NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Headline

Special Provisions for TCM Registration Released

On Feb 10, the Special Provisions for Traditional Chinese Medicines Registration (hereinafter referred to as the Special Provisions) is issued by China NMPA and will take effect on July 1, 2023.

The Special Provisions consists of 11 chapters and 82 articles, including general provisions, registration classification and marketing approval of TCMs, rational application of empirical evidence for human use, innovative TCMs, modified new drugs of TCMs, compound preparations of TCMs originated from classic recipes, TCMs with identical name and identical recipes, post-marketing changes, registration standards, drug names and package inserts of TCMs, etc.

The Special Provisions is closely connected to the newly revised Drug Administration Law and Provisions for Drug Registration. Based on the general provisions for the regulation of drug registration, the relevant requirements for the R&D of TCMs are further refined, and the regulation of R&D and registration of innovative TCMs are strengthened.

The Special Provisions fully implements the guidelines of the CPC Central Committee and the State Council on promoting the preservation, innovation and development of TCMs, fully absorbs mature experience in the reform of the drug evaluation and approval system, combines with the practice and exploration of the transformation of TCM achievements in epidemic prevention and control, and learns from domestic and foreign scientific research in drug regulation, so as to establish a comprehensive regulatory system of TCM registration for vigorously promoting the development of drug regulation through a Chinese path to modernization.

(Feb 10, 2023)

头条

《中药注册管理专门规定》发布

2月10日，国家药监局发布《中药注册管理专门规定》（以下简称《专门规定》），自2023年7月1日起施行。

《专门规定》共11章82条，包括总则、中药注册分类与上市审批、人用经验证据的合理应用、中药创新药、中药改良型新药、古代经典名方中药复方制剂、同名同方药、上市后变更、中药注册标准、药品名称和说明书等内容。《专门规定》与新修订《药品管理法》《药品注册管理办法》有机衔接，在药品注册管理通用性规定的基础上，进一步对中药研制相关要求进行细化，加强了中药新药研制与注册管理。

《专门规定》全面落实《中共中央国务院关于促进中医药传承创新发展的意见》，充分吸纳药品审评审批制度改革成熟经验，并结合疫情防控中药成果转化实践探索，借鉴国内外药品监管科学研究成果，全方位、系统地构建了中药注册管理体系，全力推进中国式药品监管现代化建设。

(2023-02-10)

Drugs

2023 National Meeting on Drug Registration Regulation and Drug Post-Marketing Regulation was Successfully Held in Beijing

On February 1, the 2023 National Meeting on Drug Registration Regulation and Drug Post-marketing Regulation was successfully held in Beijing, summarizing the work completed in 2022 and the past five years, analyzing the current situation and tasks, and deploying the priorities in 2023. Huang Guo, Member of NMPA Leading Party Members' Group and NMPA Deputy Commissioner attended the meeting and gave a speech. Li Bo, Director for Drug Safety of NMPA, attended the meeting.

The meeting fully affirmed the achievements made in drug regulation in 2022 and the past five years. In 2022, in the face of complex situations as well as urgent and difficult tasks, the drug regulatory teams nationwide fully, accurately and comprehensively implemented the new development philosophy, made overall planning for the epidemic situation and regulation, ensured both development and safety, and continuously promoted various tasks of drug regulation with unremitting determination. The whole system accelerated the review and approval of COVID-19 vaccines and drugs, continuously completed the quality regulation, and spared no effort in serving the overall situation of epidemic prevention and control; improved the accelerated markrting and registr ation

药品

2023年全国药品注册管理和药品上市后监管工作会议在京召开

2月1日，2023年全国药品注册管理和药品上市后监管工作会议在京召开，总结2022年和过去五年的工作，分析当前形势任务，部署2023年重点工作。国家药监局党组成员、副局长黄果出席会议并讲话。药品安全总监李波出席会议。

会议充分肯定了2022年和过去五年药品监管工作成效。2022年，面对错综复杂形势和急难险重任务，全国药品监管队伍完整、准确、全面贯彻新发展理念，统筹疫情和监管，统筹发展和安全，坚持不懈、矢志不渝，持续推进药品监管各项工作。全系统加快推进新冠疫苗和药品审评审批，持续做好质

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channel mechanism for drugs, and deepened the reform on review and approval system; carried out special inspection and rectification, enhanced the drug quality and safety regulation; carried out the special rectification for drug safety in a deep-going way and established a mechanism of cracking down on violations and crimes threatening drugs in a centralized manner; developed a regulatory system for online drug sales and improved the drug regulatory institutions and systems; and promoted the modernization of regulatory capacity and successfully passed the WHO NRA assessment.

The past five years witnessed great development, great reform and great progress in drug regulation in China. The drug regulatory teams have made all-out efforts to serve the overall situation of epidemic prevention and control, effectively maintained the overall stability of drug safety, actively supported the high-quality development of the pharmaceutical industry, and achieved a series of breakthroughs and landmark achievements.

Huang Guo pointed out that drug regulation has embarked on a new journey, which requires a clear understanding of the new situation and the courage to face new challenges. We should earnestly implement the "four strictest" requirements, continuously safeguard the bottom line of drug safety, deepen the reform on drug review and approval system, and increase the efficiency in drug review and approval as well as regulation according to the working visions of "Stressing Political Awareness, Enhancing regulation, Ensuring Safety, Promoting Development and Improving People's Well-Being to effectively guarantee safe, effective and accessible medication for the public.

Huang Guo stressed that the drug registration management and drug post-marketing regulation in 2023 should seek progress in five aspects includng "COVID-19 Prevention and Control, Risk Resolution, Innovative Development, Capability Enhancement and Forming a Clean Government" while maintaining stability. We should provide R&D services, emergent review and approval and quality regulation for COVID-19 vaccines and drugs and serve the overall situation of epidemic prevention and control. We should strengthen the supervision over key varieties, links and fields, consolidate and improve the achievements of special rectification actions, and effectively prevent and resolve safety risks and latent dangers. We should continuously deepen the reform on review and approval system, improve the accelerated marketing of new drugs in urgent clinical need, orphan drugs and pediatric drugs, innovate the regulatory modes and methods and promote high-quality development of the industry, We should improve laws, regulations and systems, promote the digital acceptance, review and approval of drug registration, promote the standardized development of drug inspection system, and improve regulatory efficiency. We should strengthen the construction of the Party conduct and incorrupt government, enhance the mechanism for preventing corruption, and severely punish violations of law and discipline, so as to provide a strong guarantee for promoting the modernization of drug regulation with Chinese characteristics.

(Feb 1, 2023)

量监管，全力服务保障疫情防控工作大局；健全完善药物加快上市注册通道机制，深化审评审批制度改革；开展专项检查和整治，强化质量安全监管；深入开展药品安全专项整治，建立集中打击整治危害药品违法犯罪机制；构建药品网络销售监管法规体系，完善药品监管法规制度体系；推进监管能力现代化，顺利通过世界卫生组织NRA评估。

过去的五年，我国药品监管事业实现大发展、大变革、大进步。药品监管队伍全力服务保障疫情防控大局，有效维护药品安全形势总体稳定，积极服务支持医药产业高质量发展，取得了一系列突破性进展、标志性成果。

黄果指出，药品监管踏上新征程，需要清醒认识新形势，勇于直面新挑战。要认真落实"四个最严"要求，按照"讲政治、强监管、保安全、促发展、惠民生"工作思路，持续筑牢药品安全底线，深化药品审评审批制度改革，提升药品审评审批和监管效能，切实保障人民群众用药安全有效可及。

黄果强调，2023年药品注册管理和药品上市后监管要在"疫情防控、风险化解、创新发展、能力提升、廉政建设"五条主线上实现稳中求进：做好新冠病毒疫苗药物研发服务、应急审评审批、质量监管工作，服务保障疫情防控大局；加强重点品种、重点环节、重点领域监管，巩固拓展专项整治行动成果，有效防范化解安全风险隐患；持续深化审评审批制度改革，加快临床急需新药、罕见病用药、儿童用药等上市速度，创新监管方式和手段，推动产业高质量发展；完善法规制度体系，推进药品注册受理、审评和审批全程电子化，推动药品检查体系规范化发展，提升监管效能；加强党风廉政建设，夯实防腐败机制，严惩违法违纪行为，为扎实推进中国特色药品监管现代化提供坚强保障。

（2023-02-01）

Keverprazan Hydrochloride Tablets Approved for Marketing

Recently, the class 1 innovative drug Keverprazan Hydrochloride Tablets of Jiangsu Carephar Pharmaceutical Co., Ltd. is approved for marketing by China NMPA. This drug is indicated for treating duodenal ulcer and reflux esophagitis.

The Keverprazan Hydrochloride is a new potassium-competitive acid blocker, which inhibits gastric acid secretion by combining with the K+binding site on H+-K+-ATPase. The marketing of this drug provides a new treatment option available for patients with duodenal ulcer and reflux esophagitis.

(Feb 15,2023)

国家药监局批准盐酸凯普拉生片上市

近日，国家药品监督管理局批准江苏柯菲平医药股份有限公司申报的1类创新药盐酸凯普拉生片上市。该药品适用于十二指肠溃疡和反流性食管炎的治疗。

盐酸凯普拉生是一种新型钾离子竞争性酸阻滞剂，通过与H+-K+-ATP酶上的K+结合位点结合，抑制胃酸分泌。该药品的上市为十二指肠溃疡和反流性食管炎患者提供了新的治疗选择。

(2023-02-15)

Gumarontinib Tablets Approved with Conditions for Marketing

Recently, the Class I innovative product Gumarontinib tablets of Haihe Biopharma Co., Ltd. is approved with conditions by China NMPA. This drug is indicated for treating the locally advanced or metastatic non-small cell lung cancer (NSCLC) with METex14 skipping mutation.

Gumarontinib can selectively inhibit the activity of c-Met kinase, thereby inhibiting the proliferation, migration and invasion of tumor cells. The marketing of this drug provides a new treatment option available for patients with locally advanced or metastatic NSCLC with METex14 skipping mutation.

(Mar 8,2023)

国家药监局附条件批准谷美替尼片上市

近日，国家药品监督管理局附条件批准上海海和药物研究开发股份有限公司申报的1类创新药谷美替尼片上市。该药品适用于具有间质–上皮转化因子（MET）外显子14跳变的局部晚期或转移性非小细胞肺癌的治疗。

谷美替尼能够选择性抑制c–Met激酶活性，进而抑制肿瘤细胞的增殖、迁移和侵袭。该药品的上市为具有间质–上皮转化因子（MET）外显子14跳变的局部晚期或转移性非小细胞肺癌患者提供了新的治疗选择。

(2023-03-08)

Announcement of NMPA on the Adoption of ICH Guidelines Including S1B (R1): Testing for Carcinogenicity of Pharmaceuticals and E14/S7B Questions & Answers: Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential (NMPA Announcement No. 33 [2023])

To align the technical standards for drug registration with international standards, upon deliberation, the National Medical Products Administration decided to adopt the ICH guidelines including S1B (R1): Testing for Carcinogenicity of Pharmaceuticals and E14/S7B Questions & Answers: Clinical and Nonclinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential. Relevant issues are announced as follows:

I.Sponsors shall conduct the research with reference to ICH S1B (R1) based on the current ICH S1. ICH S1B (R1) is adoptable to any research started since March 22, 2023. At the same time, ICH S1A, S1B, and S1C (R2) are still adoptable. The starting time of a research should be determined according to the Good Laboratory Practice (GLP).

II. Since July 31, 2023, E14/S7B Questions & Answers shall be adopted for drug clinical studies initiated.

III. Relevant technical guidelines are available on the official website of the Center for Drug Evaluation of NMPA. The Center for Drug Evaluation of NMPA is responsible for relevant technical guidance in the implementation of the Announcement.

It is hereby announced.

National Medical Products Administration

March 20, 2023

(Mar 22, 2023)

国家药监局关于适用《S1B(R1)：药物致癌性试验》和《E14–S7B问答：致QT/QTc间期延长及潜在致心律失常作用的临床与非临床评价问答》国际人用药品注册技术协调会指导原则的公告（2023年第33号）

为推动药品注册技术标准与国际接轨，经研究，国家药品监督管理局决定适用《S1B（R1）：药物致癌性试验》《E14–S7B问答：致QT/QTc间期延长及潜在致心律失常作用的临床与非临床评价问答》国际人用药品注册技术协调会指导原则。现就有关事项公告如下：

一、申请人可在现行S1指导原则的基础上，参考S1B（R1）指导原则的建议开展研究，2023年3月22日起开始的相关研究，均适用S1B（R1）指导原则。同时，S1A、S1B、S1C（R2）指导原则仍然适用。研究起始时间的认定遵照《药物非临床研究质量管理规范》中相关规定执行。

二、自2023年7月31日起，启动的药物临床研究相关要求适用E14–S7B问答指导原则。

三、相关技术指导原则可在国家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负责做好本公告实施过程中的相关技术指导工作。

特此公告。

国家药监局

2023年3月20日

(2023-03-22)

Leritrelvir Tablets for Treating Covid-19 Infection Approved with Conditions for Marketing

Recently, the class 1 innovative drug Leritrelvir Tablets (Chinese trade name: 乐睿灵) of Guangdong Raynovent Biotech Co., Ltd is approved for marketing with conditions by China NMPA through emergency review and approval procedure in accordance with the relevant provisions of special review and approval prescribed in the Drug Administration Law.

The Leritrelvir Teblets are oral small molecular drugs for COVID-19 infection treatment, indicated for adult patients with mild to moderate SARS-CoV-2(COVID-19) infection. Patients should use drugs strictly according to the instructions under the guidance of doctors.

The MAH is asked by NMPA to complete relevant research works of the conditional requirements within a time limit, and submits the follow-up research results as soon as possible..

(Mar 23,2023)

国家药监局附条件批准新冠病毒感染治疗药物来瑞特韦片上市

近日，国家药监局根据《药品管理法》相关规定，按照药品特别审批程序，附条件批准广东众生睿创生物科技有限公司申报的1类创新药来瑞特韦片（商品名称：乐睿灵）上市。

来瑞特韦片为口服小分子新冠病毒感染治疗药物，用于治疗轻中度新型冠状病毒感染（COVID-19）的成年患者。患者应在医师指导下严格按说明书用药。

国家药监局要求上市许可持有人继续开展相关研究工作，限期完成附条件的要求，及时提交后续研究结果。

(2023-03-23)

2023 National Meeting on ADR Monitoring was Successfully Held in Beijing

On April 4, the 2023 National Meeting on ADR Monitoring was successfully held in Beijing, summarizing the monitoring and evaluation of drugs, medical devices and cosmetic completed nationwide in 2022 and the past five years, analyzing the current situation and tasks, and deploying the priorities in 2023. Zhao Junning, Member of NMPA Leading Party Members' Group and NMPA Deputy Commissioner attended the meeting and gave a speech.

Zhao Junning fully affirmed the ADR monitoring and evaluation nationwide in 2022. He pointed out that the national monitoring and evaluation system should continuously enhance the risk monitoring of the drugs and medical devices as well as COVID-19 vaccine for epidemic prevention and control and spare no effort in serving the overall situation of epidemic prevention and control; scientifically conduct the monitoring and evaluation of drugs, medical devices and cosmetics and safeguard the bottom line of drug safety; continuously consolidate the pattern of “One Body, Two Wings” and steadily promote the construction of monitoring and evaluation system; and effectively improve the monitoring and evaluation capacities through benchmarking the international vaccine vigilance capacity, improving the institutional systems, promoting scientific research and innovation, and promoting publicity and training.

It was stressed in the meeting that 2023 is a crucial year for the implementation of the 14th Five-Year Plan. We should earnestly implement the "four strictest" requirements, steadily promote the implementation of the pharmacovigilance system according to the working visions of “Stressing Political Awareness, Enhancing Supervision, Ensuring Safety, Promoting Development and Improving People's Well-Being, continuously safeguard the bottom line of drug safety, practicably ensure the safe and effective medication for the public, support the high-quality development of the pharmaceutical industry and strive to write a new chapter in the pharmacovigilance with Chinese characteristics.

In the meeting, 7 requirements have been put forward for the drug monitoring and evaluation in 2023: First, anchor the goals and stick to them. We should fully recognize the significance of pharmacovigilance and the urgency of establishing a pharmacovigilance system; Second, act prudently from beginning to end and make persistent efforts. We should try our best to serve the overall situation of epidemic

2023年全国药品不良反应监测评价工作会议在京召开

4月4日，2023年全国药品不良反应监测评价工作会议在京召开，总结2022年和过去五年全国药品、医疗器械、化妆品监测评价工作，分析当前形势任务，研究部署2023年重点工作。国家药品监督管理局党组成员、副局长赵军宁出席会议并讲话。

赵军宁充分肯定2022年全国药品不良反应监测评价工作。他指出，全国监测评价系统持续加强疫情防控用药用械和新冠病毒疫苗风险监测，全力服务疫情防控工作大局；科学开展药械妆监测评价，牢牢守住药品安全底线；不断巩固“一体两翼”格局，扎实推动监测评价体系建设；通过对标国际疫苗警戒能力、完善制度体系、推进科研创新、促进宣传培训，有效提升监测评价能力。

会议强调，2023年是实施“十四五”规划承上启下的关键之年，要认真落实“四个最严”要求，按照“讲政治、强监管、保安全、促发展、惠民生”工作思路，扎实推进药物警戒制度实施，持续筑牢药品安全底线，切实保障人民群众用药安全有效，支持医药产业高质量发展，奋力谱写中国式药物警戒工作新篇章。

会议对2023年药品监测评价工作提出七项要求：一是锚定目标、笃行不怠，充分认识药物警戒重大意义，充分认识建立药物警戒制度的迫切性；二是慎终如始、再接再厉，全力服务疫情防控工作大局，持续发挥监测评价对疫情治疗用药用械和新冠病毒疫苗安全保障作用；三是既谋当下、又计长远，推进药

prevention and control and continue to give play to the role of monitoring and evaluation in guaranteeing the safety of drugs, medical devices and COVID-19 vaccines for epidemic treatment; Third, give consideration to both the present and the long term. We should promote the capacity building of pharmacovigilance system and ensure the high level of safety in the use of drugs, medical devices and cosmetics by the public with efficient pharmacovigilance; Fourth, people with petty shrewdness attend to trivial matters while those with greater wisdom attend to governance of institutions. We should establish a sound legal system and comprehensively strengthen the construction of a monitoring and evaluation quality management system; Fifth, consolidate the bottom line and check erroneous ideas at the outset. We should effectively guard against drug safety risks and improve the risk assessment capacity and emergency response capacity for drugs, medical devices and cosmetics; Sixth, keep moving and focus on the priorities. We should comprehensively improve our technical support capacity and continuously improve the pharmacovigilance, regulatory scientific research and intelligent monitoring and evaluation of traditional Chinese medicines; Seventh, build consensus and make coordinated promotion. We shall work hard to ensure good exchanges, publicity and training, and stimulate the vitality of social governance through monitoring and evaluation.

(Apr 4, 2023)

物警戒体系能力建设，以高效能药物警戒保障公众用药用械用妆高水平安全；四是小智治事、大智治制，建立健全法规制度体系，全面加强监测评价质量管理体系建设；五是筑牢底线、防微杜渐，有效防范药品安全风险，提高药械妆风险研判和应急处置能力；六是驰而不息、把握关键，全面提升技术支撑能力，不断提升中药药物警戒、监管科学研究、智慧监测评价水平；七是凝聚共识、协同推进，努力办好交流宣传培训，激发监测评价社会共治活力。

(2023-04-04)

Medical Devices

Third China Domestic ECMO Products Approved for Marketing

On February 23, 2023, the Extracorporeal Membrane Oxygenation auxiliary device and centrifugal pump head of Jiangsu STMED technology Inc. is approved with conditions through emergency review by China NMPA. This product is the third domestic ECMO product granted approval.

During the registration and application process of this product for emergency use, the NMPA establishes an emergency review task force, in accordance with the principle of "unified command, early intervention, fast and efficient, and scientific review and approval", with specific person in charge, giving guidance during the whole process, to accelerate the marketing and application of this product.

At present, the overall performance of the three domestic ECMO products granted approval is on par with the international level of similar products. As the constant marketing of our domestic ECMO products, the accessibility of advanced life support equipment in China is increased, which ensures the effective supply of medical devices for treating severe cases of COVID-19 and lowers the medical expenses when further meeting the clinical needs.

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

(Feb 23, 2023)

医疗器械

第三款国产ECMO产品获批上市

2023年2月23日，国家药监局经审查，附条件应急批准了江苏赛腾医疗科技有限公司研发的体外心肺支持辅助设备和离心泵泵头注册上市。该产品是第三款获批的国产ECMO产品。

作为应急审批产品，注册申报过程中，国家药监局按照“统一指挥、早期介入、快速高效、科学审批”的原则，专人负责、全程指导，确保产品尽快上市，投入使用。

目前，已获批的三款国产ECMO产品总体性能和指标基本达到国际同类产品水平，国产产品的持续获批上市，提升了我国先进生命支持设备的可及性，确保了新冠疫情重症治疗设备有效供应保障，进一步满足救治需求的同时，也降低了医疗费用支出。

后续，药品监督管理部门将持续加强产品上市后监管，保证患者用械安全。

(2023-02-23)

Hybrid Closed Loop Insulin Delivery System Approved for Marketing

Recently, the innovative product Hybrid Closed Loop Insulin Delivery System (MiniMed 670G BLE) of Medtronic MiniMed is approved by China NMPA.

The MiniMed 670G BLE consists of insulin pump kit, transmitter kit and glucose sensor. It possesses two core technologies: one is the hybrid closed-loop algorithm used in auto mode; the other is the electrochemical impedance spectroscopy technology used to check the state of the sensor, which can ensure that the glucose sensor has sufficient accuracy. The product continuously monitors the trend of glucose concentration in subcutaneous interstitial fluid through the glucose sensor worn by the patients. According to the

混合闭环胰岛素输注系统获批上市

近日，国家药品监督管理局经审查，批准了Medtronic MiniMed生产的“混合闭环胰岛素输注系统”创新产品进口注册申请。

该产品由胰岛素泵套件、发送器套件和葡萄糖传感器组成，具有两项主要核心技术：一是自动模式使用的混合闭环算法；二是用于检查传感器状态的电化学阻抗谱技术，该技术可确保葡萄糖传感器有充分的准确度。

received dynamic glucose monitoring results, the hybrid closed loop insulin pump can continuously deliver basal insulin (rates selectable by user) and boluses (amounts selectable by user) for the management of type 1 diabetes mellitus in patients 14 years of age and older. Through the SmartGuard technology, the basal insulin delivery can be automatically adjusted according to the continuous glucose monitoring results, ensuring round-the-clock blood glucose control and facilitating the life of patients with diabetes.

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

(Feb 27, 2023)

该产品通过人体佩戴的葡萄糖传感器对皮下组织间液的葡萄糖浓度趋势持续监测，根据接收的动态葡萄糖监测水平，混合闭环胰岛素泵可持续向14岁及以上Ⅰ型糖尿病患者体内输注基础量胰岛素（用户可选速率）与胰岛素大剂量输注（用户可选剂量），通过安全防护技术，可根据持续葡萄糖监测情况自动调整基础率胰岛素的输注，确保全天候的血糖可控，便利糖尿病患者的生活。

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。 (2023-02-27)

Hemodialysis Urea Clearance Calculation Software Approved for Marketing

Recently, the innovative product Hemodialysis urea clearance calculation software of Beijing IfmSoft Co., Ltd is approved by China NMPA. This is a domestic innovative product with independent intellectual property right, of which the performance is on par with advanced international standards. It is intended for the calculation of urea clearance in adult patients with maintenance hemodialysis, but not for the calculation of residual renal function.

Urea clearance is an important index to measure the adequacy of hemodialysis. At present, the calculation usually adopts the invasive blood collection method. It has some defects such as cumbersome operation and inability to keep continuously calculation, which may lead to anemia in patients. Compared with the blood collection method, the product can calculate the urea clearance rate by combining the existing indexes and hemodialysis treatment parameters of patients, and calculate the simulated body fluid volume of patients according to the local urea dynamics model. It has advantages such as non-invasive, simple operation, continuous calculation, and can adjust the dialysis plan in time, and effectively improve the dialysis effect of patients.

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

(Feb 27,2023)

血液透析尿素清除率计算软件获批上市

近日，国家药品监督管理局经审查，批准了北京英福美信息科技股份有限公司生产的“血液透析尿素清除率计算软件”创新产品注册申请。

该产品是具有自主知识产权的国内首创产品，性能指标达到国际先进水平。临床用于维持性血液透析成年患者的血液透析尿素清除率计算，不适用于残肾功能计算。

尿素清除率是衡量血液透析充分性的重要指标。目前主要采用有创方式取血法进行计算，存在操作繁琐、无法连续计算等问题，可能导致患者出现贫血。与取血法相比，该产品可结合患者已有指标和血液透析治疗参数计算尿素清除率，依据局部尿素动力学模型计算患者模拟体液量，具有无创、操作简单、可连续计算等优势，能够及时调整透析方案，有效提高患者透析效果。

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。

(2023-02-27)

Collagen Scaffold for Cartilage Repair Approved for Marketing

Recently, the innovative product Collagen Scaffold for Cartilage Repair (COLTRIX CartiRegen) of Ubiosis Co., Ltd is approved by China NMPA.

This product innovatively adopts the process sterilization during collagen extraction in manufacturing, and removes the immunogenic terminal peptide structure, which enables steady batch production of collagen materials with a complete triple helix structure. This product is mainly composed of collagen, which serves as a biological scaffold to provide space for cell adhesion, proliferation, and migration of autologous bone marrow mesenchymal stem cells (BMSCs). After the implantation of collagen scaffold for cartilage repair, the chondrocytes could be differentiated from BMSCs and migrated and proliferated in surrounding healthy cartilage tissue. Chondrocytes continuously synthesize

胶原蛋白软骨修复支架获批上市

近日，国家药品监督管理局经审查，批准了韩国Ubiosis Co., Ltd（优拜奥斯）生产的创新产品“胶原蛋白软骨修复支架”进口注册申请。

该产品在生产中创新性地采用了胶原提取的过程除菌工艺，并去除了具有免疫原性的端肽结构，能够批量化、稳定地生产出具有完整三螺旋结构的胶原蛋白材料。

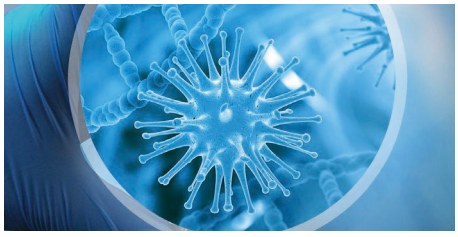
该产品以胶原蛋白为主要成分，将其作为生物支架为自体骨髓间充质干细胞（BMSCs）提供细胞粘附、增殖、迁移的空间。

and secrete type II collagen, forming new cartilage tissue and further repairing damaged cartilage. During this process, the collagen scaffold gradually degrades, and the degradation products can be absorbed by chondrocytes as nutrients or excreted from the body through metabolism.

The existing techniques for repairing cartilage injuries commonly include microfracture surgery, cartilage transplantation, chondrocyte transplantation, and joint replacement. The collagen scaffold for cartilage repair applied in conjunction with knee microfracture surgery is expected to benefit more patients as the marketing of this product.

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

(Apr 4, 2023)



胶原蛋白软骨修复支架植入后，其中的软骨细胞由BMSCs分化以及周围健康软骨组织中迁移并增殖。软骨细胞不断合成分泌II型胶原蛋白，形成新的软骨组织，进而修复缺损软骨。在此过程中，胶原蛋白支架逐步降解，降解产物可被软骨细胞作为营养物质吸收，也可经过代谢排出体外。

现有的软骨损伤修复技术常见包括微骨折术、软骨移植、软骨细胞移植以及关节置换等。胶原蛋白软骨修复支架配合膝关节微骨折术使用，产品的上市预期让更多的患者受益。

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。 (2023-04-04)

Coronary Artery CT Fractional Flow Reserve Calculation Software Approved for Marketing

Recently, the innovative product Coronary Artery CT Fractional Flow Reserve Calculation Software of Shanghai Pulse Medical Technology Co., Ltd. is approved by China NMPA.

This product calculates the CT fractional flow reserve score based on coronary CT angiography images, intended to assist in evaluating the functional myocardial ischemia status of stable coronary heart disease patients. It can help clinicians determine whether coronary artery stenosis causes myocardial ischemia and whether patients need further intervention and treatment. As a supplement to conventional imaging examinations, the marketing of corresponding software will further reduce the diagnostic time and expenditure burden on patients.

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

(Apr 4, 2023)

冠状动脉CT血流储备分数计算软件获批上市

近日，国家药品监督管理局批准了上海博动医疗科技有限公司生产的“冠状动脉CT血流储备分数计算软件”创新产品注册申请。

该产品基于冠脉CT血管造影图像计算获得CT血流储备分数，用于辅助评估稳定性冠心病患者的功能性心机缺血状态，可以帮助临床医生判断冠脉狭窄是否引起心肌缺血，确定患者是否需要进一步进行介入检查和治疗。作为传统影像学检查的补充，相应软件的上市，将有助于进一步减少患者诊断时间和支出负担。

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。 (2023-04-04)

Cosmetics

State Administration for Market Regulation Issued the Provisions for Toothpaste Regulation

Recently, the State Administration for Market Regulation issued the Provisions for Toothpaste Regulation (SAMR Decree No. 71), which shall take effect as of December 1, 2023.

Toothpaste is not only a product for daily use, but also a product closely related to people's health. It has been clearly specified in the Regulations on the Supervision and Administration of Cosmetics newly revised that: "Toothpaste shall be managed with reference to the provisions on common cosmetics". In order to implement the Regulations, standardize the production and distribution activities of toothpaste, strengthen the supervision and administration of toothpaste, ensure the quality and safety of toothpaste, safeguard the health of consumers and promote the healthy development of the toothpaste industry, the State Administration for Market Regulation and the National Medical Products Administration formulated the Provisions for Toothpaste Supervision (hereinafter referred to as the Provisions) with adherence to the principles of scientific legislation, democratic legislation and law-based legislation, and based on extensive solicitation of comments, in-depth research and full demonstration. The Provisions consist of 25 articles, mainly including the following contents:

The Provisions clearly define toothpaste as a paste product applied to the surface of human teeth by means of friction, with the main

化妆品

市场监管总局发布《牙膏监督管理办法》

近日，市场监管总局发布《牙膏监督管理办法》（国家市场监督管理总局令第71号），自2023年12月1日起实施。

牙膏既是日用消费品，更是与人民群众健康密切相关的产品。新修订的《化妆品监督管理条例》明确规定：“牙膏参照有关普通化妆品的规定进行管理”。为贯彻落实《条例》规定，规范牙膏生产经营活动，加强牙膏监督管理，保证牙膏质量安全，保障消费者健康，促进牙膏产业健康发展，市场监管总局、国家药监局坚持科学立法、民主立法、依法立法，在广泛听取意见、深入开展研究、充分论证的基础上，制定了《牙膏监督管理办法》（以下简称《办法》）。《办法》共25条，主要包括以下内容：

《办法》明确牙膏定义，将牙膏定义为以摩擦的方式，施用于人体牙齿表面，以清洁为

purpose of cleaning; standardize the efficacy management and labelling requirements for toothpaste, require that the efficacy claimed of toothpaste shall have full scientific evidence, specify the contents that shall and shall not be labelled and standardize the scope and expression of efficacy claimed; and clarify that the NMPA and the departments in charge of drug supervision and administration of the local people's governments at or above the county level shall be in charge of toothpaste supervision.

The Provisions stipulate that toothpaste is subject to filing administration, new toothpaste ingredients shall be registered or subject to filing administration according to the degree of risks, safety monitoring system shall be implemented, and new toothpaste ingredients with no safety problems upon the expiration of safety monitoring period shall be included in the catalogue of the cosmetic ingredients that have been in use formulated by the NMPA; The existing toothpaste production licensing system shall continue to be used and toothpaste production shall be issued with the Cosmetic Production License to minimize the impact on the industry while ensuring the toothpaste quality and safety.

The Provisions stipulate that toothpaste filing entities shall bear responsibility for the quality and safety as well as efficacy claimed of toothpaste; Toothpaste manufacturers and distributors shall engage in manufacturing and distribution activities in accordance with laws, regulations, mandatory national standards and technical specifications, strengthen management, be honest and self-discipline, and ensure the quality and safety of toothpaste products. In addition, in terms of legal liabilities, the Provisions also list the specific circumstances under which the Regulations on the Supervision and Administration of Cosmetics shall be followed and the Provisions for Cosmetic Registration and Filing and the provisions and the Provisions for the Regulation and Administration of Cosmetic Manufacturing and Distribution may be referenced, further clarifying the responsibilities of enterprises.

(Mar 22, 2023)

主要目的的膏状产品; 规范牙膏功效管理和标签要求，要求牙膏的功效宣称应当有充分的科学依据，明确牙膏应当标注和禁止标注的内容，规范功效宣称范围及用语。同时，明确国家药监局及县级以上地方人民政府负责药品监督管理的部门负责牙膏监管工作。

《办法》规定牙膏实行备案管理，牙膏新原料按照风险程度进行注册或者备案管理，并实行安全监测制度，安全监测期满未发生安全问题的牙膏新原料，纳入国家药监局制定的已使用的牙膏原料目录; 继续沿用现有牙膏生产许可制度，对牙膏生产颁发化妆品生产许可证，在保障产品质量安全的基础上，最大限度减少对行业的影响。

《办法》明确牙膏备案人对牙膏的质量安全和功效宣称负责; 牙膏生产经营者应当依照法律、法规、强制性国家标准、技术规范从事生产经营活动，加强管理，诚信自律，保证牙膏产品质量安全。此外，《办法》在法律责任部分还列举了依照《化妆品监督管理条例》规定和参照适用《化妆品注册备案管理办法》《化妆品生产经营监督管理办法》的具体情形，进一步明晰了企业主体责任。

(2023-03-23)

Announcement of NMPA on Issuing the Provisions for the Supervision and Administration of Online Cosmetic Distribution (NMPA Announcement No. 36 [2023])

In order to further strengthen the regulation on online cosmetic distribution, standardize online cosmetic distribution and ensure the quality and safety of cosmetics, the National Medical Products Administration has formulated the Provisions for the Supervision and Administration of Online Cosmetic Distribution in accordance with the Regulations on Supervision and Administration of Cosmetics and the Provisions for Supervision and Administration of Cosmetic Manufacturing and Distribution, which are hereby promulgated and should come into force as of September 1, 2023.

National Medical Products Administration

March 31, 2023

(Apr 4, 2023)

国家药监局关于发布《化妆品网络经营监督管理办法》的公告（2023年第36号）

为进一步强化化妆品网络经营监管工作，规范化妆品网络经营行为，保证化妆品质量安全，根据《化妆品监督管理条例》《化妆品生产经营监督管理办法》等，国家药监局组织制定了《化妆品网络经营监督管理办法》，现予公布，自2023年9月1日起施行。

国家药监局

2023年3月31日

（2023-04-04）

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.

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