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

Principal responsibilities of the departments and bureaus of National Medical Products Administration

(From the website of National Medical Products Administration)

Department of General Affairs, Planning and Finance

Responsibilities: 1.The daily operations of NMPA departments, undertaking the work related to information, security, confidentiality, public complaints and proposals, open government affairs, information technology, news publicity, etc. 2. Inspect, supervise and handle important government affairs. 3. Organize the implementation of emergency management and public opinion monitoring. 4. Mastermind, organize and implement development plans and special plans to drive the construction of administrative system and information system. 5. Undertake the budget and final accounts, finance, management of state-owned assets and internal audit for department organs and directly affiliated units. 6. Organize the drafting of documents of general affairs and important conference papers.

Department of Policies and Legal Affairs

Responsibilities: 1. Research of significant policies for supervision and administration of drugs, medical devices and cosmetics. 2. Organize the drafting of laws, regulations and departmental rules. 3. Legality review of normative documents. 4. Law enforcement supervision, administrative reconsideration, responding to administrative lawsuits, and legal audit of major cases. 5. Seamless integration of administrative law enforcement and criminal justice. 6. Work related to elevating legal literacy and legal publicity, and to the World Trade Organization. 7. Coordination of work relative to comprehensively deepening reforms. 8. Routine administration of the Vaccine QMS Office.

Department of Drug Registration (Department of TCMs and Ethno-Medicines Supervision)

Responsibilities: 1. Organize the formulation and supervise the implementation of drug standards and technical guidelines (such as Chinese Pharmacopoeia), formulate and implement drug registration management schemes. 2. Supervise the implementation of pharmaceutical non-clinical researches and Good Clinical Practice, the specifications for processing TCM slices; and implement the protection system for the categorization of TCM varieties. 3. Organize the implementation of the classified control system, inspect the R&D venues, and investigate and punish relevant illegal acts. 4. Participate in the development of the National Essential Drug List and cooperate in the implementation of the National Essential Drug System.

Department of Drug Supervision

Responsibilities: 1. Organize the formulation and supervise, as per its powers and duties, the implementation of drug GMPs; organize the formulation and guide the implementation of the Good Supply Practice and Good Use Practice. 2. Organize and guide the on-site inspections over production venues, investigate and punish serious illegal acts. 3. Organize random quality inspections and release Quality Announcements on a regular basis. 4. Organize the monitoring of adverse reactions and law-based intervention thereof. 5. The supervision and administration of radioactive, narcotic, toxic, psychotropic drugs and pharmaceutical precursor chemicals. 6. Guide and supervise

国家药品监督管理局机关各司局主要职责

（摘自国家药品监督管理局网站）

综合和规划财务司

负责机关日常运转，承担信息、安全、档案、保密、信访、政务公开、统计、信息化、新闻宣传等工作。对重要政务事项开展督查督办。组织开展应急管理和舆情监测工作。拟订并组织实施发展规划和专项建设规划，推动监督管理体系和信息化建设。承担机关和直属单位预决算、财务、国有资产管理及内部审计工作。组织起草综合性文稿和重要会议文件。

政策法规司

研究药品、医疗器械和化妆品监督管理重大政策。组织起草法律法规及部门规章草案。承担规范性文件的合法性审查工作。承担执法监督、行政复议、行政应诉、重大案件法制审核工作。承担行政执法与刑事司法衔接管理工作。承担普法宣传和涉及世界贸易组织的相关工作。承担全面深化改革的有关协调工作。承担疫苗质量管理体系QMS办公室日常工作。

药品注册管理司（中药民族药监督管理司）

组织拟订并监督实施国家药典等药品标准、技术指导原则，拟订并实施药品注册管理制度。监督实施药物非临床研究和临床试验质量管理规范、中药饮片炮制规范，实施中药品种保护制度。承担组织实施分类管理制度、检查研制现场、查处相关违法行为工作。参与制定国家基本药物目录，配合实施国家基本药物制度。

药品监督管理司

组织拟订并依职责监督实施药品生产质量管理规范，组织拟订并指导实施经营、使用质量管理规范。承担组织指导生产现场检查、组织查处重大违法行为。组织质量抽查检验，定期发布质量公告。组织开展药品不良反应监测并依法处置。承担放射性药品、麻醉药品、毒性药品及精神药品、药品类易制毒化学品监督管理工

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

the Registration Approval, Certificate Issuance and Product Release for biological products.

Department of Medical Device Registration

Responsibilities: 1. Organize the formulation and supervise the implementation of standards, classification rules, nomenclature conventions and coding rules for medical devices. 2. Draw up and implement the registration management system for medical devices. 3. Undertake the relevant medical device registration and clinical trial examination and approval. 4. Draw up and supervise the implementation of the Good Clinical Practice for Medical Devices and technical guidelines for medical device clinical trials. 5. Organize the inspection of R&D venues, investigate and punish the illegal acts.

Department of Medical Device Supervision

Responsibilities: 1. Organize the formulation and supervise, as per its powers and duties, the implementation of the GMPs for medical devices; organize the formulation and guide the implementation of the Good Supply Practice and Good Use Practice. 2. Organize and guide the on-site inspections over production venues, investigate and punish serious illegal acts. 3. Organize random quality inspections and release Quality Announcements on a regular basis. 4. Organize the monitoring of adverse reactions and law-based intervention thereof.

Department of Cosmetics Supervision

Responsibilities: 1. Organize and implement the record filling of cosmetic registration. 2. Draw up and organize the implementation of cosmetics registration record filing and classified control system for new materials. 3. Organize the formulation and supervise the implementation of standards, classification rules and technical guidelines for cosmetics. 4. Work out the cosmetic inspection system, inspect the R&D venues, perform duty-based organization and guidance over the on-site inspections of production venues, investigate and punish serious illegal acts. 3. Organize random quality inspections and release Quality Announcements on a regular basis. 6. Organize the monitoring of adverse reactions and law-based intervention thereof.

Department of Science & Technology and International Cooperation (Office of Hong Kong, Macao and Taiwan Affairs)

Responsibilities: 1. Organize the study of scientific tools and methods for implementing the review, inspection and testing of drugs, medical devices and cosmetics. 2. Study and draw up the management and service policies encouraging new technologies and new products. 3. Work out and supervise the implementation of laboratory construction standards and GLPs, the qualification accreditation conditions and inspection specifications for the inspection and testing institutions. 4. Organize the implementation of significant science & technology projects. 5. Organize and carry out exchange and cooperation with the world and Hong Kong, Macao and Taiwan regions. 6. Coordinate and participate in the development of international regulatory protocols and standards.

Department of Human Resources

Responsibilities: 1. Undertake the personnel affairs of the cadres in department organs and directly affiliated units, institutional staffing, labor wages and education; formulate and organize the implementation of personnel management system and cadre supervision system. 2. Coordinate the management of institutional staffing for department organs and directly affiliated units; the wages, allowances and subsidies of NMPA; as well as the pay-for-performance in directly affiliated units. 3. Guide the construction of relevant qualified personnel teams, coordinate management of cadre training, and strengthen the construction of talent teams. 4. Undertake the qualification management of licensed pharmacists, take charge of the qualification management of licensed pharmacists, lay down the qualification admittance system for licensed pharmacists, guide and supervise the registration in this respect.

Party committee

Responsibilities: 1. Promote the CPC

作。指导督促生物制品批签发管理工作。

医疗器械注册管理司

组织拟订并监督实施医疗器械标准、分类规则、命名规则和编码规则。拟订并实施医疗器械注册管理制度。承担相关医疗器械注册、临床试验审批工作。拟订并监督实施医疗器械临床试验质量管理规范、技术指导原则。承担组织检查研制现场、查处违法行为工作。

医疗器械监督管理司

组织拟订并依职责监督实施医疗器械生产质量管理规范，组织拟订并指导实施医疗器械经营、使用质量管理规范。承担组织指导生产现场检查、组织查处重大违法行为工作。组织质量抽查检验，定期发布质量公告。组织开展不良事件监测并依法处置。

化妆品监督管理司

组织实施化妆品注册备案工作。拟订并组织实施化妆品注册备案和新原料分类管理制度。组织拟订并监督实施化妆品标准、分类规则、技术指导原则。承担拟订化妆品检查制度、检查研制现场、依职责组织指导生产现场检查、查处重大违法行为工作。组织质量抽查检验，定期发布质量公告。组织开展不良反应监测并依法处置。

科技和国际合作司（港澳台办公室）

组织研究实施药品、医疗器械和化妆品审评、检查、检验的科学工具和方法。研究拟订鼓励新技术新产品的管理与服务政策。拟订并监督实施实验室建设标准和管理规范、检验检测机构资质认定条件和检验规范。组织实施重大科技项目。组织开展国际交流与合作，以及与港澳台地区的交流与合作。协调参与国际监管规则和标准的制定。

人事司

承担机关和直属单位的干部人事、机构编制、劳动工资和教育工作，拟订人事管理及干部监督制度并组织实施。统筹管理机关和直属单位机构编制，统筹管理工资、津贴补贴及直属单位绩效工资等。指导相关人才队伍建设工作，统筹管理干部培训，加强人才队伍建设。承担执业药师资格管理工作，负责执业药师资格准入管理，制定执业药师资格准入制度，指导监督执业药师注册工作。

机关党委

负责推进机关和在京直属单位党的政治

political, ideological, organizational, work style-related, and disciplinary construction for NMPA organs and its directly affiliated units in Beijing, taking system construction as the mainline. 2. Conduct the management and supervision of CPC party members and provide education and service to them. 3. Undertake the Construction of Honest Party Conduct and Clean Government, as well as anti-corruption operations. 4. Guide the group league organizations (mass organizations) of NMPA directly affiliated organs to carry out work and promote the building up of spiritual civilization. 5. Undertake the inspection work of NMPA CPC Party Group, coordinate the organization and implementation of the internal inspection and the Central Party Committee inspection.

Bureau of Retired Officials

Responsibilities: 1. Service management for retired (veteran) cadres. 2. Party committee construction for retired (veteran) cadres, as well as education and administration for retired (veteran) party members and cadres. 3. Put into effect the political status and material amenities of retired (veteran) cadres and organize cultural activities. 4. Funds management for retired (veteran) cadres of NMPA organs. 5. Direct the work relative to retired (veteran) cadres of NMPA directly-affiliated units.

(October 16, 2018)

建设、思想建设、组织建设、作风建设、纪律建设，把制度建设贯穿其中。对党员进行教育、管理、监督和服务。承担党风廉政建设和反腐败工作。指导直属机关群团组织开展工作，推进精神文明建设。承担局党组巡视工作，负责内部巡视的组织实施和中央巡视的协调配合。

离退休干部局

负责机关离退休干部服务管理工作。负责机关离退休干部党的建设，承担机关离退休党员干部教育管理监督工作。负责落实机关离退休干部政治、生活待遇，组织开展文化活动。承担机关离退休经费管理工作。指导直属单位离退休干部工作。

（2018-10-16）

NMPA and NHC Jointly Issued the *Announcement on Issues Pertaining to the Review and Approval of Overseas New Drugs Catering to Clinical Urgent Needs*

On October 30, 2018, the National Medical Products Administration (NMPA) and National Health Commission of China (NHC) jointly issued the "Announcement on Issues Pertaining to the Review and Approval of Overseas New Drugs Catering to Clinical Urgent Needs", which reads as follows:

To implement the policies set forth in relevant executive meetings of the State Council and speed up the review & approval of overseas new drugs catering to clinical urgent needs, NMPA and NHC jointly organize the drafting of the "Work Procedures for Review and Approval of Overseas New Drugs Catering to Clinical Urgent Needs" and the requirements for application dossiers (see Attachment), which are hereby released.

Work Procedures for Review and Approval of Overseas New Drugs Catering to Clinical Urgent Needs

To implement the policies set forth in the executive meeting of the State Council on June 20, in accordance with the Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Reform of Examination & Approval System to Encourage Innovation in Drugs and Medical Devices (General Office [2017] No. 42) , and the CFDA Opinions on Fueling Pharmaceutical Innovation via Prioritized Review & Approval (CFDA Department of Drug and Cosmetics Supervision [2017] No. 126) and other relevant provisions, NMPA and NHC have established special channels for review & approval of overseas new drugs catering to clinical urgent needs. The work procedures are hereby announced as follows:

I. Scope of drug varieties applicable to special channel review & approval

New drugs that have been marketed in the United States, European Union, or Japan within the recent ten years but not marketed

国家药品监督管理局 国家卫生健康委员会发布《关于临床急需境外新药审评审批相关事宜的公告》

2018年10月30日，国家药品监督管理局国家卫生健康委员会发布《关于临床急需境外新药审评审批相关事宜的公告》，全文如下：

为落实国务院常务会议有关会议精神，加快临床急需的境外上市新药审评审批，国家药品监督管理局会同国家卫生健康委员会组织起草了《临床急需境外新药审评审批工作程序》及申报资料要求（见附件），现予发布。

临床急需境外新药审评审批工作程序

为落实6月20日国务院常务会议精神，依据中共中央办公厅 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）、《食品药品监管总局关于鼓励药品创新实行优先审评审批的意见》（食药监药化管〔2017〕126号）等有关规定，国家药品监督管理局、国家卫生健康委员会建立专门通道对临床急需的境外已上市新药进行审评审批，现将工作程序公布如下：

一、专门通道审评审批的品种范围

近十年在美国、欧盟或日本上市但未在我国境内上市的新药，符合下列情形之一的：

（一）用于治疗罕见病的药品；

（二）用于防治严重危及生命疾病，且尚无有效治疗或预防手段的药品；

in China, provided that they are:

(1) Drugs for treatment of orphan diseases;

(2) Drugs for prevention and cure of serious life-threatening diseases against which no effective therapeutic or preventional instrument is available in China to date;

(3) Drugs for prevention and cure of serious life-threatening diseases with obvious clinical advantages.

II. Selection of varieties

NMPA and NHC shall organize and carry out the selection of varieties according to the above-mentioned criteria. The selection process shall adhere to the clinical value-oriented principle and follows the principles of openness, fairness and justice. The specific procedures are as follows:

(1) Initial screening. The Center for Drug Evaluation of NMPA (hereinafter referred to as CDE) shall organize experts to sort out new drugs marketed in the United States, the European Union and Japan in the past ten years but not marketed in China, and initially screen out the list of varieties that meet the requirements of this Procedure.

(2) Expert argumentation. NMPA and NHC shall convene expert demonstration meetings to demonstrate the list of varieties that were initially screened, and select a list of varieties that meet the requirements of this Procedure based on expert opinions.

(3) Public notification. CDE shall publicize the list of selected varieties to the public. Where objections arise to the publicized varieties, the party of interest shall submit a written opinion to CDE within 5 days as from the public notification and explain the reasons. For varieties facing objections, argumentations shall be made separately and the concluding decision shall be notified to all parties concerned.

(4) Announcement. CDE shall issue a list of varieties that are incorporated into the special channel review and approval.

III. Review and approval procedures

For all varieties in the list for special channel review and approval, if the certificate holder for the first marketing of the drug (in the United States, the European Union or Japan) believes that there is no ethnic difference, the registration process can advance in the following procedures:

(1) Communication and exchange. Applicants should submit an application for Class I Conference to CDE in accordance with the "Administrative Measures for Drug R&D and Communication of Technical Review".

(2) Application. Where a consensus is reached through communication, the applicant shall prepare materials according to the requirements for the application dossiers (see Annex) and submit an application as per the following conditions:

1. For varieties whose applicants have not submitted an application for clinical trial or marketing before the issuance of these Procedures, the applicants can apply to CDE for drug marketing.

2. For varieties whose applicants have submitted an application for clinical trials for which the technical review has not been completed before the issuance of this Procedures, the applicants can submit an application in written form to CDE to adjust the clinical application to the marketing application, and supplement all the research materials obtained overseas and the materials supporting the non-existence of any ethnic differences.

3. For varieties with ongoing clinical trials, the applicant may submit an application for marketing to CDE and continue to advance the trials. After completing the clinical trial, the applicant should submit

（三）用于防治严重危及生命疾病，且具有明显临床优势的药品。

二、品种遴选

国家药品监督管理局、国家卫生健康委员会按照上述品种范围，组织开展品种遴选。遴选工作坚持以临床价值为导向，遵循公开、公平、公正的原则，具体程序如下：

（一）初步筛选。国家药品监督管理局药品审评中心（以下简称药审中心）组织专家对近十年在美国、欧盟和日本上市但未在我国境内上市的新药进行梳理，初步筛选出符合本程序要求的品种名单。

（二）专家论证。国家药品监督管理局、国家卫生健康委员会召开专家论证会，对初步筛选的品种名单进行论证，根据专家意见遴选出符合本程序要求的品种名单。

（三）公示。药审中心将遴选出的品种名单向社会公示，对公示品种提出异议的，应在5日内向药审中心提交书面意见并说明理由。对异议品种，另行组织论证后作出决定并通知各相关方。

（四）公布。国家药品监督管理局药品审评中心发布纳入专门通道审评审批的品种名单。

三、审评审批程序

凡列入专门通道审评审批品种名单的，其在美国、欧盟或日本首次上市的持证商经研究认为不存在人种差异的，可按以下程序开展注册工作：

（一）沟通交流。申请人应按照《药物研发与技术审评审批沟通交流管理办法》要求向药审中心提出Ⅰ类会议申请。

（二）申请。经沟通交流形成一致意见的，申请人应按申报资料要求（见附）准备资料并根据以下情况提出申请：

1. 本程序发布前尚未提出临床或上市申请的品种，申请人可向药审中心提出上市申请。

2. 本程序发布前已提交临床申请尚未完成技术审评的品种，申请人可向药审中心提出书面申请，将临床申请调整为上市申请，补交境外取得的全部研究资料和不存在人种差异的支持性材料。

3. 对正在开展临床试验的品种，申请人可向药审中心提出上市申请并继续推进临床试验。完成临床试验后，申请人应以补充申请的形式向药审中心提交研究报告。

4. 本程序发布前已递交上市申请的品种，申请人可向药审中心补交境外取得的全部研究资料和不存在人种差异的支持性材料。

a research report to CDE in the form of a supplementary application.

4. For varieties with marketing applicants already submitted before the issuance of the program, the applicant may supplement to CDE all the research materials obtained overseas and the materials supporting the non-existence of any ethnic differences.

5. For varieties already marketed in Japan or China's Hong Kong, Macao, and Taiwan regions with sufficient clinical use cases. The applicants can provide research reports on drug use in the above-mentioned countries and regions with relevant analysis, and may not provide research data on ethnic differences.

6. The applicants shall submit concurrently relevant materials, test samples, reference materials, experimental materials, etc. for review and control of drug standards to the National Institute for Food and Drug Control (NIFDC) as required. The specific requirements are separately formulated by NIFDC.

(3) Review. CDE shall establish special channels for technical review, which shall be completed within 3 months after acceptance for orphan diseases treatment drugs; and 6 months after acceptance for other overseas new drugs, barring the time taken by the applicants for preparing supplementary dossiers.

Where supplementary dossiers are required during the review, the applicant shall be informed to supplement the information during the professional review phase; and may also adopt the method of rotating submission of dossiers via the Applicants' Window in a timely manner after communication and exchange.

(4) Approval. NMPA shall make an examination & approval decision within 10 working days after receiving the review materials submitted by CDE.

IV. Work requirements

(1) Applicants for overseas new drugs should formulate risk management and control plans, timely report adverse reactions, assess risks, propose improvement measures, conduct continuous study on marketed drugs, and complete relevant research according to approval requirements.

(2) For products manufactured before obtaining the approval proof documents of import drugs in China, under the premise of the Applicants' assurance that the production process and registration standards of the drugs are in alignment with those approved by NMPA, the drugs can be allowed for import and shall be tested according to law.

(3) Upon completion of the marketing approval by NMPA, clinical trial data verification may be conducted if required by technical review. Furthermore, the monitoring and re-evaluation of post-marketing adverse reactions shall be reinforced, and emergency control measures such as market-out and withdrawal from use shall apply to drugs found with serious adverse reactions.

Annex: Requirements for Application Dossiers (omitted)

(October 30, 2018)

5. 已在日本或中国香港、澳门、台湾地区上市，有充分临床使用病例的药品，申请人提供上述国家及地区药品使用情况研究报告，并进行相关分析，可暂不提供人种差异研究资料。

6. 申请人应按要求同步向中国食品药品检定研究院提交用于药品标准复核检验的相关资料、检验用样品、标准物质、实验材料等。具体要求由中国食品药品检定研究院另行制定。

（三）审评。药审中心建立专门通道开展审评，对罕见病治疗药品，在受理后3个月内完成技术审评；对其他境外新药，在受理后6个月内完成技术审评。上述时限不包括申请人补充资料所占用的时间。

审评期间需要申请人补充资料的，可在专业审评阶段通知企业补充资料；申请人也可在进行沟通交流后，采取滚动式提交资料的方式，通过申请人之窗及时补充资料。

（四）审批。国家药品监督管理局在接到药审中心报送的审核材料后10个工作日作出审批决定。

四、工作要求

（一）境外新药申请人应制定风险管控计划，及时报告发生的不良反应，评估风险情况，提出改进措施，并对上市药品进行持续研究，按审批要求完成相关研究工作。

（二）对获得我国进口药品批准证明文件前生产的产品，申请人在保证产品生产工艺及注册标准与国家药品监督管理局核定的工艺及标准一致的前提下，允许进口并依法进行检验。

（三）国家药品监督管理局完成上市审批后，可根据技术审评需要开展临床试验数据核查。同时，加强上市后不良反应监测与再评价，已确认发生严重不良反应的药品，可以采取停止销售、使用的紧急控制措施。

附：申报资料要求(略)

(2018-10-30)

NMPA Issued Statistical Guidelines for Bioequivalence Studies and Technical Guidelines for Research on Bioequivalence of Highly Variable Drugs

To ensure the smooth development of the conformance evaluation of generic drugs, NMPA has researched and developed the "Statistical Guidelines for Bioequivalence Studies" and the "Technical Guidelines for Research on Bioequivalence of Highly Variable Drugs", which was released on October 29, 2018.

(October 29, 2018)

国家药品监督管理局发布关于生物等效性研究的统计学指导原则和高变异药物生物等效性研究技术指导原则

为保障仿制药一致性评价工作的顺利开展，国家药品监督管理局研究制定了《生物等效性研究的统计学指导原则》《高变异药物生物等效性研究技术指导原则》，于2018年10月29日发布。 (2018-10-29)

Announcement of NMPA on Issuing the *Administrative Measures for Communication of Drug R&D and Technical Review*

As per the Opinions of the General Office of the CPC Central Committee and the General Office of the State Council Deepening the Reform of Examination & Approval System to Encourage Innovation in Drugs and Medical Devices (General Office [2017] No. 42), NMPA has formulated and released on October 8, 2018 the Administrative Measures for Communication of Drug R&D and Technical Review. The Announcement shall come into force as from the date of issuance. The Administrative Measures for Drug R&D and Communication of Technical Review (Interim) issued by the former CFDA on June 2, 2016 (announcement No. 94 of 2016) shall be repealed simultaneously.

(October 8, 2018)

国家药品监督管理局发布《药物研发与技术审评沟通交流管理办法》

为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》（厅字〔2017〕42号），国家药品监督管理局制定了《药物研发与技术审评沟通交流管理办法》，于2018年10月8日发布。公告自发布之日起执行。原食品药品监管总局于2016年6月2日发布的《药物研发与技术审评沟通交流管理办法（试行）》（2016年第94号通告）同时废止。

（2018-10-08）

NMPA Issued the *Announcement on the Direct Reporting of Adverse Reactions by Marketing Authorization Holders*

As per the Drug Administration Law of the People's Republic of China, and the Opinions of the General Office of the CPC Central Committee and the General Office of the State Council Deepening the Reform of Examination & Approval System to Encourage Innovation in Drugs and Medical Devices (General Office [2017] No. 42), in order to further improve the ADR monitoring system and implement the principal responsibility of ADR reporting by drug Marketing Authorization Holders (incl. pharmaceutical manufacturing enterprise holding the drug approval number, hereinafter referred collectively as the Holders). On September 30, 2018, NMPA issued the Announcement on the Direct Reporting of Adverse Reactions by Marketing Authorization Holders, which will become effective as from January 1, 2019.

(September 30, 2018)

国家药品监督管理局发布《关于药品上市许可持有人直接报告不良反应事宜的公告》

根据《中华人民共和国药品管理法》、《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），为进一步完善药品不良反应监测制度，落实药品上市许可持有人（包括持有药品批准文号的药品生产企业，以下简称持有人）不良反应报告主体责任，2018年9月30日，国家药品监督管理局发布《关于药品上市许可持有人直接报告不良反应事宜的公告》，公告自2019年1月1日起实施。（2018-09-30）

Medical Devices

NMPA Issued the *Guidelines for Registration Review of Medical Devices for Prevention and Cure of Orphan Diseases*

As per the Opinions of the General Office of the CPC Central Committee and the General Office of the State Council Deepening the Reform of Examination & Approval System to Encourage Innovation in Drugs and Medical Devices (General Office [2017] No. 42), to strengthen the registration management of medical device products, further escalate the quality of registration review, and encourage the R&D of medical devices for orphan diseases prevention and treatment, NMPA has organized the formulation of and released on October 18, 2018 the Guidelines for Registration Review of Medical Devices for Prevention and Cure of Orphan Diseases.

(October 18, 2018)

医疗器械

国家药品监督管理局发布《用于罕见病防治医疗器械注册审查指导原则》

为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》（厅字〔2017〕42号），加强医疗器械产品注册管理，进一步提高注册审查质量，鼓励用于罕见病防治医疗器械研发，国家药品监督管理局组织制定了用于罕见病防治医疗器械注册审查指导原则，于2018年10月18日发布。（2018-10-18）

The Newly Revised Catalogue of Medical Devices Exempted from Clinical Trials Released

As per the Opinions of the General Office of the CPC Central Committee and the General Office of the State Council Deepening the Reform of Examination & Approval System to Encourage Innovation in Drugs and Medical Devices (General Office [2017] No. 42), to further the reform of the "Streamlining Administration, Delegating Powers, Improving Regulation and Optimizing Services" in the medical device sector, NMPA has organized the revision of the Catalogue of Medical Devices Exempted from Clinical Trials (hereinafter referred to as the Exemption Catalogue), collated and revised the first three batches of Exemption Catalogues on the basis of the Classification Catalogue for Medical Devices revised and published in 2017 (hereinafter referred to as the new Classification Catalogue), a new batch of medical devices (including in vitro diagnostic reagents) exempted from clinical trials was incorporated to form a newly revised Catalogue of Medical Devices Exempted from Clinical Trials (hereinafter referred to as the New "Exemption Catalogue").

The new Exemption Catalogue covers 1,248 items of medical devices exempted from clinical trials, which are divided into "medical device products" and "in vitro diagnostic reagent products", covering respectively 855 medical device products and 393 in vitro diagnostic reagent products. Compared with the first three batches of Exemption Catalogues, 84 new medical device products and 277 new in vitro diagnostic reagent products were added. The new Exemption Catalogue is maximally consistent with the new Classification Catalogue to facilitate applicants to better identify products. All Exemption Catalogues issued previously for various batches of medical devices are integrated to facilitate applicants' enquiries.

(September 30, 2018)

《新修订的免于进行临床试验医疗器械目录》发布

为深入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》（厅字〔2017〕42号），持续深化医疗器械领域“放管服”改革，国家药监局组织开展了免于进行临床试验医疗器械目录（以下简称豁免目录）的制修订工作，结合2017年修订发布的《医疗器械分类目录》（以下简称新《分类目录》）对已发布的前三批豁免目录进行整理和修订，在此基础上与新一批免于进行临床试验的医疗器械（含体外诊断试剂）产品目录整合，形成新修订的《免于进行临床试验医疗器械目录》（以下简称新《豁免目录》）。

新《豁免目录》共包括免于进行临床试验的医疗器械1248项，分为“医疗器械产品”和“体外诊断试剂产品”两个部分，分别涵盖855项医疗器械产品和393项体外诊断试剂产品。较前三批豁免目录新增医疗器械产品84项，新增体外诊断试剂产品277项。新《豁免目录》与新《分类目录》最大程度保持一致，以便于申请人更好地识别产品，并整合历次发布的各批豁免目录，方便申请人查询。

（2018-09-30）

NMPA Issued the Announcement on the Issuance of the Guidelines for Management Representatives of Medical Device Manufacturers

To further clarify the responsibilities of management representatives in the quality management system, strengthen the manufacturers' awareness of principal responsibility for quality of medical devices, and improve their quality management level, according to the "Administrative Measures for the Supervision of Medical Device Manufacturing" (CFDA Order No. 7) and the "Good Manufacturing Practice for Medical Devices" (CFDA Announcement No. 64 of 2014), NMPA has organized the formulation of the "Management Guide for the Guidelines for Management Representatives of Medical Device Manufacturers", which has been released on September 30, 2018.

(September 30, 2018)

国家药品监督管理局发布《医疗器械生产企业管理者代表管理指南》

为进一步明确管理者代表在质量管理体系中的职责，强化医疗器械生产企业质量主体责任意识，提升质量管理水平，根据《医疗器械生产监督管理办法》（国家食品药品监督管理总局令第7号）和《医疗器械生产质量管理规范》（国家食品药品监督管理总局公告2014年第64号），国家药品监督管理局组织制定了《医疗器械生产企业管理者代表管理指南》，于2018年9月30日发布。

（2018-09-30）

NMPA Issued the *Announcement on the Cleanup Results of Normative Documents for Medical Devices (1998-2013)*

As per the requirements of the "Governing by Law Construction Program (2015-2020)" of the CPC Central Committee and State Council, to effectively implement the "legislation, revision, revocation and interpretation" of drug administration legal system, and comprehensively promote the law-based administration, NMPA organized the cleanup of the medical device normative documents from 1998 to 2013, and decided to abolish and declare the invalidation of a batch of normative documents. On September 27, 2018, the "Catalogue of NMPA Remain-Effective Medical Device Normative Documents (1998-2013)" and the Catalogue of NMPA Medical Device Normative Documents (1998-2013) Abolished and Declare as Invalid were published.

Unless otherwise expressly provided, the abolishment and annulment of the above normative documents shall not, without exception, tarnish the effectiveness of the past decisions made as based on these documents. (September 27, 2018)

国家药品监督管理局发布《关于医疗器械规范性文件（1998—2013年）清理结果的公告》

根据中共中央、国务院印发的《法治政府建设实施纲要（2015—2020年）》的要求，为做好药品监管法律制度“立改废释”工作，全面推进依法行政，国家药品监督管理局组织对1998—2013年医疗器械规范性文件进行了清理，并决定废止和宣布失效一批规范性文件。2018年9月27日，《国家药品监督管理局继续有效的医疗器械规范性文件目录（1998—2013年）》和《国家药品监督管理局废止和宣布失效的医疗器械规范性文件目录（1998—2013年）》公布。

对上述予以废止或者宣布失效的规范性文件，除另有明确规定外，均不涉及过去根据这些文件所作出处理决定的效力。

（2018-09-27）

General Information

Distribution in Full Swing for the First Supplement to the 2015 Edition of the Pharmacopoeia of the People's Republic of China

The First Supplement to the 2015 Edition of the Pharmacopoeia of the People's Republic of China has been published and fully distributed by China Pharmaceutical Science and Technology Publishing House Co., Ltd.

The Supplement contains the varieties and general requirements of the first, second, third and fourth Volumes of the 2015 Edition of the Chinese Pharmacopoeia, wherein Volume I recorded 1 new medicinal material, 32 new admissions of Chinese patent medicine, and 112 revised varieties; Volume II recorded 60 new admissions, 136 revisions; Volume II recorded 1 new admission, 43 revisions, 4 new General Requirements, 2 revised General Requirements; and Volume IV recorded 3 revised general requirements, and 42 revised excipients. (October 15, 2018)

综合信息

《中国药典》2015年版第一增补本全面发行

《中国药典》2015年版第一增补本已由中国医药科技出版社有限公司出版并全面发行。

该增补本收载了《中国药典》2015年版一部、二部、三部、四部增修订的品种和通则。其中一部收载新增药材1个，新增中成药32个，修订品种112个；二部收载新增品种60个，修订品种136个；三部收载新增品种1个，修订品种43个，新增通则4个，修订通则2个；四部修订通则3个，修订辅料品种42个。（2018-10-15）

Notes: • All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version.
• For electronic version of the Newsletter please visit http://www.ccfdie.org

备 注： • Newsletter中所有中文信息摘自报刊及网络。英文均系中文翻译。
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