

(June 30, 2020)

医疗器械

国家药品监督管理局发布医用成像器械通用名称命名指导原则等3项指导原则

为进一步规范医疗器械通用名称，加强医疗器械全生命周期管理，国家药品监督管理局组织制定了《医用成像器械通用名称命名指导原则》《有源植入器械通用名称命名指导原则》和《口腔科器械通用名称命名指导原则》，于2020年6月22日发布。

（2020-06-30）

NMPA Issues 5 Technical Review Guidances for the Registration of Tendon and Ligament Fixation Systems and Others

To strengthen the supervision and guidance over medical device registration, and further improve the quality of registration review, NMPA organized to formulate and released on June 5, 2020 the *Technical Review Guidance for the Registration of Tendon and Ligament Fixation Systems*, *Technical Review Guidance for the Registration of 3D Printed Acetabular Cups*, *Technical Review Guidance for the Registration of 3D Printed Artificial Vertebral Body*, *Technical Review Guidance for the Registration of Facial Implant Prostheses for Plastic Surgery*, and *Technical Review Guidance for the Registration of Total Knee Prosthesis Systems*.

(June 5, 2020)

国家药品监督管理局发布肌腱韧带固定系统等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，国家药品监督管理局组织制定了《肌腱韧带固定系统注册技术审查指导原则》《3D打印髋臼杯产品注册技术审查指导原则》《3D打印人工椎体注册技术审查指导原则》《整形用面部植入假体注册技术审查指导原则》《全膝关节假体系统产品注册技术审查指导原则》，于2020年6月5日发布。

（2020-06-05）

NMPA Issues *Guidance for On-Site Inspection of Independent Software Appended in Good Manufacturing Practice for Medical Devices*

To strengthen the supervision and inspection over medical device manufacturers' implementation of the *Good Manufacturing Practice for Medical Devices* and its appendix - independent software, and guide the regulatory authority to carry out on-site inspections and evaluation of inspection results, NMPA organized to formulate and released on June 4, 2020 the *Guidance for On-Site Inspection of Independent Software Appended in Good Manufacturing Practice for Medical Devices*.

(June 4, 2020)

国家药品监督管理局印发医疗器械生产质量管理规范独立软件现场检查指导原则

为加强医疗器械生产企业实施《医疗器械生产质量管理规范》及其附录独立软件的监督检查，指导监管部门开展现场检查和检查结果评估，国家药监局组织制定了《医疗器械生产质量管理规范独立软件现场检查指导原则》，于2020年6月4日发布。

（2020-06-04）

NMPA Issues *Guidelines for Evaluation of Changes in Raw Materials of Passive Medical Devices*

To strengthen the supervision and guidance over medical device registration and further improve the quality of registration review, NMPA organized to formulate and released on May 19, 2020 the *Guidelines for Evaluation of Changes in Raw Materials of Passive Medical Devices*.

(May 19, 2020)

国家药品监督管理局发布无源医疗器械产品原材料变化评价指南

为加强医疗器械产品注册工作的监督和指导，进一步提高注册审查质量，国家药品监督管理局组织制定了《无源医疗器械产品原材料变化评价指南》，于2020年5月19日发布。（2020-05-19）

NMPA Issues *Technical Review Guidance for the Registration of Dengue Virus Nucleic Acid Detection Reagents*

To strengthen the supervision and guidance over medical device registration and further improve the quality of registration review, NMPA organized to formulate and released on May 14, 2020 the *Technical Review Guidance for the Registration of Dengue Virus Nucleic Acid Detection Reagents*.

(May 14, 2020)

国家药品监督管理局发布登革病毒核酸检测试剂注册技术审查指导原则

为加强医疗器械产品注册工作的监督和指导，进一步提高注册审查质量，国家药品监督管理局组织制定了《登革病毒核酸检测试剂注册技术审查指导原则》，于2020年5月14日发布。（2020-05-14）

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。
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