NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心
SERVIER
施维雅(天津)制药有限公司

National Medical Products Administration issued the *Announcement on Issues Pertaining to the One-off Import of Reference Drugs for Biological Products in Clinical Trials*

On November 30, 2018, National Medical Products Administration (NMPA) issued the *Announcement on the One-off Import of Reference Drugs for Biological Products in Clinical Trials*, which reads as follows:

To implement the relevant policies set forth in the *Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Reform of the Review & Approval System to Encourage the Innovation of Drugs and Medical Devices* (General Office [2017] No. 42), support and encourage the development of biosimilar drugs, and better meet the needs of the public for drug use, it is hereby decided to grant the one-off import of biological products that meet the following criteria for use as reference drugs in clinical trials. The relevant issues are hereby announced as follows:

1. The range of biological products that can be applied for one-off import includes:

   (1) Brand-name biological products that have been approved for registration in China, but are not available in the domestic market to drug R&D institutions or manufacturers;

   (2) Brand-name biological products that have been marketed abroad, and approved for clinical trials but not yet approved for registration in China.

2. NMPA shall entrust the Center for Drug Evaluation to handle the acceptance, review and approval of the one-off import of reference drugs of biological products for clinical trials.

3. This Announcement shall enter into force as from the date of promulgation. Where the *Announcement on Issues Pertaining to the One-Off Import of Control Drugs for Purpose of R&D, or the Technical Guidelines for the R&D and Evaluation of Biosimilar Drugs (Interim)* contradicts with this Announcement, this announcement shall prevail.

(November 30, 2018)

国家药品监督管理局发布《关于临床试验用生物制品参照药品一次性进口有关事宜的公告》

2018年11月30日，国家药品监督管理局发布《关于临床试验用生物制品参照药品一次性进口有关事宜的公告》，内容如下：

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）的有关要求，支持和鼓励生物类似药的研发，更好地满足公众用药需求，现决定对符合以下条件、用于临床试验参照药的生物制品，可予以一次性进口。现将有关事项公告如下：

一、可以申请一次性进口的生物制品范围包括：

（一）国内已经批准注册，但药品研发机构或者生产企业无法及时从国内市场获得的原研生物制品；

（二）国外已上市、国内尚未批准注册但已获批开展临床试验的原研生物制品。

二、国家药品监督管理局委托药品审评中心负责办理临床试验用生物制品参照药品一次性进口的受理、审查及审批。

三、本公告自发布之日起实施。《关于研制过程中所需研究用对照药品一次性进口有关事宜的公告》、《生物类似药研发与评价技术指导原则（试行）》与本公告不一致的，以本公告为准。

(2018-11-30)

NMPA Issued the *Announcement on Cessation of Production, Sales and Use of Composite Terfenadine Tablets and Terfenadine, Ibuprofen and Pseudoephedrine Capsules*

On November 30, 2018, NMPA issued the *Announcement on Cessation of Production, Sales and Use of Composite Terfenadine Tablets and Terfenadine, Ibuprofen and Pseudoephedrine Capsules* as follows:

As per Article 42 of the Drug Administration Law of the People's Republic of China and Article 40 of the Regulations for Implementation of the Drug Administration Law of the People's Republic of China, NMPA has organized a re-evaluation which has identified in the Composite Terfenadine Tablets and Terfenadine, Ibuprofen and Pseudoephedrine Capsules the adverse reactions relative to cardiotoxicity, rendering the risk of use outfooting the

国家药品监督管理局发布《关于停止生产销售使用特酚伪麻片和特洛伪麻胶囊的公告》

2018年11月30日，国家药品监督管理局发布《关于停止生产销售使用特酚伪麻片和特洛伪麻胶囊的公告》，内容如下：

根据《中华人民共和国药品管理法》第四十二条和《中华人民共和国药品管理法实施条例》第四十条规定，经国家药品监督管理局组织再评价，认为特酚伪麻片和特洛伪麻胶囊存在心脏毒性不良反应，使用风险大于获益，决定自即日起停止特酚伪麻片和特洛伪麻胶囊

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

benefit. NMPA therefore decided the immediate cessation of production, sales and use of the two drugs in China, with their drug approval documents revoked forthright. The two drugs that have been on the market shall be recalled by the manufacturers in full before December 31, 2018. The recalled products shall be destroyed in situ under the supervision of the drug administration departments directly governing the manufacturers.

(November 30, 2018)

在我国的生产、销售和使用，撤销相关药品批准证明文件。已上市销售的特酚伪麻片和特洛伪麻胶囊由生产企业负责召回，召回工作应于2018年12月31日前完成，召回产品由企业所在地药品监督管理部门监督销毁。

(2018-11-30)

NMPA Issued the *Notice on the Issuance of the Regulations on the Administration of Export Sales Certificates for Drugs*

On November 13, 2018, NMPA issued the *Notice on the Issuance of the Regulations on the Administration of Export Sales Certificates for Drugs*, which reads as follows:

To further standardize the handling for the Drug Export Sales Certificate and provide facilitative services for China's drug exports, NMPA has formulated the *Regulations on the Administration of Export Sales Certificates for Drugs*, which is hereby released for strict implementation accordingly. The relevant matters are notified as follows:

1. Drug administration departments of all provinces (autonomous regions, municipalities) shall, according to the requirements of the *Notice of the General Office of the State Council on the Issuance of Implementation Program for Furtherance of the "Internet + Government Affairs Service" and the One Network, One Door, One Time (One Network Online Service, One Door Offline Service and One Time On-Site Service)* Reform (State Council General Office [2018] No. 45) and this Notice, optimize the internal application approval procedures, shorten the time limit for processing, and actively promote online acceptance and certification, to facilitate export enterprises. Where conditions are met, paper photocopy application can be replaced by electronic submission as appropriate.

2. NMPA shall establish a unified drug export sales certification information management system. Before the system is officially put into operation, the food and drug administration departments of all provinces (autonomous regions and municipalities) shall upload the certification data, including the original document (in pdf file format), via the drug production and supervision information direct reporting system. After the information management system is online, the certification data information shall be transmitted as per the system requirements.

3. NMPA shall offer the review opinions in relation to the relevant variety credentials provided by the international organizations with relevant agreements with China as stated in Article 4 of the Regulations. Food and drug administration departments of all provinces (autonomous regions and municipalities) can handle the matter according to the review opinions of NMPA.

4. All local departments should strengthen supervision over manufacturers of export pharmaceuticals, and strictly follow the inspection standards and scales in accordance with the Good Manufacturing Practice for Drugs, attaching importance to the implementation of supplier audits and data reliability requirements. While providing certification services to enterprises, all local departments shall urge enterprises to keep production in full compliance; if they fail to meet the requirements, timely measures shall be taken.

5. The Regulations shall be implemented as from the date of promulgation. The Notice of the former State Drug Administration on the Issuance of Administrative Measures for Issuing the Certificate of Sales of Pharmaceutical Products (SDA Department of Drug Supervision [2001] No. 225) shall be repealed simultaneously.

(November 13, 2018)

国家药品监督管理局发布《关于印发药品出口销售证明管理规定的通知》

2018年11月13日，国家药品监督管理局发布《关于印发药品出口销售证明管理规定的通知》，内容如下：

为进一步规范《药品出口销售证明》的办理，为我国药品出口提供便利和服务，国家药品监督管理局制定了《药品出口销售证明管理规定》，现予发布，请遵照执行。有关事项通知如下：

一、请各省（区、市）局按照《国务院办公厅关于印发进一步深化“互联网+政务服务”推进政务服务“一网、一门、一次”改革实施方案的通知》（国办发〔2018〕45号）和本通知要求，完善内部申请办事流程，压缩办理时限，积极推行网上受理和出证，为出口企业提供便利。信息化条件成熟的，可视情况逐步以电子提交代替纸质复印件申报。

二、国家局将建设统一的药品出口销售证明信息管理系统。在该系统正式上线运行前，各省（区、市）局通过药品生产和监管信息直报系统上传出证数据信息，包含证明文件原件（pdf文件格式）。信息管理系统上线后，按系统要求传送出证数据信息。

三、关于本规定第四条中“与我国有相关协议的国际组织提供的相关品种证明文件”，由国家局提出审核意见。各省（区、市）局可依据国家局审核意见予以办理。

四、请各地对出口药品生产企业加强监管，按照药品生产质量管理规范，严格把握检查标准和尺度，重点关注企业执行供应商审计和落实数据可靠性要求的情况。各地为企业提供出证服务的同时，督促企业持续合规生产；发现不符合要求的，及时采取措施。

五、本规定自发布之日起施行，原国家药品监督管理局《关于印发〈出具“药品销售证明书”若干管理规定〉的通知》（国药监安〔2001〕225号）同时废止。

(2018-11-13)

NMPA Issued the *Announcement on the Release of Technical Guidelines for Clinical Trials of Antipsychotics*

To guide and standardize the clinical trials of antipsychotic drugs, NMPA has organized the formulation of the Technical Guidelines for Clinical Trials of Antipsychotics, which has been released on November 8, 2018.

(November 8, 2018)

国家药品监督管理局发布关于《抗精神病药物的临床试验技术指导原则》的通告

为指导和规范抗精神病药物临床试验，国家药品监督管理局组织制定了《抗精神病药物的临床试验技术指导原则》，于2018年11月8日发布。 (2018-11-08)

NMPA Announcement on the Release of Technical Guidelines for Clinical Trials of Drugs for Bipolar Disorder

To guide and standardize the clinical trials of therapeutic drugs for bipolar disorder, NMPA has organized the formulation of the Technical Guidelines for Clinical Trials of Drugs for Bipolar Disorder, which has been released on November 8, 2018.

(November 8, 2018)

国家药品监督管理局发布关于《双相障碍治疗药物的临床试验技术指导原则》的通告

为指导和规范双相障碍治疗药物临床试验，国家药品监督管理局组织制定了《双相障碍治疗药物的临床试验技术指导原则》，于2018年11月8日发布。 (2018-11-08)

NMPA Issued the *Technical Guidelines for Clinical Research of New TCM Drugs for Symptom Complex*

To inherit and carry forward the characteristics and advantages of TCM diagnosis and treatment, improve the technical evaluation system that conforms to TCM characteristics, and implement the relevant *Provisions for Drug Registration* and the Supplementary Provisions for TCM Registration, NMPA has organized the formulation of the *Technical Guidelines for Clinical Research of New TCM Drugs for Symptom Complex*, which has been released on November 6, 2018.

(November 6, 2018)

国家药品监督管理局发布《证候类中药新药临床研究技术指导原则》

为继承和发扬中医药诊疗特色和优势，完善符合中药特点的技术评价体系，落实《药品注册管理办法》《中药注册管理补充规定》的相关规定，国家药品监督管理局组织制定了《证候类中药新药临床研究技术指导原则》，于2018年11月6日发布。

(2018-11-06)

General Administration of Customs and NMPA Issued the *Announcement on Implementing Network Verification of Seven Kinds of Regulatory Documents Including the Customs Clearance Form for Imported Drugs*

On November 1, 2018, the General Administration of Customs and NMPA jointly promulgated the *Announcement on Implementing Network Verification of Seven Kinds of Regulatory Documents Including the Customs Clearance Form for Imported Drugs*, which reads as follows:

To further optimize the business environment at the port and promote cross-border trade facilitation, the General Administration of Customs and NMPA decided to implement electronic data network verification on seven types of regulatory documents such as the Customs Clearance Form for Imported Drugs. The relevant issues are hereby announced as follows:

1. As from the date of promulgation of this Announcement, network verification shall be applied to electronic data for import and export permit of narcotic and psychotropic

海关总署 国家药品监督管理局发布《关于<进口药品通关单>等7种监管证件实施联网核查的公告》

2018年11月1日，海关总署 国家药品监督管理局发布《关于<进口药品通关单>等7种监管证件实施联网核查的公告》，内容如下：

为进一步优化口岸营商环境，促进跨境贸易便利化，海关总署、国家药品监督管理局决定对《进口药品通关单》等7种监管证件实施电子数据联网核查。现将有关事项公告如下：

一、自本公告发布之日起，在全国范围

drugs (incl. permits for import & export of narcotic drugs and psychotropic drugs), import medical device record filing/ registration certificate (incl. medical device registration certificate, Class-I medical device record-filing certificate), *Hygiene Permit for Importation of Special-Purpose Cosmetics, and Hygiene Permit for Importation of Non-special-purpose Cosmetics* as well as the electronic customs declaration form for imports and exports.

2. From the date of issuance of this Announcement, in Hangzhou and Qingdao Customs, the Pilot of online verification of electronic data of *Customs Clearance Form for Imported Drugs, the Drug Import Permit and Drug Export Permit* for anabolic steroid and peptide hormone preparations, as well as the electronic customs declaration form for imports and exports shall be conducted.

3. Drug administration department at all levels shall issue the above-mentioned documents as per the provisions of relevant laws and regulations, and transmit the electronic data of the documents to the customs, who shall conduct verification checks in customs clearance and handle the import and export procedures as required. Regarding the documents issued before the implementation of network verification, the holders of such paper documents can handle the import and export procedures at the customs within the validity period.

4. Customs declaration enterprises may declare to the customs in a paperless manner as per the provisions of the paperless reform of customs clearance operations. On account of the audit requirements of the customs and drug administration departments, or failures of computer management systems and network communications, etc., paperless declaration can be converted to paper declaration or supplemented with paper documents.

5. Enterprises can log in to China International Trade "Single Window" to check the electronic data transmission status of the documents.

6. The China E-port Information Data Center is the technical support department for network verification.

Contact China E-port Information Data Center: 010-95198. (November 1, 2018)

内实施麻精药品进出口准许证（包括麻醉药品进口准许、麻醉药品出口准许、精神药物进口准许、精神药物出口准许），进口医疗器械备案／注册证（包括医疗器械注册证、第一类医疗器械备案凭证），以及《进口特殊用途化妆品卫生许可批件》《进口非特殊用途化妆品卫生许可批件》电子数据与进出口货物报关单电子数据的联网核查。

二、自本公告发布之日起，在杭州、青岛海关开展《进口药品通关单》和蛋白同化制剂、肽类激素《药品进口准许证》《药品出口准许证》电子数据与进出口货物报关单电子数据的联网核查试点。

三、药品监督管理部门根据相关法律法规的规定签发上述证件，将证件电子数据传输至海关，海关在通关环节进行比对核查，并按规定办理进出口手续。联网核查实施前已签发的证件，企业可凭纸质证件在有效期内向海关办理进出口手续。

四、报关企业按照海关通关作业无纸化改革的规定，可采用无纸方式向海关申报。因海关和药品监督管理部门审核需要，或计算机管理系统、网络通信故障等原因，可以转为有纸报关作业或补充提交纸质证件。

五、企业可登陆中国国际贸易“单一窗口”查询证件电子数据传输状态。

六、中国电子口岸数据中心为联网核查的技术支持部门。

中国电子口岸数据中心联系方式：010-95198。 (2018-11-01)

NMPA Issued the *Guiding Opinions on the Construction of Drug Information Traceability System*

To implement the Opinions of the *General Office of the State Council on Accelerating the Construction of Traceability System for Important Products* (State Council General Office [2015] No. 95), and further improve the quality and safety guarantee level of pharmaceutical products, according to the CFDA *Opinions on Urging Food and Drug Manufacturers and Distributors to Improve the Traceability System* and the Ministry of Commerce and other departments' *Guiding Opinions on Promoting the Construction of Information Traceability System for Important Products*, and other relevant regulations, on November 2, 2018, NMPA issued the *Guiding Opinions on the Construction of Drug Information Traceability System*. (November 1, 2018)

国家药品监督管理局发布《关于药品信息化追溯体系建设的指导意见》

为贯彻落实《国务院办公厅关于加快推进重要产品追溯体系建设的意见》（国办发〔2015〕95号），进一步提高药品质量安全保障水平，根据《食品药品监管总局关于推动食品药品生产经营者完善追溯体系的意见》和商务部等部门《关于推进重要产品信息化追溯体系建设的指导意见》等有关规定，2018年11月2日，国家药品监督管理局发布《关于药品信息化追溯体系建设的指导意见》。 (2018-11-01)

Medical Devices

NMPA Issued the *Guidelines for Technical Review of the Registration of 3 Medical Devices Including Surgical Gauze Dressings*

To strengthen the supervision and guidance over the registration of medical device products and further improve the quality of registration examination, NMPA has organized the formulation of the *Guidelines for Technical Review of the Registration of Surgical Gauze Dressings (2018 Revised Edition), Guidelines for Technical Review of the Registration of Anastomats / Staplers* (2018 Revised Edition), and *Guidelines for Technical Review of the Registration of Single-use Suction Catheters*, which have been released on December 4, 2018.

(December 4, 2018)

医疗器械

国家药品监督管理局发布《外科纱布敷料等3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《外科纱布敷料注册技术审查指导原则（2018年修订）》《吻（缝）合器产品注册技术审查指导原则（2018年修订）》《一次性使用吸痰管注册技术审查指导原则》，于2018年12月4日发布。（2018-12-04）

NMPA Comprehensive Department Issued the *Check Points and Judging Principles for Clinical Trials of Medical Devices*

To strengthen the supervision and management of the clinical trial process of medical devices, and guide the corresponding supervisory departments to carry out supervision and inspection work for clinical trials of medical devices, as per the requirements of the *Provisions for Medical Device Registration and the Good Clinical Practice for Medical Devices*, NMPA organized the formulation of the *Check Points and Judging Principles for Clinical Trials of Medical Devices*, which has been released on November 28, 2018.

(November 28, 2018)

国家药品监督管理局综合司印发《医疗器械临床试验检查要点及判定原则》

为加强医疗器械临床试验过程的监督管理，指导监管部门开展医疗器械临床试验监督检查工作，根据《医疗器械注册管理办法》和《医疗器械临床试验质量管理规范》要求，国家药品监督管理局组织制定了《医疗器械临床试验检查要点及判定原则》，于2018年11月28日发布。（2018-11-28）

NMPA Revised and Released the *Special Examination Procedures for Innovative Medical Devices*

To implement the Regulations for the Supervision and Administration of Medical Devices and the National Innovation-Driven Development Strategy, and the policies set forth in the *Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Reform of Review & Approval System to Encourage Innovation in Drugs and Medical Devices* and the Opinions of the State Council on Reforming the Review & Approval System for Drugs and Medical Devices, NMPA actively implemented the special review and approval procedures for innovative medical devices to encourage the R&D of medical devices, and good results have been achieved.

On February 7, 2014, the former CFDA issued the *Special Procedures for Examination & Approval of Innovative Medical Devices (Interim)*, which took effect on March 1, 2014. To further promote the reform of the review and approval system, encourage medical device innovation, deepen the supply-side structural reform, and the reform of *Streamlining Administration, Delegating More Powers to Lower-level Governments and Society, Improving Regulation and Optimizing Services*, and stimulate the high-quality development of

国家药品监督管理局修订发布《创新医疗器械特别审查程序》

为贯彻实施《医疗器械监督管理条例》《国家创新驱动发展战略》，贯彻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》和国务院《关于改革药品医疗器械审评审批制度的意见》，国家药品监督管理局积极实施创新医疗器械特别审批程序，鼓励医疗器械研发创新，取得了良好成效。

2014年2月7日，原国家食品药品监督管理总局发布了《创新医疗器械特别审批程序（试行）》，自2014年3月1日起施行。为深入推进审评审批制度改革，鼓励医疗器械创新，深化供给侧结构性改革和“放管服”改革要求，激励产业创新高质量发展，国家药品监督管

industrial innovation, NMPA has conducted multiple researches, organized special studies, solicited opinions of all rank and file, researched and modified the Procedures. On November 5, 2018, the newly revised *Special Procedures for Examination & Approval of Innovative Medical Devices* was promulgated, and will take effect as from December 1, 2018.

(November 5, 2018)

理局多次开展调研，组织专题研究，多方征求意见，对程序进行研究修改，于2018年11月5日发布了新修订的《创新医疗器械特别审查程序》。特别审查程序自2018年12月1日起施行。 (2018-11-05)

General Information

CDE Released the List of the First Batch of Overseas New Drugs Urgently Needed in Clinical Settings

On November 1, 2018, the Center for Drug Evaluation (CDE) issued the *Notice on the Issuance of the List of the First Batch of Overseas New Drugs Urgently Needed in Clinical Settings*, which reads as follows:

To implement the policies set forth in the State Council executive meetings and speed up the entry of overseas new drugs urgently needed in clinical practice to China, NMPA and the National Health Commission have formulated the Work Procedures for Review and Approval of Overseas New Drugs Catering to Clinical Urgent Needs, and selected 48 of such drugs via expert consultation procedures, the list of which has been published on the website of CDE. Among them, 8 varieties have been approved for marketing in the near future, and the list of the other 40 varieties is hereby announced to the public in accordance with the procedures.

The application for marketing of varieties listed in the list of new overseas drugs urgently needed in clinical settings can be submitted directly in accordance with the *Work Procedures for Review and Approval of Overseas New Drugs Catering to Clinical Urgent Needs*. CDE has established a special channel to speed up the review. For not-yet-declared product, you can contact us at any time to submit an application for marketing ASAP.

综合信息

药品审评中心发布第一批临床急需境外新药名单

2018年11月1日，药品审评中心发布《关于发布第一批临床急需境外新药名单的通知》，内容如下：

为落实国务院常务会议有关会议精神，加快临床急需境外新药进入我国，国家药品监督管理局、国家卫生健康委员会制定了《临床急需境外新药审评审批工作程序》，并按程序组织专家遴选出48个临床急需境外新药，该名单前期已在我中心网站公示。其中，8个品种已在近期获批上市，现将其他40个品种名单按程序对外公布。

列入临床急需境外新药名单的品种，可按照《临床急需境外新药审评审批工作程序》提交相关资料，直接提出上市申请，我中心建立专门通道加快审评。尚未申报的品种，可随时提出与我中心进行沟通交流，尽快提出上市申请。

Annex附件：

List of urgently needed overseas new drugs in clinical practice (first batch)

临床急需境外新药名单（第一批）

序号 Serial number	药品名称（活性成分） Drug Name (active ingredient)	企业名称（持证商） Company Name (certificate holder)	首次批准地 Place of first approval	欧美日首次批准日期 First approved date in Europe, America and Japan	治疗领域 Therapeutic areas
1	Siltuximab	Janssen Biotech, Inc.	美国 United States	2014/4/23	免疫系统 Immune system
2	Elosulfase Alfa	Biomarin Pharmaceutical Inc.		2014/2/14	内分泌和代谢病 Endocrine and metabolic diseases
3	Selexipag	ActelionPharmaceuticalsLtd		2015/12/21	呼吸系统 Respiratory system
4	Brodalumab	Kyowa Hakko Kirin Co., Ltd.	日本 Japan	2016/7/4	皮肤疾病；免疫系统 Skin disease; immune system
5	Canakinumab	Novartis Pharmaceuticals Corporation	美国 United States	2009/6/17	免疫系统疾病 Immune system disease
6	Denosumab	Amgen Europe B.V.	欧盟 EU	2010/5/26	肿瘤 Tumor
7	Fingolimod Hcl Ora Lcapsules	Novartis Pharmaceuticals Corp	美国 United States	2010/9/21	免疫系统疾病 Immune system disease
8	Ponatinib	Ariad Pharmaceuticals Inc		2012/12/14	肿瘤 Tumor
9	Vedolizumab	Takeda Pharmaceuticals U.S.A., Inc.		2014/5/20	消化系统 Digestive system

10	Eliglustat	Genzyme Corp	美国 United States	2014/8/19	内分泌和代谢病 Endocrine and metabolic diseases
11	Secukinumab	Novartis Pharma K.K.	日本 Japan	2014/12/26	皮肤疾病；免疫系统 Skin disease; immune system
12	Ixekizumab	ELILILLYANDCOMPANY	美国 United States	2016/3/22	
13	Enasidenib mesylate	CELGENECORP		2017/8/1	肿瘤 Tumor
14	Icatibant	Shire Orphan Therapies GmbH	欧盟 EU	2008/7/11	心脑血管疾病 Cardiovascular and cerebrovascular disease
15	Dalfampridine	Acorda Therapeutics Inc	美国 United States	2010/1/22	免疫系统疾病 Immune system disease
16	Vismodegib	Genentech Inc		2012/1/30	肿瘤 Tumor
17	Apremilast	Celgene Corp		2014/3/21	免疫系统；皮肤病 Immune system; skin disease
18	Rilonacept	Regeneron		2008/2/27	免疫系统疾病 Immune system disease
19	Tetrabenazine	Prestwick		2008/8/15	精神障碍；神经系统疾病 Mental disorder; nervous system disease
20	Ecallantide	Dyax Corp.		2009/12/1	血液系统疾病 Blood system disease
21	Velaglucerase Alfa	Shire Human Genetic Therapies Inc		2010/2/26	内分泌和代谢疾病 Endocrine and metabolic diseases
22	Tafamidis	Pfizer Ltd	欧盟 EU	2011/11/16	神经系统 Nervous system
23	Taliglucerase Alfa	Pfizer Inc	美国 United States	2012/5/10	内分泌和代谢病 Endocrine and metabolic diseases
24	Lomitapide	Aegerion Pharmaceuticals Inc		2012/12/21	心脑血管疾病 Cardiovascular and cerebrovascular disease
25	Mipomersen Sodium	Genzyme Corp		2013/1/29	
26	Dinutuximab	United Therapeutics Corporation		2015/3/10	肿瘤 Tumor
27	Sonidegib	Novartis Pharmaceuticals Corp		2015/7/24	
28	Olaratumab	礼来 Eli Lilly		2016/10/19	
29	Nusinersen	BIOGENIDECINC		2016/12/23	肌肉骨骼系统 Musculoskeletal system
30	Deutetrabenazine	TEVABRANDEDPHARM		2017/4/3	
31	Dinutuximab Beta	EUSA Pharma (UK) Limited	欧盟 EU	2017/5/8	肿瘤 Tumor
32	Cenegermin (Recombinant Human Nerve Growth Factor)	Dompe farmaceutici s.p.a.		2017/7/6	眼部疾病 Eye disease
33	Guselkumab	JANSSENBIOTECH	美国 United States	2017/7/13	皮肤病；免疫系统 Skin disease; immune system
34	Vestronidase Alfa-Vjbk	ULTRAGENYXPHARMINC		2017/11/15	内分泌和代谢病 Endocrine and metabolic diseases
35	Shingrix Zoster Vaccine Recombinant, Adjuvanted	GlaxoSmithKline Biological products Rue de l"Institut 89, B1330 Rixensart, Belgium Lic # 1617		2017/10/20	感染性疾病 Infectious disease
36	Luxturna Voretigene Neparvovec	Spark Therapeutics, Inc. 3737 Market Street, Suite 1300, Philadelphia, PA, 19104 Lic# 2056		2017/12/19	眼部疾病 Eye disease
37	Vernakalant Hydrochloride	Cardiome UK Limited	欧盟EU	2010/9/1	心脑血管疾病 Cardiovascular and cerebrovascular disease
38	Vorapaxar	Merck Sharp And Dohme Corp	美国 United States	2014/5/8	
39	Ledipasvir And Sofosbuvir	Gilead Sciences Inc		2014/10/10	感染性疾病 Infectious disease
40	Sofosbuvir; Velpatasvir; Voxilaprevir	Gilead Sciences Inc		2017/7/18	

(Therapeutic targets, indications, and reasons for listed as clinical imperative: Omitted)

(November 1, 2018)

〔治疗靶点、适应症、列为临床急需原因略〕

〔2018-11-01〕

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。

• 电子版Newsletter阅览请登录网站http://www.ccfdie.org

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