2024 Volume 2

NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Headline

NMPA Announcement on the Matters Related to Optimizing the Application for Marketing and Registration of Drugs Manufactured Overseas and Marketed in China to be Transferred to Domestic Manufacturing (No. 49, 2024)

To further optimize the foreign investment environment, promote the high-quality development in the pharmaceutical industry, improve the drug accessibility, and meet our people's need, in accordance with the requirements of the Opinions on Further Optimizing the Foreign Investment Environment and Increasing the Efforts to Attract Foreign Investments (GF [2023] No. 11) issued by State Council, and the NMPA Announcement on Provisions for Post-approval Changes of Drugs (Interim) (No. 8, 2021), regarding the optimization of the application procedures for marketing and registration of drugs manufactured overseas and marketed in China to be transferred to domestic manufacturing, the relevant matters are hereby announced as follows:

I. For drugs manufactured overseas and marketed in China to be transferred to domestic manufacturing, domestic applicants shall submit the application according to the requirements and procedures for drug marketing registration application.

II. For drugs manufactured overseas and marketed in China to be transferred to domestic manufacturing, applicants can submit the original application dossiers of the overseas-manufactured drugs, along with the relevant research data on the transfer to domestic production, in order to support the drug marketing registration application. The specific requirements for the dossiers will be developed and issued by the Center for Drug Evaluation of NMPA.

III. The NMPA shall include the application for marketing and registration of originator chemical drugs and biological products to be transferred to domestic manufacturing in the scope of priority review and approval.

It is hereby announced.

National Medical Products Administration

April 19, 2024

(April 23, 2024)

头条

国家药监局关于优化已在境内上市的境外生产药品转移至境内生产的药品上市注册申请相关事项的公告（2024年第49号）

为进一步优化外商投资环境，促进医药行业高质量发展，提高药品可及性，满足人民群众的用药需求，根据国务院《关于进一步优化外商投资环境加大吸引外商投资力度的意见》（国发〔2023〕11号）、《国家药监局关于发布〈药品上市后变更管理办法（试行）〉的公告》（2021年 第8号）要求，优化已在境内上市的境外生产药品转移至境内生产的药品上市注册申请的申报程序。现将有关事项公告如下：

一、已在境内上市的境外生产药品转移至境内生产的，应当由境内申请人按照药品上市注册申请的要求和程序提出申请。

二、已在境内上市的境外生产药品转移至境内生产的,可提交境外生产药品的原注册申报资料，并提交转移至境内生产的相关研究资料，以支持其药品上市注册申请。具体申报资料要求由国家药监局药品审评中心另行制定发布。

三、对原研的化学药品和生物制品转移至境内生产的药品上市注册申请，国家药监局纳入优先审评审批适用范围。

特此公告。

国家药监局

2024年4月19日

(2024-04-23)

Drugs

NMPA Announcement on Issuing the Procedures for Assessment of Drug Control Institutions of Technetium-Labeled and Positron Radioactive Pharmaceuticals (No. 21 of 2024)

To implement the NMPA Opinions on Reform and Improvement of the Review and Approval Management System of Radioactive Pharmaceuticals, encourage drug control institutions with the ability and conditions to carry out the construction of technetium-labeled and positron radioactive pharmaceuticals testing capacity, and increase the number of qualified control institutions, the NMPA organized to formulate the Procedures for Assessment of

药品

国家药监局关于发布锝标记及正电子类放射性药品检验机构评定程序的公告（2024年第21号）

为落实《国家药监局关于改革完善放射性药品审评审批管理体系的意见》，鼓励有能力和条件的药品检验机构开展锝标记及正电子类放射性药品检验能力的建设，增加有资质的检

Published by
China Center for Food and Drug International Exchange

Drug Control Institutions of Technetium-Labeled and Positron Radioactive Pharmaceuticals, which are hereby issued and shall come into force as of the date of issuance. National Institutes for Food and Drug Control shall, as per its duties, guide the construction of relevant control institutions.

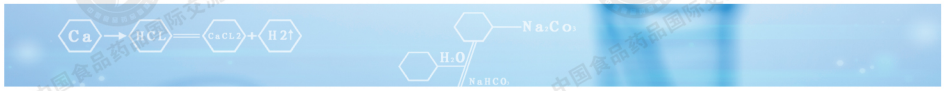
It is hereby announced.

Annex: Procedures for Assessment of Drug Control Institutions of Technetium-Labeled and Positron Radioactive Pharmaceuticals by NMPA

National Medical Products Administration

March 7, 2024

(March 14, 2024)



验机构，国家药监局组织制定了锝标记及正电子类放射性药品检验机构评定程序，现予发布，自发布之日起施行。中国食品药品检定研究院依职责做好相关检验机构建设的指导工作。

特此公告。

附件：国家药监局锝标记及正电子类放射性药品检验机构评定程序

国家药监局

2024年3月7日

(2024-03-14)

Tunlametinib Capsules approved with conditions for marketing by China NMPA

Recently, the Category 1 innovative drug Tunlametinib Capsules (Chinese trade name: 科露平) of Shanghai KeChow Pharmaceuticals Co. Ltd was approved with conditions for marketing by the National Medical Products Administration with priority review and approval, which is applicable to patients with advanced melanoma containing anti-PD-1/PD-L1 treatment failure of the NRAS mutation.

Tunlametinib is a selective mitogen-activated protein kinase 1 and 2 (MEK1/2) inhibitor that exerts antitumor effects by inhibiting MEK1/2 kinase activity. The marketing of this drug provides a new treatment option for patients with advanced melanoma containing anti-PD-1/PD-L1 treatment failure of the NRAS mutation.

(March 15, 2024)

国家药监局附条件批准妥拉美替尼胶囊上市

近日，国家药品监督管理局通过优先审评审批程序附条件批准上海科州药物研发有限公司申报的1类创新药妥拉美替尼胶囊（商品名：科露平）上市，适用含抗PD-1/PD-L1治疗失败的NRAS突变的晚期黑色素瘤患者。

妥拉美替尼是选择性丝裂原活化蛋白激酶激酶1和2（MEK1/2）抑制剂，通过抑制MEK1/2激酶的活性发挥抗肿瘤作用。该药品的上市为抗PD-1/PD-L1治疗失败的NRAS突变的晚期黑色素瘤患者提供了新的治疗选择。

(2024-03-15)

Innovative TCM Qinwei Granules Approved for Marketing by China NMPA

Recently, the Category 1.1 innovative traditional Chinese medicine (TCM) Qinwei Granules of Chengdu Huaxi Natural Medicine Co Ltd was approved for marketing by the National Medical Products Administration.

Randomized, double-blinded and placebo-controlled multicenter clinical trials had been conducted to evaluate the safety and efficacy of the medicine. The results showed that the group receiving the experimental medicine outperformed the placebo group in indicators including disappearance time and disappearance rate of joint pain.

This medication helps clear heat, remove dampness, dispel pathogenic wind, promote blood circulation, unblock meridians, and relieve pain. It is used for the treatment of acute gouty arthritis diagnosed as syndrome of wind and dampness transforming into heat with symptoms including joint pain, joint swelling, local joint fever and thirst. The marketing of this TCM provides another treatment option for patients with acute gouty arthritis.

(March 15, 2024)

国家药监局批准中药创新药秦威颗粒上市

近日，国家药品监督管理局批准了成都华西天然药物有限公司申报的中药1.1类创新药秦威颗粒上市。

该药品开展了随机、双盲、安慰剂平行对照的多中心临床试验。临床试验研究结果显示，关节疼痛消失时间、消失率等疗效指标，试验组优于安慰剂组。

该药品清热除湿祛风、活血通络止痛，用于急性痛风性关节炎风湿郁热证的治疗，症见关节疼痛、关节肿胀、关节局部发热、口渴喜饮等。该药品的上市为急性痛风性关节炎患者提供了又一种治疗选择。

(2024-03-15)

The 6th Asian Network Meeting was held

On April 24, the 6th Asian Network Meeting (ANM) was held in a combination of online and offline sessions. Heads of national medical products regulatory authorities of China, India, Indonesia, Japan, South Korea, Malaysia, the Philippines, Singapore, Thailand and Vietnam shared their latest regulatory status and engaged in the in-depth exchanges around topics such as innovative drug R&D in Asia from a regulatory perspective, digitization, and enhancing drug accessibility for patients. Huang Guo, Deputy Commissioner of the NMPA, attended the meeting by video and delivered a speech.

During the meeting, the representative from the Chinese side highlighted that in recent years, the National Medical Products Administration has actively promoted the reform of the drug review and approval system, strengthened the quality and safety supervision of the whole life cycle, and made every effort to promote the innovative and high-quality development within the pharmaceutical industry. It is hoped that through the exchanges, we can jointly promote the enhancement of drug regulatory capacity and standards in the Asian region.

(April 25, 2024)

第六届亚洲监管网络会议召开

4月24日，第六届亚洲监管网络会议（Asian Network Meeting）以线上线下相结合的方式召开。中国、印度、印度尼西亚、日本、韩国、马来西亚、菲律宾、新加坡、泰国和越南十个国家的药品监管机构负责人，分享了各自最新监管动态，围绕从监管角度看待亚洲创新药物研发、数字化和提升患者药物可及性等议题，开展深入交流。国家药监局党组成员、副局长黄果以视频形式出席会议并致辞。

中方在会上表示，近年来，中国国家药监局积极推动药品审评审批制度改革，强化全生命周期质量安全监管，全力推动医药产业创新发展、高质量发展。希望通过交流，共同促进亚洲地区药品监管能力和水平的提升。

（2024-04-25）

Iptacopan Hydrochloride Capsules Approved for Marketing by China NMPA

Recently, the Category I innovative drug Iptacopan Hydrochloride Capsules (trade name: FABHALTA) of Novartis Pharma Schweiz AG was approved for marketing by the National Medical Products Administration with priority review and approval, which is applicable for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH) who have not previously received complement inhibitor therapy.

Iptacopan hydrochloride binds to factor B (FB) in the complement bypass pathway, regulating C3 cleavage, downstream effector production, and amplification of the terminal pathway, controlling C3b-mediated extravascular hemolysis and terminal complement-mediated intravascular hemolysis. The marketing of this drug provides a new treatment for adult patients with paroxysmal nocturnal hemoglobinuria.

(April 30, 2024)

国家药监局批准盐酸伊普可泮胶囊上市

近日，国家药品监督管理局通过优先审评程序批准Novartis Pharma Schweiz AG申报的1类创新药盐酸伊普可泮胶囊（商品名：飞赫达）上市，适用于治疗既往未接受过补体抑制剂治疗的阵发性睡眠性血红蛋白尿症(PNH)成人患者。

盐酸伊普可泮与补体旁路途径中的 B 因子(FB)结合,调节 C3 的裂解、下游效应物的产生和末端途径的放大,控制 C3b 介导的血管外溶血和末端补体介导的血管内溶血。该品种上市为阵发性睡眠性血红蛋白尿症成人患者提供了新的治疗手段。

（2024-04-30）

Entinostat Tablets Approved for Marketing by China NMPA

Recently, the Category I innovative drug Entinostat Tablets (Chinese trade name: 景助达) of Taizhou EOC Pharma Co. Ltd was approved for marketing by the National Medical Products Administration. The drug is used in combination with an aromatase inhibitor for the treatment of patients with locally advanced or metastatic breast cancer who are hormone receptor (HR) positive and human epidermal growth factor receptor-2 (HER-2) negative after endocrine therapy.

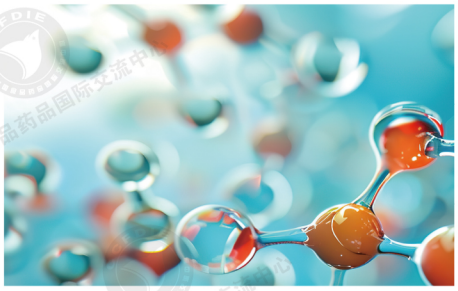
Entestat tablet is a histone deacetylase (HDAC) inhibitor, which can selectively inhibit class I and IV HDACs, inhibit cell proliferation, promote terminal differentiation and/or induce apoptosis, and exert antitumor effects. The

国家药监局批准恩替司他片上市

近日，国家药品监督管理局批准泰州亿腾景昂药业股份有限公司申报的1类创新药恩替司他片（商品名：景助达）上市。该药品联合芳香化酶抑制剂用于治疗激素受体（HR）阳性、人类表皮生长因子受体-2（HER-2）阴性，经内分泌治疗复发或进展的局部晚期或转移性乳腺癌患者。

marketing of this drug provides a new treatment option for patients with locally advanced or metastatic breast cancer who are hormone receptor (HR) positive and human epidermal growth factor receptor-2 (HER-2) negative.

(April 30, 2024)



恩替司他片是一种组蛋白去乙酰化酶（HDAC）抑制剂,可选择性抑制I类和IV类HDACs，抑制细胞增殖、促进终末分化和/或诱导凋亡，发挥抗肿瘤作用。该药品上市为激素受体（HR）阳性、人类表皮生长因子受体-2（HER-2）阴性的局部晚期或转移性乳腺癌患者提供了新的治疗选择。

（2024-04-30）

Medical device

CT Image-aided Detection Software for Intracranial Aneurysms Approved for Marketing

Recently, the innovative product CT Image-aided Detection Software for Intracranial Aneurysms of Hangzhou Deepwise was approved by China NMPA.

This product consists of software installation programs, including browser and server ends, used for displaying, processing, measuring, and analyzing CT angiography images of the head and neck arteries, and assisting in the detection of intracranial aneurysms of 3 mm and above.

This product adopts head and neck vessel centerline extraction and vessel segmentation technology, which greatly improves the sensitivity of intracranial aneurysm detection, and is of great significance in improving patients' quality of life and increasing their survival rate.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(March 1, 2024)

医疗器械

颅内动脉瘤CT造影图像辅助检测软件获批上市

近日，国家药品监督管理局批准了杭州深睿博联科技有限公司“颅内动脉瘤CT造影图像辅助检测软件”创新产品注册申请。

该产品由软件安装程序组成，包括浏览器端和服务器端，用于头颈动脉CT血管造影图像的显示、处理、测量和分析，对颅内3mm及以上动脉瘤进行辅助检测。

该产品采用头颈血管中心线提取和血管分割技术，大大提高了颅内动脉瘤检出的敏感性，对于改善患者生活质量、提高患者生存率具有重要意义。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

（2024-03-01）

Disposable Cardiac Pulsed Electric Field Ablation Catheter Approved for Marketing

Recently, the innovative product Disposable Cardiac Pulsed Electric Field Ablation Catheter of Hangzhou Deno Electrophysiology Medical Technology Inc. was approved by China NMPA.

The product consists of a catheter and connecting cables, and is used in conjunction with Cardiac Pulsed Electric Field Ablation System of the Company to treat atrial fibrillation by controlling and releasing pulsed electric field energy with appropriate intensity, which selectively produces irreversible electroporation damage only to cardiac myocytes at the site of the lesion to be treated. This product provides additional options for the treatment of drug-refractory, recurring, symptomatic, and paroxysmal atrial fibrillation.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(March 11, 2024)

一次性使用心脏脉冲电场消融导管获批上市

近日，国家药品监督管理局批准了杭州德诺电生理医疗科技有限公司“一次性使用心脏脉冲电场消融导管”创新产品注册申请。

该产品由导管和连接电缆组成，与该公司生产的心脏脉冲电场消融仪配合使用，通过控制、释放适当强度的脉冲电场能量，有选择性地仅对需要治疗病灶部位的心肌细胞产生不可逆的电穿孔损伤，从而达到治疗房颤的目的。该产品为药物难治性、复发性、症状性、阵发性房颤的治疗提供了更多选择。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

（2024-03-11）

Ion Endoluminal System and Other Products Approved for Marketing

Recently, four innovative products Ion Endoluminal System and Other 4 Products of Intuitive Surgical, Inc. were approved by China NMPA.

The Ion Endoluminal System, Fully Articulating Catheter, Visual Probe Catheter, Catheter Guide and supporting passive accessories produced by the company are used in conjunction with shape sensing fiber optic technology for bronchial navigation positioning.

Compared with similar products already on the market, this product has a smaller outer diameter for fiber optic positioning catheters, which can enter deeper lung airways. At the same time, the product technology is stable, accurate, and not easily disturbed, which can effectively reduce the incidence of complications such as pneumothorax and bleeding, and is of great significance for improving patient survival rates.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(March 21, 2024)

支气管导航操作控制系统等产品获批上市

近日，国家药品监督管理局批准了直观医疗公司Intuitive Surgical，Inc.“支气管导航操作控制系统”等4个创新产品注册申请。

该公司生产的支气管导航操作控制系统、支气管导航光纤定位导管、支气管导航可视化探头导管、支气管导航光纤定位导管导引器及配套无源附件配合使用，采用形状感知光纤技术进行支气管导航定位。

与已上市同类产品相比，该产品光纤定位导管外径更小，可进入到更深的肺部气道，同时产品技术稳定、精准，不易受到干扰，可有效降低气胸和出血的并发症率，对于提高患者生存率具有重要意义。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

（2024-03-21）

Combined Glucometer Approved for Marketing

Recently, the innovative product Combined Glucometer of Hangzhou Jingce Medical Technology Co., Ltd. was approved by China NMPA.

This product is composed of invasive blood glucose detection module, non-invasive blood glucose detection module, metabolic heat probe, environmental temperature and humidity monitoring module and display screen. As a supplement to existing fingertip blood glucose monitoring, it is suitable for daily self blood glucose monitoring of type 2 diabetes patients.

The product is the first of its kind in China to estimate blood glucose concentration through non-invasive detection of metabolic heat level. Diabetes patients can achieve the goal of blood glucose measurement by measuring the dynamic characteristics of oral deep body temperature, which helps to reduce the pain of patients and reduce the cost of measurement.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(April 11, 2024)

组合血糖仪获批上市

近日，国家药品监督管理局批准了江苏精策医疗科技有限公司“组合血糖仪”创新产品注册申请。

该产品由有创血糖检测模块、无创血糖检测模块、代谢热探头、环境温湿度监测模块和显示屏组成，作为现有指尖血糖监测的补充，适用于2型糖尿病患者日常自我血糖监测。

该产品通过无创检测代谢热水平估算血糖浓度，属国内首创。糖尿病患者可通过测量口腔深部体温动态特征达到血糖测量的目的，有助于减少患者痛苦、减轻测量成本。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

（2024-04-11）

Oligosaccharide Chain Detection Kit (Fluorophore-Assisted Carbohydrate Electrophoresis) Approved for Marketing

Recently, the innovative product Oligosaccharide Chain Detection Kit (Fluorophore-Assisted Carbohydrate Electrophoresis) of Jiangsu SysDiagno Biotech Co., Ltd. was approved by China NMPA.

This product is independently developed in China, and uses capillary electrophoresis to qualitatively detect 9 oligosaccharide chains in human serum samples, which is used for the auxiliary diagnosis of primary hepatocellular carcinoma in patients with cirrhosis of Hepatitis B in the clinic. This product assists in

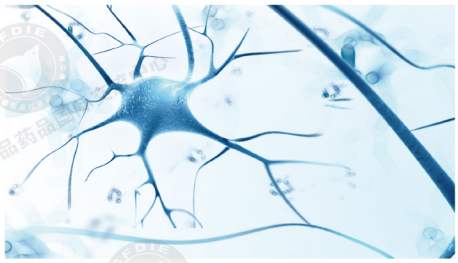
寡糖链检测试剂盒（荧光毛细管电泳法）获批上市

近日，国家药品监督管理局批准了江苏先思达生物科技有限公司“寡糖链检测试剂盒（荧光毛细管电泳法）”创新产品注册申请。

该产品系我国自主研发，采用毛细管电泳法对人体血清样本中的9个寡糖链进行定性检

diagnosis through non-invasive testing methods, which helps in the prevention and treatment of primary hepatocellular carcinoma. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(April 11, 2024)



测，用于临床上乙肝肝硬化患者原发性肝细胞癌的辅助诊断。该产品通过非侵入性检测方法辅助诊断，有助于原发性肝细胞癌防治。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

（2024-04-11）

Oligosaccharide Chain Detection Kit (Fluorophore-Assisted Carbohydrate Electrophoresis) Approved for Marketing

Recently, the innovative product Oligosaccharide Chain Detection Kit (Fluorophore-Assisted Carbohydrate Electrophoresis) of Jiangsu SysDiagno Biotech Co., Ltd. was approved by China NMPA.

This product is independently developed in China, and uses capillary electrophoresis to qualitatively detect 9 oligosaccharide chains in human serum samples, which is used for the auxiliary diagnosis of primary hepatocellular carcinoma in patients with cirrhosis of Hepatitis B in the clinic. This product assists in diagnosis through non-invasive testing methods, which helps in the prevention and treatment of primary hepatocellular carcinoma. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(April 11, 2024)

寡糖链检测试剂盒（荧光毛细管电泳法）获批上市

近日，国家药品监督管理局批准了江苏先思达生物科技有限公司“寡糖链检测试剂盒（荧光毛细管电泳法）”创新产品注册申请。

该产品系我国自主研发，采用毛细管电泳法对人体血清样本中的9个寡糖链进行定性检测，用于临床上乙肝肝硬化患者原发性肝细胞癌的辅助诊断。该产品通过非侵入性检测方法辅助诊断，有助于原发性肝细胞癌防治。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

（2024-04-11）

MoyoAssist® Extracorporeal Ventricular Assist Device and Extracorporeal Ventricular Assist Pump Head and Circuit Approved for Marketing

Recently, the innovative products MoyoAssist® Extracorporeal Ventricular Assist Device and Extracorporeal Ventricular Assist Pump Head and Circuit of magAssist Inc. (Suzhou) were approved for marketing.

The MoyoAssist® Extracorporeal Ventricular Assist Device consists of maglev motor, console and accessories. The Extracorporeal Ventricular Assist Pump Head and Circuit consists of centrifugal pump head, side-hole straight joint, luer taper, circuit clamp, and cable tie. The two products are used in combination, connected to blood vessels to form a bypass branch. The pump head blade is driven to rotate by console and maglev motor, to provide kinetic energy for the blood pressurization, used for cardiac postoperative patients temporary extracorporeal mechanical circulation assistance.

The product adopts full magnetic levitation blood pump technology with anti-vibration and anti-twisting properties as well as better blood flow field design, which can effectively reduce the average incidence of blood compatibility-related complications.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(April 28, 2024)

体外心室辅助设备和体外心室辅助泵头及管路获批上市

近日，国家药品监督管理局批准了心擎医疗（苏州）股份有限公司“体外心室辅助设备”和“体外心室辅助泵头及管路”创新产品注册申请。

体外心室辅助设备由磁悬浮马达、控制主机和配件组成，体外心室辅助泵头及管路由离心泵泵头、侧孔直通接头、鲁尔帽、管道夹和扎带组成。两产品联合使用，与血管相连形成旁回支路，通过控制主机和磁悬浮马达驱动泵头内叶轮悬浮转动，为血液增压提供动能，用于心脏术后患者临时体外机械循环辅助。

该产品采用全磁悬浮血泵技术，具有抗振动、抗扭摆性能以及较好的血液流场设计，可有效降低血液相容性相关并发症的平均发生率。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

（2024-04-28）

Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter and Symplicity G3™ Renal Denervation RF Generator Approved for Marketing

Recently, the innovative products Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter and Symplicity G3™ Renal Denervation RF Generator of Medtronic, Inc.

一次性使用多极肾动脉射频消融导管和肾动脉射频消融仪获批上市

近日，国家药品监督管理局批准了美敦力公司“一次性使用多极肾动脉射频消融导管”和

were approved by China NMPA.

The Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter consists of an electrode array, catheter, catheter handle, catheter connecting cable, and straightening tool, and the Symplicity G3™ Renal Denervation RF Generator consists of generator, remote control, power cord, and DVI-D cable. The above two products are used together, the RF Generator can transmit the radiofrequency energy through the catheter electrode to the renal artery vascular endothelium, use the current thermal effect to inactivate the sympathetic nerves around the renal artery vasculature, and block the sympathetic nerve's excitatory conduction, so as to achieve the purpose of reducing the patient's blood pressure.

This product reduces blood pressure through physically blocking sympathetic nerve excitatory conduction, which can effectively avoid the influence of patient compliance, drug half-life and other factors compared with traditional drug treatment, and provides a new adjunctive treatment for patients with refractory hypertension.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(April 30, 2024)

"肾动脉射频消融仪"创新产品注册申请。

一次性使用多极肾动脉射频消融导管由电极阵列、导管、导管手柄、导管连接电缆和矫直工具组成，肾动脉射频消融仪由发生器、遥控器、电源线和DVI-D电缆组成。上述两产品配套使用，射频消融仪可将射频能量经过导管电极传递至肾动脉血管内膜，利用电流热效应使肾动脉血管周围交感神经失活，阻断交感神经的兴奋传导，达到降低患者血压的目的。

该产品通过物理方式阻断交感神经兴奋传导来降低血压，与传统药物治疗方式相比，可有效避免患者依从性、药物半衰期等因素影响，为难治性高血压患者提供了新的辅助治疗方式。

药品监督管理部门将加强该产品上市后监管，保护患者用械安全。

（2024-04-30）

Cosmetics

Announcement on Issuing the Guideline for the Collection and Reporting of Adverse Reactions to Cosmetics by Cosmetic Registrant and Filing Entity (Interim)

To regulate and guide cosmetic registrants and filing entities to carry out the collection and reporting of adverse reactions to cosmetics, according to the Regulations on Supervision and Administration of Cosmetics, the Provisions for Supervision and Administration of Manufacturing and Marketing of Cosmetics, the Provisions for the Administration of Adverse Reaction Monitoring of Cosmetics and other relevant provisions, in accordance with the requirements of the National Medical Products Administration, the National Center for ADR Monitoring organized to formulate the Guideline for the Collection and Reporting of Adverse Reactions to Cosmetics by Cosmetic Registrant and Filing Entity (Interim), which is hereby issued.

Annex: Guidelines for the Collection and Reporting of Adverse Reactions to Cosmetics by Cosmetic Registrant and Filing Entity (Interim)

(April 19, 2024)

化妆品

关于发布《化妆品注册人、备案人收集和报告化妆品不良反应指南（试行）》的通知

为规范和指导化妆品注册人、备案人开展化妆品不良反应收集和报告相关工作，依据《化妆品监督管理条例》《化妆品生产经营监督管理办法》《化妆品不良反应监测管理办法》等有关规定，按照国家药品监督管理局要求，国家药品不良反应监测中心组织制定了《化妆品注册人、备案人收集和报告化妆品不良反应指南（试行）》，现予发布。

附件：《化妆品注册人、备案人收集和报告化妆品不良反应指南（试行）》

（2024-04-19）

NMPA Announcement on Several Measures to Optimize the Management of Cosmetic Safety Assessment (No. 50, 2024)

To further optimize the management of cosmetic safety assessment and orderly promote the implementation of the cosmetic safety assessment system, according to the Regulations on Supervision and Administration of Cosmetics, the Provisions for Registration and Notification of Cosmetics and the Technical Guidance for the Safety Evaluation of Cosmetics (2021 Edition) (hereinafter referred to as the Guidance) and other relevant regulatory requirements, the NMPA formulated Several Measures to Optimize the Management of Cosmetic Safety Assessment, which are hereby issued and will come into force from May 1, 2024.

The relevant issues are announced as follows:

国家药监局关于发布优化化妆品安全评估管理若干措施的公告（2024年第50号）

为进一步优化化妆品安全评估管理工作，有序推进化妆品安全评估制度实施，根据《化妆品监督管理条例》《化妆品注册备案管理办法》《化妆品安全评估技术导则（2021年版）》（以下简称《导则》）等相关法规要求，国家药监局制定了《优化化妆品安全评估管理若干措施》，现予以发布，自2024年5月1日起施行。有关事宜公告如下：

I. Classified management for cosmetic safety assessment data shall be implemented. Some qualified general cosmetics are allowed to submit the basic conclusions of the safety assessment, with the safety assessment report filed by the cosmetics enterprise for reference.

II. In view of the need for a certain period of cosmetic R&D, to avoid redundant investment of enterprise R&D resources, cosmetic registrants or filing entities can still submit a simplified version of the safety assessment report that meets the requirements of the Guidance when applying for registration or filing prior to May 1, 2025.

It is hereby announced.

Annex: Several Measures to Optimize the Management of Cosmetic Safety Assessment

National Medical Products Administration

April 22, 2024

(April 22, 2024)

一、对化妆品安全评估资料实施分类管理，允许部分符合条件的普通化妆品提交安全评估基本结论，安全评估报告由化妆品企业存档备查。

二、鉴于化妆品研发需要一定周期，为了避免企业研发资源重复投入，在2025年5月1日前，化妆品注册人、备案人申请注册或者进行备案时仍可以提交符合《导则》要求的简化版安全评估报告。

特此公告。

附件：优化化妆品安全评估管理若干措施

国家药监局

2024年4月22日

(2024-04-22)

NMPA Announcement on Provisions for Cosmetic Inspections (No. 52, 2024)

To strengthen the supervision and administration and regulate cosmetic inspections, according to the Regulations on Supervision and Administration of Cosmetics, the Provisions for Registration and Notification of Cosmetics and the Provisions for Supervision and Administration of Cosmetic Manufacturing and Distribution, the NMPA formulated the Provisions for Cosmetic Inspections, which is hereby issued and will come into force from November 1, 2024.

It is hereby announced.

Annex: Provisions for Cosmetic Inspections

National Medical Products Administration

April 26, 2024

(April 29, 2024)

国家药监局关于发布《化妆品检查管理办法》的公告（2024年第52号）

为加强化妆品监督管理，规范化妆品检查工作，根据《化妆品监督管理条例》《化妆品注册备案管理办法》《化妆品生产经营监督管理办法》等法规、规章，国家药监局组织制定了《化妆品检查管理办法》，现予公布，自2024年11月1日起施行。

特此公告。

附件：化妆品检查管理办法

国家药监局

2024年4月26日

(2024-04-29)

Notes:
- All the Chinese information in the Newsletter is from newspapers and the Internet. All English articles are translated from the Chinese version. In case of any discrepancy, the Chinese version shall prevail.
- For e-copy of the Newsletter, please visit http://www.ccfdie.org

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