NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Drugs

Meeting on drug, medical device, cosmetic regulation in China held during 4th CIIE

A meeting on the regulation of drugs, medical devices and cosmetics in China was held on Nov 6 in Shanghai during the fourth China International Import Expo (CIIE).

The meeting was hosted by the National Medical Products Administration (NMPA) and the China International Import Expo Bureau, and co-organized by the Shanghai Medical Products Administration, the China Chamber of Commerce for Import and Export of Medicines and Health Products, and the medical device committee of the CIIE Enterprise Alliance.

Xu Jinghe, deputy commissioner of the NMPA, and Ren Hongbin, vice-minister of commerce, attended and spoke at the meeting.

There were over 150 attendees, including delegates from the NMPA, the Ministry of Commerce, the National Healthcare Security Administration, provincial-level medical products administrations, and pharmaceutical, medical device and cosmetic enterprises from home and abroad, as well as media representatives.

Xu stressed that many enterprises in the highly globalized industries of drugs, medical devices and cosmetics have industrial chains and value chains all over the world. In the new era and new development stage, realizing high-quality development of drugs, medical devices and cosmetics will surely provide more opportunities for a large number of international enterprises to enter China's vast market.

Since its establishment, the NMPA has adhered to a people-centered development philosophy, upheld its mission of protecting and promoting public health, continued to deepen the reform of review and approval systems, comprehensively strengthened the full life cycle quality supervision of drugs, vigorously enhanced the construction of professional inspection teams and further promoted the modernization of drug regulatory systems and capabilities. Currently, various measures are underway to push forward reform in an orderly and effective manner, and significant results have been achieved.

He said that at present, drug regulators at all levels are earnestly implementing the *Implementing Opinions of the General Office of the State Council on Comprehensively Strengthening the Capacity Building of Drug Supervision*. In the future, the NMPA will continue to intensify its regulatory system and capacity building in such areas as fulfilling regulatory missions, improving legislation, promoting regulatory systems, innovating regulatory methods, strengthening professional team construction and enhancing international exchanges. Working together with related departments, the NMPA will make new and greater contributions to the building of a community with a shared future for mankind and to the protection and promotion of human health.

As one of the supporting activities of the fourth CIIE, the meeting expounded on China's policies on accelerating drug priority review and approval, self-inspection management requirements of medical device registration as well as cosmetics regulation. It briefed the progress in scientific and international drug regulation and negotiations on drug catalog access, enabling domestic and overseas enterprises to better understand China's market and regulatory orientations.

(November 09, 2021)

药品

中国药品医疗器械化妆品监管政策交流会在第四届进博会期间举办

11月6日上午，由国家药品监督管理局、中国国际进口博览局主办，上海市药品监督管理局、中国医药保健品进出口商会和中国国际进口博览会参展商联盟医疗器械专业委员会承办的中国药品医疗器械化妆品监管政策交流会于第四届中国国际进口博览会期间在沪举办。国家药品监督管理局副局长徐景和、商务部副部长任鸿斌出席会议并致辞。来自国家药监局、商务部、国家医保局、相关省市药监局，以及海内外药械妆企业、新闻媒体150余位代表参加了本次交流会。

徐景和指出，作为高度全球化的产业，许多药品、医疗器械和化妆品拥有遍布全球的产业链和价值链。新时代新阶段，实现药品、医疗器械和化妆品的高质量发展，必将为众多国际企业进入中国广阔的市场提供更多的机遇。

国家药监局组建以来，认真贯彻落实习近平总书记有关药品安全的要求，坚持以人民为中心的发展思想，坚守保护和促进公共健康的使命，持续深化审评审批制度改革，全面加强药品全生命周期质量监管，大力加强职业化专业化检查员队伍建设，不断推进药品监管体系和监管能力的现代化，各项改革举措正在有序有力推进，并已取得显著成效。

徐景和表示，当前，全系统正在认真贯彻落实《国务院办公厅关于全面加强药品监管能力建设的实施意见》。未来国家药监局将继续在践行监管使命、完善法律制度、健全监管体系、创新监管方式、提升队伍素质、强化国际交流等方面持续加强监管体系和监管能力建设，与有关部门共同努力，为推动构建人类命运共同体，保护和促进人类健康做出新的更大的贡献。

本次交流会是第四届进口博览会配套活动之一，会议解读了加速药品优先审评审批、医疗器械注册自检管理要求及化妆品监管相关政策，介绍了药品监管科学化与国际化进展、药品目录准入谈判工作等，帮助广大海内外企业进一步了解中国市场和监管导向，取得了良好效果。

(2021-11-09)

Published by
China Center for Food and Drug International Exchange

NMPA CDE Announcement on Issuing the *Technical Guidance for Clinical Trials of Drugs for the Treatment of Acute Non-Variceal Upper Gastrointestinal Bleeding*

In order to further standardize and guide the clinical trials of drugs for the treatment of acute non-variceal upper gastrointestinal bleeding and provide technical specifications that can be referred to, the Center for Drug Evaluation has organized to develop the *Technical Guidance for Clinical Trials of Drugs for the Treatment of Acute Non-Variceal Upper Gastrointestinal Bleeding* under the deployment of the National Medical Products Administration, which was issued and implemented on August 6, 2021 upon the review and approval of the NMPA. (August 06, 2021)

国家药监局药审中心关于发布《急性非静脉曲张性上消化道出血治疗药物临床试验技术指导原则》的通告

为进一步规范和指导急性非静脉曲张性上消化道出血治疗药物临床试验，提供可参考的技术规范，在国家药品监督管理局的部署下，药审中心组织制定了《急性非静脉曲张性上消化道出血治疗药物临床试验技术指导原则》，经国家药品监督管理局审查同意，于2021年8月6日发布并施行。 (2021-08-06)

NMPA CDE Announcement on Issuing the *Guidance for Immunogenicity Study of Generic Drugs of Low Molecular Weight Heparin (Interim)*

In order to standardize the research and development of low molecular weight heparin products and promote the study and evaluation of the chemical generic drugs for injection, the CDE has organized to develop the *Guidance for Immunogenicity Study of Generic Drugs of Low Molecular Weight Heparin (interim)* under the deployment of the NMPA, which was issued and implemented on August 6, 2021 upon the review and approval of the NMPA. (August 06, 2021)

国家药监局药审中心关于发布《低分子量肝素类仿制药免疫原性研究指导原则（试行）》的通告

为规范低分子量肝素类产品的研究和开发，促进化学仿制药品注射剂的研究和评价工作，在国家药品监督管理局的部署下，药审中心组织制定了《低分子量肝素类仿制药免疫原性研究指导原则（试行）》，经国家药品监督管理局审查同意，于2021年8月6日发布并施行。 (2021-08-06)

NMPA Announcement on Issuing the List of Medical and Pharmaceutical Journals Approved to Advertise Prescription Drugs

According to the *Advertisement Law of the People's Republic of China*, upon the consultation with the National Health Commission, the *Journal of Alzheimer's Disease and Related Diseases* is approved to be included in the list of medical and pharmaceutical journals approved to advertise prescription drugs.

(August 27, 2021)

国家药监局关于公布允许发布处方药广告的医学药学专业刊物名单的通告

根据《中华人民共和国广告法》规定，经商国家卫生健康委，同意将《阿尔茨海默病及相关病杂志》列入允许发布处方药广告的医学、药学专业刊物名单。

(2021-08-27)

List of Medical and Pharmaceutical Journals Approved to Advertise Prescription Drugs
允许发布处方药广告的医学、药学专业刊物名单

Serial No. 序号	Name of Journal 刊物中文名称	CN No. CN刊号	Place of Registration 登记地	Advertisement Business License No. 广告经营许可证号
1	Journal of Alzheimer's Disease and Related Disorders 阿尔茨海默病及相关病杂志	CN10-1536/R	Beijing 北京	JDGSGDZ No. 20180001 京东工商广登字 20180001号

NMPA CDE Announcement on Issuing the *Technical Guidance for Quality Control Study of Nano Drugs (interim), Technical Guidance for Non-Clinical Pharmacokinetic Study of Nano Drugs (interim), and Technical Guidance for Non-Clinical Safety Evaluation Study of Nano Drugs (interim)*

In order to standardize and guide the study and evaluation of nano drugs, under the deployment of the National Medical Products Administration, the Center for Drug Evaluation has organized to formulate the *Technical Guidance for Quality Control Study of Nano Drugs (interim), Technical Guidance for Non-Clinical Pharmacokinetic Study of Nano Drugs (interim),* and *Technical Guidance for Non-Clinical Safety Evaluation Study of Nano Drugs (interim)*, which were issued and implemented on August 27, 2021 upon review and approval by the National Medical Products Administration. (August 27, 2021)

国家药监局药审中心关于发布《纳米药物质量控制研究技术指导原则（试行）》《纳米药物非临床药代动力学研究技术指导原则（试行）》《纳米药物非临床安全性评价研究技术指导原则（试行）》的通告

为规范和指导纳米药物研究与评价，在国家药品监督管理局的部署下，药审中心组织制定了《纳米药物质量控制研究技术指导原则（试行）》《纳米药物非临床药代动力学研究技术指导原则（试行）》《纳米药物非临床安全性评价研究技术指导原则（试行）》，经国家药品监督管理局审查同意，于2021年8月27日发布并施行。（2021-08-27）

NMPA Announcement on Adding the Medication Information for Children to the Package Insert of Cisplatin injections and Other Varieties

In order to better meet the clinical medication needs of children, upon the study and demonstration, the package inserts of Cisplatin injections and other varieties may be added with the children users and dosage and usage for children according to the requirements. The relevant issues are hereby announced as follows:

I. The marketing authorization holders of relevant varieties may, based on the *Provisions for Drug Registration* and in accordance with corresponding revision suggestions, submit the supplementary application to the Center for Drug Evaluation of NMPA, revise the [Indications] and [Usage and Dosage] in the package insert, and simultaneously improve the safety information and other relevant contents in the package insert. If revision relates to the drug label, the latter shall be modified together.

II. After the approval of corresponding supplementary application is obtained, the marketing authorization holders of relevant varieties shall collect and report the ADR information in time, and conduct risk control and pharmacovigilance for pediatric medication.

(September 29, 2021)

国家药品监督管理局关于顺铂注射剂等品种说明书增加儿童用药信息的公告

为更好满足儿童临床用药需求，经研究论证，顺铂注射剂等药品的说明书可以按要求增加儿童使用人群及用法用量。现将有关事项公告如下：

一、相关品种的上市许可持有人可依据《药品注册管理办法》等有关规定，按照相应修订建议，向国家药监局药品审评中心提出补充申请，修订说明书【适应症】和【用法用量】项有关内容，并同时完善说明书安全性信息等相关内容。修订内容涉及药品标签的，应当一并进行修订。

二、相应补充申请批准后，相关品种的上市许可持有人应及时收集并报告不良反应信息，做好儿童用药的风险控制及药物警戒工作。（2021-09-29）

NPMA Announcement on Implementing the Application with Electronic Common Technical Documents

In order to implement the *Opinions on Deepening the Reform of Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices* issued by General Office of the Central Committee of the CPC and the General Office of State Council, and *Implementing Opinions of the General Office of the State Council on Comprehensively Strengthening the Capacity Building of Drug Supervision*, realize the electronic submission of drug registration application and improve the "Internet + Drug Regulation" application service level, the National Medical Products Administration comprehensively carried out and promoted the application with electronic common technical document (eCTD). The relevant issues related to eCTD application

国家药监局关于实施药品电子通用技术文档申报的公告

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）和《国务院办公厅关于全面加强药品监管能力建设的实施意见》（国办发〔2021〕16号）文件精神，实现药品注册申请的电子申报，提升“互联网+药品监管”应用服务水平，国家药品监督管理局全面开展和推进了药品

are hereby announced as follows:

I. Implementation date and scope

As of December 29, 2021, the marketing authorization of chemicals with Registration Categories 1 and 5.1, therapeutic biological products with Registration Category 1 and preventive biological products with Registration Category 1 may be applied according to eCTD.

II.Format of eCTD application dossiers and implementation requirements

Applicants should prepare and submit the eCTD application dossiers on CD-ROM as required by the eCTD technical documents (Attachments 1-4), and submit the paper dossiers within 5 working days upon the acceptance of the eCTD registration application dossiers. If an applicant fails to submit the paper dossiers within the specified time, the drug registration process will be terminated. At the same time, the applicant should make commitment that the electronic dossiers submitted is completely consistent with the paper dossiers. The applicant should bear the responsibilities for any problem arising from the inconsistency.

III. Other matters and requirements

In order to ensure a steady promotion of the eCTD and minimize its impact on the application, applicants can still choose the existing registration method for the above registration applications.

For registrations application with eCTD submission, there is no need for applicants to submit the CD-ROM of the application dossiers for verification and inspection and the CD-ROM of clinical trial database separately.

The relevant technical guidance may be accessed on the website of the Center for Drug Evaluation of NMPA. The Center for Drug Evaluation of NMPA shall be responsible for relevant technical guidance during the implementation of this Announcement.

(Attachment: omitted)

(September 30, 2021)

电子通用技术文档（eCTD）申报相关工作。现将实施eCTD申报有关事项公告如下：

一、 实施时间和实施范围

自2021年12月29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类的上市许可申请，可按照eCTD进行申报。

二、 eCTD申报资料格式和实施要求

申请人应按照eCTD技术文件（附件1—4）要求准备和提交eCTD申报资料光盘，并在eCTD注册申请新报资料受理后5个工作日内，提交纸质资料。申请人如未按照规定时间提交纸质资料，按终止药品注册程序处理。同时，申请人应承诺所提交的电子资料与纸质资料内容完全一致，如因资料一致性产生的任何问题由申请人自行承担。

三、 其他事项和要求

为确保eCTD稳步推进，减少对申报工作的影响，对于上述注册申请，申请人仍可选择现有注册方式进行注册申报。

采用eCTD申报的注册申请，申请人无需再单独提交核查检验用申报资料光盘和临床试验数据库光盘。

相关技术指导原则可在国家局药品监督管理局药品审评中心网站查询。国家药品监督管理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。

（附件：略）　　（2021-09-30）

NMPA Announcement on Revising the Package Insert of Antiviral Syrup, Capsules, Soft Capsules, Pills (Concentrated Pills), Dropping Pills, Tablets, Effervescent Tablets, Chewable Tablet, Oral Liquid, And Granules

In accordance with the results of adverse drug reaction assessment, to further guarantee the safety of people in the use of drug, the NMPA decided to revise such items as [Adverse reactions], [Contraindications] and [Precautions] in the package inserts of antiviral syrup, capsules, soft capsules, pills (concentrated pills), dropping pills, tablets, effervescent tablets, chewable tablet, oral liquid, and granules. The relevant issues are hereby announced as follows:

I. The marketing authorization holders of the said products shall, in accordance with the *Provisions for Drug Registration* and the revision requirements for the package insert (see Attachments 1 and 2) of antiviral syrup, capsules, soft capsules, pills (concentrated pills), dropping pills, tablets, effervescent tablets, chewable tablet, oral liquid and granules (both prescription drugs and OTC), file a report as such before December 27, 2021 to provincial medical products regulatory authority.

Where the contents of revision involve the drug label, the label shall be revised along with all the others; the other contents of the label and package insert shall be consistent with those originally approved. For the drugs produced from the date of filing, the original package insert shall not be used

国家药监局关于修订抗病毒糖浆、胶囊、软胶囊、丸（浓缩丸）、滴丸、片、泡腾片、咀嚼片、口服液、颗粒药品说明书的公告

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决定对抗病毒糖浆、胶囊、软胶囊、丸（浓缩丸）、滴丸、片、泡腾片、咀嚼片、口服液、颗粒说明书【不良反应】、【禁忌】和【注意事项】项进行统一修订。现将有关事项公告如下：

一、上述药品的上市许可持有人均应依据《药品注册管理办法》等有关规定，按照抗病毒糖浆、胶囊、软胶囊、丸（浓缩丸）、滴丸、片、泡腾片、咀嚼片、口服液、颗粒的处方药、非处方药说明书修订要求（见附件1、2），于2021年12月27日前报省级药品监督管理部门备案。

修订内容涉及药品标签的，应当一并进

any more. All package inserts and labels of ex-factory drugs shall be changed within 9 months after the said revision had been filed by the marketing authorization holder of drug.

II. The marketing authorization holder of drug shall conduct in-depth research on the occurrence mechanism of new adverse reactions, take effective measures to publicize the training on drug use and safety issues, to guide the physician, pharmacist and patient to use the medicine rationally.

III. The clinicians and pharmacists shall carefully read the revised contents of said package inserts. Drug options should be based on comprehensive benefit / risk analysis as per the new revisions.

IV. The patients should carefully read the package inserts before medication, and strictly comply with the medication orders for prescription drugs.

V. Provincial medical products regulatory authorities shall urge the drug marketing authorization holders of the product within their respective jurisdiction to revise the package inserts and replacement of the labels and package inserts as required and impose severe punishment in accordance with the law for violations of laws and regulations.

It is hereby announced.

(Attachment: omitted) (October 12, 2021)

行修订，说明书及标签其他内容应当与原批准内容一致。自备案之日起生产的药品，不得继续使用原药品说明书。药品上市许可持有人应当在备案后9个月内对已出厂的药品说明书及标签予以更换。

二、药品上市许可持有人应当对新增不良反应发生机制开展深入研究，采取有效措施做好药品使用和安全性问题的宣传培训，指导医师、药师和患者合理用药。

三、临床医师、药师应当仔细阅读上述药品说明书的修订内容，在选择用药时，应当根据新修订说明书进行充分的获益/风险分析。

四、患者用药前应当仔细阅读药品说明书，使用处方药的，应严格遵医嘱用药。

五、省级药品监督管理部门应当及时督促行政区域内上述药品的药品上市许可持有人按要求做好相应说明书修订和标签、说明书更换工作，对违法违规行为依法严厉查处。

特此公告。

（附件：略） （2021-10-12）

NMPA CDE Announcement on Issuing the *Technical Guidance for Clinical Trials of Anti-HIV Infectious Drugs*

In order to guide and standardize the clinical trials of anti-HIV new drugs and promote the research and development of innovative drugs, the CDE has formulated the *Technical Guidance for Clinical Trials of Anti-HIV Infectious Drugs*, which was issued and implemented on October 12, 2021 upon the review and approval by the National Medical Products Administration.

(October 13, 2021)

国家药监局药审中心关于发布《抗HIV感染药物临床试验技术指导原则》的通告

为指导和规范抗HIV新药的临床试验，促进创新药物的研发，药审中心制定了《抗HIV感染药物临床试验技术指导原则》，经国家药品监督管理局审查同意，于2021年10月12日发布并施行。 （2021-10-13）

NMPA CDE Announcement on Issuing the *Guidance for the Preparation of Application Dossiers for TCM Theory of Compound Preparations of New Chinese Medicines (interim)* and the *Guidance for the Preparation of the Package Inserts of Compound Preparations of Chinese Medicines in Ancient Classic Prescriptions (interim)*

In order to speed up the construction of the evidence system for TCM registration evaluation combining TCM theory, experiences in human use and clinical trials, and standardize the preparation of application dossiers of TCM theory and the package inserts of compound preparations of Chinese medicines in ancient classic prescriptions, under the deployment of the National Medical Products Administration, the CDE has organized to formulate the *Guidance for the Preparation of Application Dossiers for TCM Theory of Compound Preparations of New Chinese Medicines (interim)* and the *Guidance for the Preparation of the Package Inserts of Compound Preparations of Chinese Medicines in Ancient Classic Prescriptions*

国家药监局药审中心关于发布《中药新药复方制剂中医药理论申报资料撰写指导原则（试行）》《古代经典名方中药复方制剂说明书撰写指导原则（试行）》的通告

为加快构建中医药理论、人用经验和临床试验相结合的中药注册审评证据体系，规范中医药理论申报资料和古代经典名方中药复方制剂说明书相关内容的撰写，在国家药品监督管理局的部署下，药审中心组织制定了《中药新药复方制剂中医药理论申报资料撰写指导原则（试行）》和《古代经典名方中药复方制剂说明书撰写指导原则（试

(interim), which has, per the requirements of the Notice of the NMPA Comprehensive Department on Issuing the *Release Procedures for Pharmaceutical Technical Guidance*, been issued and implemented on October 15, 2021 upon the review and approval by the National Medical Products Administration.

(October 15, 2021)

行）》。根据《国家药监局综合司关于印发药品技术指导原则发布程序的通知》（药监综药管〔2020〕9号）要求，经国家药品监督管理局审查同意，于2021年10月15日发布并施行。 （2021-10-15）

Medical Devices

NMPA Announcement on Issuing 2 Guidance including the Guidance for Nomenclature of the Generic Names of Neurosurgical and Cardiovascular Surgical Devices

To further standardize the generic names of medical devices and strengthen the whole life cycle management for them, the NMPA has organized to formulate the *Guidance for Nomenclature for Generic Names of Neurosurgical and Cardiovascular Surgical Devices*, and *Guidance for Nomenclature for Generic Names of Devices for Medical Diagnosis*, Examination and Monitoring, which were issued on August 25, 2021.

(August 25, 2021)

医疗器械

国家药监局关于发布神经和心血管手术器械通用名称命名指导原则等2项指导原则的通告

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《神经和心血管手术器械通用名称命名指导原则》《医用诊察和监护器械通用名称命名指导原则》，于2021年8月25日发布。 （2021-08-25）

NMPA Announcement on Issuing the *Guidance for Evaluation of the Safety and Efficacy of Medical Devices Using Nano Materials-Part 1: System Framework*

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration review, the NMPA has organized to formulate the *Guidance for Evaluation of the Safety and Efficacy of Medical Devices Using Nano Materials-Part 1: System Framework*, which was issued on August 26, 2021.

(August 26, 2021)

国家药监局关于发布应用纳米材料的医疗器械安全性和有效性评价指导原则第一部分：体系框架的通告

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《应用纳米材料的医疗器械安全性和有效性评价指导原则第一部分：体系框架》，于2021年8月26日发布。 （2021-08-26）

NMPA Announcement on Matters Concerning the Implementation of the *Provisions for Medical Device Registration and Filing and the Provisions for In-vitro Diagnostic Reagent Registration and Filing*

The Provisions for Medical Device Registration and Filing (SAMR Decree No.47) and the *Provisions for In-vitro Diagnostic Reagent Registration and Filing* (SAMR Decree No.48) (hereinafter collectively referred to as the *Provisions*) were issued and implemented as of October 1, 2021. In order to implement the *Provisions*, the relevant matters are hereby announced as follows:

I. Treatment to application projects already accepted for registration before implementation of the Provisions

For registration application projects already accepted before the implementation of the *Provisions* but with the approval decision not yet made, drug regulatory authority should continue the review and approval according to original provisions, and issue the registration certificate of medical devices for those met the marketing requirements. For registration renewal, the starting date of the validity period of registration certificate

国家药品监督管理局关于实施《医疗器械注册与备案管理办法》《体外诊断试剂注册与备案管理办法》有关事项的通告

《医疗器械注册与备案管理办法》（国家市场监督管理总局令第47号）和《体外诊断试剂注册与备案管理办法》（国家市场监督管理总局令第48号）（以下统称《办法》）已发布，自2021年10月1日起施行。为做好《办法》实施工作，现将有关事项通告如下：

一、关于《办法》实施前已受理注册申请项目的处理

《办法》实施前已受理但尚未作出审批决定的注册申请项目，药品监督管理部门按照原规定继续审评审批，符合上市条件的，发给医疗器械注册证。延续注册的注册证有效期起始日执行《办法》第八十四条规定。

should follow Article 84 of the *Provisions*.

II. Test report involved in supplementary materials

For registration application projects already accepted before the implementation of the *Provisions* but with the approval decision not yet made, if the supplementary materials involve test report, the registration applicant shall entrust a qualified medical device testing institution to issue supplementary test report; If the QMS verification of the registration applicant covers the test capacity, the supplementary self-test report can also be submitted in accordance with the *Provisions* and relevant requirements.

III. Review of the application projects already accepted for registration before implementation of the new mandatory standards

Unless otherwise specified in the standard documents issued and implemented by NMPA, a medical device with the application already accepted for registration before implementation of the new standards can be reviewed and approved according to original provisions where the mandatory standards cited in the product technical requirements have changed. As of the date of implementation of the new standards, enterprises shall fully implement the new standards and their products shall meet the requirements of the new standards.

IV. Biological test of medical devices

If the biological evaluation of a medical device involves biological test, the applicant should submit the biological test report as part of the study materials when applying for registration. For biological tests, medical device testing institutions qualified for biological test shall be entrusted to carry out such tests according to relevant standards. Biological test reports issued by foreign laboratories should be attached with the quality assurance documents demonstrating its compliance with GLP laboratory requirements.

V. Registration (filing) forms for imported medical devices and domestically manufactured medical devices

For imported medical devices, overseas registration applicants (filing applicants) shall apply for registration (handle the filing). For medical devices manufactured in China by overseas enterprises, domestic manufacturing enterprises shall apply for registration (handle the filing) as the registration applicants (filing applicants).

VI. Filing of Class I medical devices

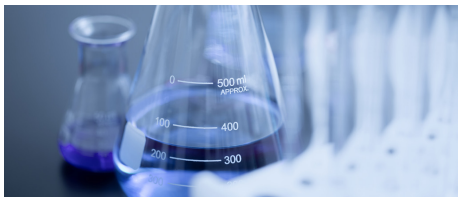
No clinical evaluation data shall be submitted for the filing of Class I medical devices.

VII. Documents related to medical device registration management

(I) After the implementation of the *Provisions*, the documents related to the medical device registration management listed in the attachment shall be abolished simultaneously.

(II) For items not covered in the *Provisions*, if there are explicit provisions in the medical device registration management documents previously issued by NMPA, such provisions shall still be implemented.

(September 29, 2021)



二、关于补正材料涉及的检验报告

《办法》实施前已受理但尚未作出审批决定的注册申请项目，如补正材料涉及检验报告，注册申请人应当委托具有资质的医疗器械检验机构出具补充检验报告；如注册申请人的体系核查涵盖了检验能力，也可以按照《办法》及相关要求提交补充自检报告。

三、关于新的强制性标准实施之日前受理注册申请项目的审查

对于申请注册的医疗器械，其产品技术要求中引用的强制性标准发生变化的，除国家药监局在发布实施标准文件中另有规定外，在新标准实施之日前受理注册的，可以按照原标准进行审评审批。自新标准实施之日起，企业应当全面实施新标准，产品应当符合新标准要求。

四、关于医疗器械生物学试验

医疗器械生物学评价中涉及生物学试验的，其生物学试验报告由申请人在申请注册时作为研究资料提交。开展生物学试验，应当委托具有生物学试验资质的医疗器械检验机构按照相关标准进行试验。国外实验室出具的生物学试验报告，应当附有国外实验室表明其符合GLP实验室要求的质量保证文件。

五、关于进口医疗器械和境内生产的医疗器械注册（备案）形式

进口医疗器械，应当由境外注册申请人（备案人）申请注册（办理备案）；境外企业在境内生产的医疗器械，应当由境内生产的企业作为注册申请人（备案人）申请注册（办理备案）。

六、关于第一类医疗器械备案

第一类医疗器械备案不需提交临床评价资料。

七、关于医疗器械注册管理相关文件

（一）《办法》实施后，附件中所列的医疗器械注册管理相关文件同时废止。

（二）《办法》中未涉及的事项，如国务院药品监督管理部门以前发布的医疗器械注册管理的文件中有明确规定的，仍执行原规定。

（2021-09-29）

NMPA Announcement on Issuing the *Provisions for Administration of Self-Test for Medical Device Registration*

In order to strengthen the management of medical device registration, standardize the self-test for registration carried out by registration applicants and ensure the orderly implementation of test for medical device registration, the NMPA organized to formulate the *Provisions for Self-Test for Medical Device Registration* according to the *Regulations for*

国家药监局关于发布《医疗器械注册自检管理规定》的公告

为加强医疗器械注册管理，规范注册申请人注册自检工作，确保医疗器械注册检验工作有序开展，根据《医疗器械监督管理

the Supervision and *Administration of Medical Devices* (State Council Decree No.739), *Provisions for Medical Device Registration and Filing* (SAMR Decree No.47) and *Provisions for In-vitro Diagnostic Reagent Registration and Filing* (SAMR Decree No.48). *The Provisions for Self-Test for Medical Device Registration* was issued and implemented on October 22, 2021. (October 22, 2021)

条例》（国务院令第739号）及《医疗器械注册与备案管理办法》（市场监管总局令第47号）、《体外诊断试剂注册与备案管理办法》（市场监管总局令第48号），国家药品监督管理局组织制定了《医疗器械注册自检管理规定》，于2021年10月22日发布并施行。

（2021-10-22）

Cosmetics

NMPA Announcement on Issuing the *Provisions for the Supervision and Administration of Children's Cosmetics*

In order to regulate the production and distribution activities of children's cosmetics, strengthen the supervision and administration of children's cosmetics and ensure the safety of children in the use of cosmetics, according to the *Regulations for the Supervision and Administration of Cosmetics* and other laws and regulations, the National Medical Products Administration has organized to formulate the *Provisions for the Supervision and Administration of Children's Cosmetics* (hereinafter referred to as the *Provisions*), which was issued on October 8. The issues related to the implementation of the *Provisions* are hereby announced as follows:

I. Except for the requirements for labels, other provisions on children's cosmetics shall come into force on January 1, 2022.

II. As of May 1, 2022, children's cosmetics under application for registration or filing must be labeled according to the *Provisions*; as for the children's cosmetics for which registration or filing application has been previously made and labelling and identification fails to comply with the *Provisions*, the cosmetics registrants and filing applicants must complete the update of product labels prior to May 1, 2023, so as to make them comply with the *Provisions*.

III. Provisions related to marks for children's cosmetics will be issued separately.

(October 08, 2021)

化妆品

国家药监局关于发布《儿童化妆品监督管理规定》的公告

为规范儿童化妆品生产经营活动，加强儿童化妆品监督管理，保障儿童使用化妆品安全，依据《化妆品监督管理条例》等法律法规，国家药监局组织制定了《儿童化妆品监督管理规定》（以下简称《规定》），于10月8日公布，并就《规定》实施有关事宜公告如下：

一、除标签的要求以外，其他关于儿童化妆品的规定自2022年1月1日起施行。

二、自2022年5月1日起，申请注册或者进行备案的儿童化妆品，必须按照《规定》进行标签标识；此前申请注册或者进行备案的儿童化妆品，未按照《规定》进行标签标识的，化妆品注册人、备案人应当在2023年5月1日前完成产品标签的更新，使其符合《规定》。

三、儿童化妆品标志另行公布。

（2021-10-08）

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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