CHINA FOOD AND DRUG 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 Drug Administration and NHC Issued the *Announcement on Matters Concerning the Optimization of Drug Registration Review & Approval*

As per the *Opinions on Deepening the Review and Approval System Reform and Encouraging the Drug and Medical Device Innovation* of the General Office of the CPC Central Committee and the General Office of the State Council (CPC Central Committee & State Council [2017] No. 42), and the *Opinions on the Reform of the Review & Approval System for Drugs and Medical Devices* of the State Council (State Council [2015] No. 44), to improve the efficiency of the review and approval for marketing of innovative drugs, and scientifically simplify the procedures thereof, on May 23, 2018, National Drug Administration and National Health Commission (NHC) issued the *Announcement on Matters Concerning the Optimization of Drug Registration Review & Approval* ([2018] No. 23), as announced in relation to the following matters:

1. Further implement the work mechanism of priority review & approval of drugs. For the drugs for prevention and treatment of diseases that are seriously life-threatening and that have no effective treatment means, and rare diseases, the Center for Drug Evaluation, CFDA (CDE) will establish a communication and exchange mechanism with the applicants, strengthen the guidance over drug R&D, and prioritize the allocation of resources for review, inspection, examination and approval of registration applications that have been included in the scope of priority review & approval so as to speed up review & approval.

2. For the drugs already marketed overseas for prevention and treatment of diseases that are seriously life-threatening and that have no effective treatment means, and rare diseases, if applicants for registration of these imported drugs have confirmed after study there is no any ethnic difference, they can directly apply for drug marketing registrations via submitting the clinical trial data obtained overseas. For the applications for clinical trials of the above-mentioned imported drugs that have been accepted and submitted for exemption of clinical trials before the issuance of this Announcement, the import can be directly approved so long as the drugs are in compliance with the *Provisions for Drug Registration* and related regulations.

3. Carry out drug test based on product safety risk control requirements. After the drug clinical trial application is accepted, CDE shall propose a test request as deems as necessary and notify the applicant to issue a test report on the clinical trial sample on its own or by commissioning the testing agency within the specified time; and if CDE considers the test as unnecessary, such notification shall not be made. For clinical trial applications accepted before December 1, 2017, if CDE deems that there is no need for testing, the relevant testing agency shall be notified to terminate the testing and CDE shall go directly for review & approval. Where the testing agency has made a test conclusion that the sample is nonconforming, CDE shall not approve the clinical trial.

4. After canceling the file verification procedures for registration renewal of

国家药品监督管理局 国家卫生健康委员会发布《关于优化药品注册审评审批有关事宜的公告》

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）、《国务院关于改革药品医疗器械审评审批制度的意见》（国发〔2015〕44号），提高创新药上市审批效率，科学简化审批程序，2018年5月23日，国家药品监督管理局 国家卫生健康委员会发布《关于优化药品注册审评审批有关事宜的公告》（2018年第23号），就有关事宜公告如下：

一、进一步落实药品优先审评审批工作机制，对防治严重危及生命且尚无有效治疗手段疾病以及罕见病药品，国家食品药品监督管理总局药品审评中心（以下简称药审中心）建立与申请人之间的沟通交流机制，加强对药品研发的指导，对纳入优先审评审批范围的注册申请，审评、检查、审批等各环节优先配置资源，加快审评审批。

二、对于境外已上市的防治严重危及生命且尚无有效治疗手段疾病以及罕见病药品，进口药品注册申请人经研究认为不存在人种差异的，可以提交境外取得的临床试验数据直接申报药品上市注册申请。对于本公告发布前已受理并提出减免临床试验的上述进口药品临床试验申请，符合《药品注册管理办法》及相关文件要求的，可以直接批准进口。

三、基于产品安全性风险控制需要开展药品检验工作。药品临床试验申请受理后，药审中心经评估认为需要检验的，提出检验要求，通知申请人在规定时间内自行或委托检验机构对临床试验样品出具检验报告；药审中心经评估认为无需检验的，不再通知开展检验工作。2017年12月1日前受理的药品临床试验申请，药审中心经评估认为无需检验的，通知相关检验机构终止检验并继续审评审批工作。检验机构已作出不符合规定的检验结论的，药审中心不批准其临床试验申请。

四、取消进口药品再注册核档程序，进口

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imported drugs, all the relevant accepted registration renewal application dossiers shall be forwarded to CDE for review and approval. Applications for registration renewal of imported drugs that have been accepted before the issuance of this Announcement, including those with file verification opinion stated as exempt from specification review, shall be transferred to CDE for review and approval. The various types of temporary import administrative approval decisions currently made by National Drug Administration shall be adjusted to be made by CDE on behalf of National Drug Administration.

5. The *Imported Drug Registration Certificate* and the *Pharmaceutical Product Registration Certificate* shall be subject to new numbering rules; after registration renewal and supplementary application for imported drugs are approved, the above certificates will not be renumbered (see the Annex for specific numbering rules).

6. This Announcement shall be implemented as of the date of issuance. Matters not covered herein shall be handled in accordance with the existing regulations.

Annex: Numbering Rules for Approval Documents for Imported Drugs (omitted)

(May 23, 2018)

药品再注册申请受理后，全部资料转交药审中心审评审批。对于本公告发布前已受理的进口药品再注册申请，包括进口再注册核档意见为无需质量标准复核的注册申请，统一转入药审中心进行审评审批。将目前由国家药品监督管理局作出的各类临时进口行政审批决定，调整为由药审中心以国家药品监督管理局名义作出。

五、对《进口药品注册证》和《医药产品注册证》实施新的编号规则，进口药品再注册及补充申请获得批准后，不再重新编号（具体编号规则见附件）。

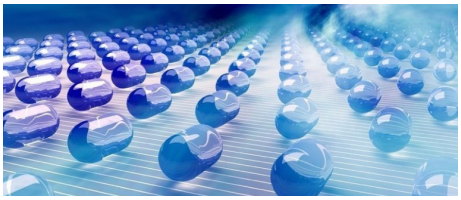
六、本公告自发布之日起实施。本公告中未涉及的事项，仍按照现有规定执行。

附件：进口药品批准证明文件编号规则(略)

（2018-05-23）

National Drug Administration Issued the *Announcement on 12 Varieties of Drugs (Fourth Batch) Accredited by Quality & Efficacy Consistency Evaluation of Generic Drugs Including Atorvastatin Calcium Tablets*

On May 22, 2018, National Drug Administration issued the *Announcement on 12 Varieties of Drugs (Fourth Batch) Accredited by Quality & Efficacy Consistency Evaluation of Generic Drugs Including Atorvastatin Calcium Tablets*. Information for the package inserts, enterprise study reports and bioequivalence test data of the above varieties can be found on the Website of the Center for Drug Evaluation, CFDA.



In addition, to regulate the use of the identification of "Accredited by Consistency Evaluation", National Drug Administration has prepared the instructions on its use.

(May 22, 2018)

国家药品监督管理局发布《关于阿托伐他汀钙片等12个品种规格通过仿制药质量和疗效一致性评价的公告（第四批）》

2018年5月22日，国家药品监督管理局发布《关于阿托伐他汀钙片等12个品种规格通过仿制药质量和疗效一致性评价的公告（第四批）》，上述品种的说明书、企业研究报告及生物等效性试验数据信息可登录国家食品药品监督管理总局药品审评中心网站查询。

此外，为规范"通过一致性评价"标识的使用，国家药品监督管理局编写了关于"通过一致性评价"标识使用有关事宜的说明。

（2018-05-22）

National Drug Administration Issued the *Announcement on Detailed Rules for Strengthening the Implementation of Confidentiality Management for Drug Review and Approval Information*

To safeguard the legitimate rights and interests of drug registration applicants, regulate and strengthen the confidentiality management of the review & approval information, and ensure efficient and lawful conduct of drug review & approval, National Drug Administration has formulated and issued on May 17, 2018 the *Detailed Rules for Strengthening the Implementation of Confidentiality Management for Drug Review and Approval Information as*

国家药品监督管理局发布《关于加强药品审评审批信息保密管理的实施细则》的通告

为维护药品注册申请人的合法权益，规范和加强审评审批信息保密管理，确保药品审评审批工作合法高效运行，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印发〈关于深化审评审批制

per the Drug Administration Law of the People's Republic of China, the *Opinions of the General Office of the CPC Central Committee and the General Office of the State Council on Deepening the Review and Approval System Reform and Encouraging the Drug and Medical Device Innovation*, and the *Administrative Measures of the China Food and Drug Administration for Confidentiality of Review & Approval Information of Drugs and Medical Devices*, etc..

(May 17, 2018)

度改革鼓励药品医疗器械创新的意见〉的通知》《国家食品药品监督管理总局药品医疗器械审评审批信息保密管理办法》等，国家药品监督管理局制定了《关于加强药品审评审批信息保密管理的实施细则》，于2018年5月17日发布。 (2018-05-17)

National Drug Administration Released the *Announcement on Strengthening the On-site Inspection of Registration Applications for Chemical Generic Drug Injections*

To implement the requirements of the *Opinions on Deepening the Review and Approval System Reform and Encouraging the Drug and Medical Device Innovation* of the General Office of the CPC Central Committee and the General Office of the State Council (CPC Central Committee & State Council [2017] No. 42), strictly review and approve drug injections to ensure safety and effectiveness, National Drug Administration decided to strengthen the on-site inspection of registration applications for chemical generic injections. On May 14, 2018, the related issues are announced as follows:

1. Since the date of issuance of this Announcement, for registration applications for chemical generic injections that have been accepted by the provincial drug regulatory authorities and are being reviewed and approved by National Drug Administration , the latter shall reinforce the intensity of for-cause inspection. The Center for Drug Evaluation, CFDA (hereinafter referred to as CDE) shall, on the basis of rigorous review, proffer requests as necessary for on-site inspection, which shall be performed by the Center for Food and Drug Inspection of CFDA (hereinafter referred to as CFDI).

2. On-site inspection shall be required for:

   (1) Changes in prescriptions, manufacturing processes, inner packaging materials, and production equipment of injections, which fall into Category III changes or major changes as per the *Technical Guidelines for Study on the Changes of Marketed Chemical Drugs (I) and the Technical Guidelines for Study on the Manufacturing Process Changes of Marketed Chemical Drugs*.

   (2) Changes in the production sites (production lines) of the domestically-made preparations.

   (3) Initial application for registration of chemical drug injections whose production line has not yet produced other varieties.

   (4) Applications found with doubtful authenticity and other problems in the review process, awaiting verification.

   (5) Applications that need to be verified for complaints & reports on the truthfulness and reliability issues.

3. CFDI will conduct on-site inspection of applications for registration of chemical generic injections based on the review needs, and notify the applicants for registration. The inspection focuses on the applicant's overall implementation of the drug GMP and sterility assurance level of the variety under application for registration, as well as the dynamic production batch status upon application, including the consistency of the application dossier with the production batch, and the authenticity of the application dossier, etc. When necessary, CFDI may require registration applicant

国家药品监督管理局发布《关于加强化学仿制药注射剂注册申请现场检查工作的公告》

为落实中共中央办公厅、国务院办公厅《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》（厅字〔2017〕42号）的要求，严格药品注射剂审评审批，保障药品安全、有效，国家药品监督管理局决定加强对化学仿制药注射剂注册申请开展现场检查。2018年5月14日，就有关事宜公告如下：

一、自本公告发布之日起，对已由省级药品监管部门受理并正在国家药品监督管理局审评审批的化学仿制药注射剂注册申请，国家药品监督管理局将加大有因检查的力度，国家食品药品监督管理总局药品审评中心（以下简称药审中心）在严格审评的基础上，根据审评需要提出现场检查需求，由国家食品药品监督管理总局食品药品审核查验中心（以下简称核查中心）实施现场检查。

二、需要现场检查的情况包括：

（一）注射剂的处方、工艺、内包材、生产设备发生变更，属于《已上市化学药品变更研究的技术指导原则（一）》《已上市化学药品生产工艺变更研究技术指导原则》规定的III类变更或重大变更的情形的。

（二）国产制剂的生产地点（生产线）发生变更的。

（三）首次申报化学药注射剂型，相应生产线尚未生产过其他品种的。

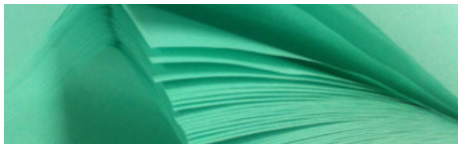
（四）审评过程发现真实性存疑等需要核实的。

（五）收到真实性和可靠性问题投诉举报线索需要核实的。

三、核查中心将根据审评需要对化学仿制药注射剂注册申请开展现场检查，并通知注册申请人。检查重点包括注册申请人整体实施药品生产质量管理规范水平与申报品种无菌保证能力，以及品种申报时动态生产批次情况，包括生产批量等与申报资料的一致性、真实性等相关内容。必要时，核查中

to arrange dynamic production and sampling testing during inspection.

4. For cases in Items (1) and (2) of Paragraph 2, after the review is completed, CDE will not notify the provincial drug regulatory authorities to repeat the production site inspection.



5. If the applicant finds that the contents of the application for registration of the relevant chemical generic injection are inauthentic or incomplete, it may apply for withdrawal before the CFDI informs the on-site inspection. After the on-site inspection is notified, the application for withdrawal will no longer be accepted.

6. Inauthenticity or even fraud issues found in the on-site inspection will be investigated and severely dealt with according to law. (May 14, 2018)

心可要求注册申请人在检查期间安排动态生产和抽样检验。

四、属于第二条（一）和（二）情况的，待审评结束后，药审中心不再通知省级药品监管部门重复进行生产现场检查。

五、注册申请人发现相关化学仿制药注射剂注册申请内容存在不真实、不完整等问题的，可以在核查中心通知现场检查前申请撤回。通知现场检查后不再接受撤回申请。

六、对现场检查发现存在真实性问题甚至弄虚作假的，将依法严肃查处。

（2018-05-14）

National Drug Administration Issued the *Announcement on Adjusting the Management Categories of 19 Varieties Including Banlangen Effervescent Tablets*

According to the *Regulations for Classification Management of Prescription Drugs and OTC Drugs (Interim)* (Former SDA Order No. 10), after argumentation and examination, on May 8, 2018, National Drug Administration issued the *Announcement on Adjusting the Management Categories of 19 Varieties Including Banlangen Effervescent Tablets*, has transferred 18 drugs including Banlangen Effervescent Tablets from prescription drugs to OTC drugs, and Rheumatism Analgesic Plaster from category B OTC drugs to category A OTC drugs since it is no longer in line with the current principle for determination of category B OTC drugs. (May 8, 2018)

国家药品监督管理局发布《关于调整板蓝根泡腾片等19个品种管理类别的公告》

根据《处方药与非处方药分类管理办法（试行）》（国家药品监督管理局令第10号）的规定，经国家药品监督管理局组织论证和审定，2018年5月8日，发布《关于调整板蓝根泡腾片等19个品种管理类别的公告》，将板蓝根泡腾片等18种药品由处方药转换为非处方药；伤湿止痛膏已不符合目前乙类非处方药确定原则，由乙类非处方药转换为甲类非处方药。（2018-05-08）

National Drug Administration Issued the *Technical Guidelines for the Study of Compatibility of Chemical Drugs and Elastomeric Seals (Interim)*

To guide the study on the compatibility of pharmaceuticals and packaging container systems, establish and improve the guideline system for study thereof, National Drug Administration organized to formulate the *Technical Guidelines for the Study of Compatibility of Chemical Drugs and Elastomeric Seals (Interim)*, which was released on May 3, 2018. (May 3, 2018)

国家药品监督管理局发布《化学药品与弹性体密封件相容性研究技术指导原则（试行）》

为指导药品与包装容器系统的相容性研究工作，建立并完善药品与包装相容性研究指导原则体系，国家药品监督管理局组织制定了《化学药品与弹性体密封件相容性研究技术指导原则（试行）》，于2018年5月3日发布。（2018-05-03）

National Drug Administration Issued the *Announcement on Matters Concerning the Inspection of Imported Chemical Drugs for Customs Clearance*

On April 26, 2018, National Drug Administration issued the *Announcement on Matters Concerning the Inspection of Imported Chemical Drugs for Customs Clearance* ([2018] No. 12). The full text is as follows:

国家药品监督管理局发布《关于进口化学药品通关检验有关事项的公告》

2018年4月26日，国家药品监督管理局发布《关于进口化学药品通关检验有关事项的公告》（2018年第12号），全文如下：

Following the executive meeting of the State Council, to reduce the drug burden of the majority of patients, especially cancer patients, and provide them with more medication options, the relevant matters regarding the inspection of imported chemical drugs for customs clearance are announced as follows:

1. Imports of chemical APIs and preparations (excluding chemical drugs sold for the first time in China) are no longer subject to compulsory inspection batch by batch. For record filing of imported chemical drugs, the drug regulatory authorities at the ports shall no longer issue the *Notice for Inspection of Imported Drugs at the Port*, and the drug testing agencies will no longer conduct port inspection on imported chemical drugs.

2. Marketing Authorization Holders of imported drugs shall bear all legal responsibilities for manufacturing, sales and distribution of imported drugs and reports of adverse reactions, etc. They shall ensure persistent compliance of production process, continuous study on marketed drugs, and high level quality and safety of drugs. They shall submit standard substances to the National Institute for Food and Drug Control (NIFDC) in accordance with relevant regulations.

3. Drug regulatory authorities at all levels shall strengthen the supervisory sampling inspection of the marketing for imported drugs, intensify regulatory actions, and investigate and deal with the violations of laws and regulations in accordance with the law.

4. The drug regulatory authority in jurisdiction of the port shall submit to NIFDC the information summary of record filing for imported drugs in accordance with relevant regulations.

5. The inspection tasks with sampling of imported chemical drugs completed before the issuance date of this Announcement shall be continued by drug testing agency in jurisdiction of the port.

6. This Announcement shall be implemented as of the date of issuance.

(May 8, 2018)

为落实国务院常务会议精神，减轻广大患者特别是癌症患者药费负担并有更多用药选择，现就进口化学药品通关检验有关事项公告如下：

一、进口化学原料药及制剂（不含首次在中国销售的化学药品）在进口时不再逐批强制检验。口岸所在地药品监督管理部门在办理进口化学药品备案时不再出具《进口药品口岸检验通知书》，口岸药品检验所不再对进口化学药品进行口岸检验。

二、进口药品上市许可持有人须对进口药品的生产制造、销售配送、不良反应报告等承担全部法律责任，应确保生产过程持续合规，确保对上市药品进行持续研究，保障药品质量安全。进口药品上市许可持有人应当按照相关规定向中国食品药品检定研究院提交标准物质。

三、各级药品监管部门应当加强对进口药品的市场监督抽检，加大监督检查力度，发现违法违规行为的，严格依法查处。

四、口岸所在地药品监管部门应当按照相关规定向中国食品药品检定研究院报送进口药品备案信息汇总。

五、本公告发布之日前已经完成抽样的进口化学药品检验任务，各口岸药品检验机构继续按原规定开展检验工作。

六、本公告自发布之日起实施。

（2018-05-08）

National Drug Administration Issued the *Announcement on Matters Concerning the Import Clearance of Pharmaceutical Raw Materials and Excipients*

On April 24, 2018, National Drug Administration issued the *Announcement on Matters Concerning the Import Clearance of Pharmaceutical Raw Materials and Excipients* ([2018] No. 8), which reads as follows:

According to the *Decision of the State Council on Canceling a Batch of Administrative Licensing Items* (State Council [2017] No. 46, hereinafter referred to as Document No. 46), and the former CFDA's *Announcement on Adjusting the Review & Approval Items of APIs, Pharmaceutical Excipients and Packaging Materials* ([2017] No. 146, hereinafter referred to as Announcement No. 146), to regulate the import clearance of APIs and pharmaceutical excipients, the relevant issues are hereby announced as follows:

1. For imported APIs, the importer may go through the *Imported Drug Customs Clearance Form* at the port drug regulatory authority with the approval documents for APIs, Certificate of Origin, packing list, bill of lading, freight invoice, and factory inspection report, etc.

2. The approval documents for APIs shall include one of the following:

   (1) *Imported Drug Registration Certificate* for imported APIs. For the imported APIs approved before

国家药品监督管理局发布《关于药用原辅料进口通关有关事宜的公告》

2018年4月24日，国家药品监督管理局发布《关于药用原辅料进口通关有关事宜的公告》（2018年第8号），内容如下：

根据《国务院关于取消一批行政许可事项的决定》（国发〔2017〕46号，以下简称46号文件）、原国家食品药品监督管理总局《关于调整原料药、药用辅料和药包材审评审批事项的公告》（2017年第146号，以下简称146号公告），为规范原料药及药用辅料的进口通关，现将有关事宜公告如下：

一、对于进口原料药，进口单位可凭原料药批准证明文件、原产地证明、装箱单、提运单、货运发票、出厂检验报告书等资料，到口岸药品监管部门办理《进口药品通关单》。

二、原料药批准证明文件包括以下内容

the issuance of Announcement No. 146, the *Imported Drug Registration Certificate* shall continue to be valid during the period of validity. If the said validity period expires, the *Imported Drug Registration Certificate* shall be provided and may be further used in the original drug or for study.

(2) For APIs with registration number in line with the requirements of Announcement No. 146, and identified as the APIs approved for use in marketed preparations, the search results for "APIs Registration Data" publicly notified in the Center for Drug Evaluation, CFDA (hereinafter referred to as CDE) portal website shall be provided to the pharmaceutical enterprise using the APIs for use or for study.

(3) For APIs with registration number in line with the requirements of Announcement No. 146, but not yet identified as the APIs approved for use in marketed preparations, the search results for "APIs Registration Data" publicly notified in CDE portal website shall be provided for study purpose only.

(4) The *Imported Drug Approval Letter* for APIs: if the APIs intended for study purpose do not have a registration number, the *Imported Drug Approval Letter* shall be provided for study purpose only.

(5) Other approval documents permitting the import of APIs.

3. For pharmaceutical excipients included in the *Announcement on Adjusting the Trade Names and Numbers of Drugs in the List of Imported Drugs* ([2011] No. 104) jointly issued by the former State Food and Drug Administration and the General Administration of Customs, the importer may go through the Imported Drug Customs Clearance at the port drug regulatory authority with approval documents for pharmaceutical excipients, Certificate of Origin, packing list, bill of lading, freight invoice, and factory inspection report, etc. The port drug regulatory authority shall indicate in the *Imported Drug Customs Clearance Form* with "Pharmaceutical excipients only, non-pharmaceuticals, port inspection exempted". Other pharmaceutical excipients that are not included in the above-mentioned *List of Imported Drugs* do not need to go through the *Imported Drug Customs Clearance Form*. The relevant matters concerning import customs clearance shall be implemented in accordance with the relevant provisions of the customs authority.

4. The approval documents for pharmaceutical excipients shall include one of the following:

(1) *Imported Drug Registration Certificate* for pharmaceutical excipients. For pharmaceutical excipients approved before the issuance of No. 46 Document, the *Imported Drug Registration Certificate* shall remain valid during the period of validity. If the validity period expires, the *Imported Drug Registration Certificate* shall be provided, and the imported pharmaceutical excipients may be further used in the original drug, or for study purpose.

(2) For pharmaceutical excipients with registration number obtained in accordance with the requirements of Announcement No. 146, and identified as pharmaceutical excipients approved for use in the marketed preparations, the search results for "Pharmaceutical Excipient Registration Data" publicly notified in CDE portal website shall be provided to the pharmaceutical enterprise using the pharmaceutical excipients for use or for study.

之一：

（一）进口原料药的《进口药品注册证》。146号公告发布前获得批准的进口原料药，《进口药品注册证》在有效期内继续有效，有效期届满的，应当提供该《进口药品注册证》，可以在原药品中继续使用，或供研究使用。

（二）按146号公告要求获得登记号，且已标识为获准在上市制剂中使用的原料药，应当提供国家食品药品监督管理总局药品审评中心（以下简称药审中心）门户网站对社会公示的“原料药登记数据”检索结果，供使用该原料药的制剂企业使用，或供研究使用。

（三）按146号公告要求获得登记号，尚未标识为获准在上市制剂中使用的原料药，应当提供药审中心门户网站对社会公示的“原料药登记数据”检索结果，仅供研究使用。

（四）原料药的《进口药品批件》：拟供研究使用的原料药尚未获得登记号的，应当提供《进口药品批件》，仅供研究使用。

（五）允许原料药进口的其他批准证明文件。

三、对于列入原国家食品药品监督管理局和海关总署联合发布的《关于调整〈进口药品目录〉有关商品名称及编号的公告》（2011年第104号）附件中的药用辅料，进口单位可凭药用辅料证明文件、原产地证明、装箱单、提运单、货运发票、出厂检验报告书等资料，到口岸药品监管部门办理《进口药品通关单》。口岸药品监管部门应在《进口药品通关单》中注明“本品为药用辅料，非药品，无需进行口岸检验”。未列入上述《进口药品目录》中的其他药用辅料不需办理《进口药品通关单》，进口通关相关事宜按照海关部门有关规定执行。

四、药用辅料证明文件包括以下内容之一：

（一）药用辅料的《进口药品注册证》。46号文件发布前获得批准的药用辅料，《进口药品注册证》在有效期内继续有效，有效期届满的，应当提供该《进口药品注册证》，所进口的药用辅料可在原药品中继续使用，或供研究使用。

（二）按146号公告要求获得登记号，且已标识为获准在上市制剂中使用的药用辅料，应当提供药审中心门户网站对社会公示的“药用辅料登记数据”检索结果，供使用该药用辅料的制剂企业使用，或供研究使用。

（三）按146号公告要求获得登记号，

(3) For pharmaceutical excipients with registration number obtained in accordance with the requirements of Announcement No. 146, but not yet identified as pharmaceutical excipients approved for use in the marketed preparations, the search results for "Pharmaceutical Excipient Registration Data" publicly notified in CDE portal website shall be provided for study purpose only.

(4) Other approval documents permitting the import of pharmaceutical excipients. (April 24, 2018)

尚未标识为获准在上市制剂中使用的药用辅料，应当提供药审中心门户网站对社会公示的“药用辅料登记数据”检索结果，仅供研究使用。

（四）允许药用辅料进口的其他批准证明文件。 (2018-04-24)

Medical Devices

National Drug Administration Issued Four Guidelines for Technical Review of Registration Including the Guidelines for Technical Review of Surgical Microscope Registration

To strengthen the supervision and guidance over the medical device registration and further improve the registration review quality, National Drug Administration has formulated the *Guidelines for Technical Review of Surgical Microscope Registration*, the *Guidelines for Technical Review of Medical Clean Bench Registration*, the *Guidelines for Technical Review of Ophthalmotonometer Registration*, and the *Guidelines for Technical Review of Pulse Wave Velocity and Ankle-brachial Index Testing Product Registration* which were released on May 18, 2018.

(May 18, 2018)

医疗器械

国家药品监督管理局发布手术显微镜等4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《手术显微镜注册技术审查指导原则》《医用洁净工作台注册技术审查指导原则》《眼压计注册技术审查指导原则》《脉搏波速度和踝臂指数检测产品注册技术审查指导原则》，于2018年5月18日发布。 (2018-05-18)

National Drug Administration Issued Two Guidelines for Preclinical Study and Clinical Trials of Coronary Drug-eluting Stents

To strengthen the supervision and guidance over the medical device registration and further improve the registration review quality, National Drug Administration organized to formulate the *Guidelines for Preclinical Study of Coronary Drug-eluting Stents* and the *Guidelines for Clinical Trials of Coronary Drug-eluting Stents* which were released on May 11, 2018.

(May 11, 2018)

国家药品监督管理局发布冠状动脉药物洗脱支架临床前研究及临床试验两个指导原则

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《冠状动脉药物洗脱支架临床前研究指导原则》《冠状动脉药物洗脱支架临床试验指导原则》，于2018年5月11日发布。 (2018-05-11)

National Drug Administration Issued Four Guidelines for Technical Review of Registration Including the Guidelines for Technical Review of Insufflator Registration

To strengthen the supervision and guidance over the medical device registration and further improve the registration review quality, National Drug Administration organized to formulate the *Guidelines for Technical Review of Insufflator Registration*, the *Guidelines for Technical Review of Medical Cryopreservation Box Registration*, the *Guidelines for Technical Review of Electronic Urinary Volume Meter Registration*, and the *Guidelines for Technical Review of Electronic Colpomicroscope Registration* which were released on April 24, 2018.

(April 24, 2018)

国家药品监督管理局发布气腹机等4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《气腹机注册技术审查指导原则》《医用低温保存箱注册技术审查指导原则》《电子尿量计注册技术审查指导原则》《电子阴道显微镜注册技术审查指导原则》，于2018年4月24日发布。

(2018-04-24)

Annual Report for National Medical Device Adverse Event Monitoring (2017) Released

On May 23, 2018, National Drug Administration issued the Annual Report for National Medical Device Adverse Event Monitoring (2017), which covers the progress of medical device adverse event (MDAE) monitoring, the overall status of MDAE reporting, statistical analysis of MDAE reports, the 2017 key MDAE monitoring, the release of MDAE Vigilance Express, and the quality assessment of MDAE reports. The Report presents a rather full-fledged reflection of China's MDAE monitoring in 2017.

By and large, in 2017, the national MDAE reporting showed a good development trend. The number of reports continued to grow and topped 370,000. The average number of reports per million population has reached 282. Among them, 326,622 reports were from user units, accounting for 86.83% of the total number of reports; and 8,655 (2.30%) were from manufacturers; 40,754 (10.83%) were from distributors; and 120 (0.03%) were from individuals. The reports involving Class III medical devices amounted to 154,192, accounting for 40.99% of the total; and 181,175 (48.16%), 25,555 (6.79%) and 15,235 (4.05%) reports were related to Class II medical devices, Class I medical devices and unknown categories of medical devices, respectively.

In 2017, a total of 1,431 key monitoring sentinel points were set up across the country; 990 investigations in various forms, 143 training sessions, and 97 expert consultation meetings were conducted; and 2.29 million monitoring data were actively collected. Furthermore, the National Center for Adverse Drug Reaction Monitoring released a total of six issues of Medical Device Vigilance Express, covering safety information of 32 products such as bioabsorbable intravascular stents and implantable cardioverter defibrillator.

图1. 2013-2017年全国医疗器械不良事件报告数量
Figure 1. Numbers of National Medical Device Adverse Event Reports from 2013 to 2017

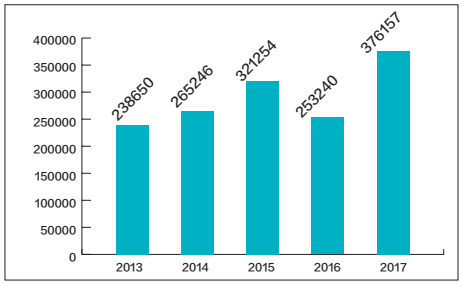
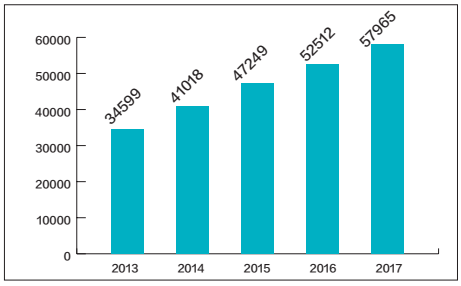


图2. 2013-2017年全国死亡及严重伤害可疑不良事件报告数比较
Figure 2. A Comparison of Numbers of Reports on Suspected Adverse Events Resulting in Death and Serious Injuries in China from 2013 to 2017



(May 23, 2018)

《国家医疗器械不良事件监测年度报告（2017年）》发布

2018年5月23日，国家药品监督管理局发布了2017年医疗器械不良事件监测年度报告，报告包括医疗器械不良事件监测工作进展、医疗器械不良事件报告总体情况、医疗器械不良事件报告统计分析、2017年重点监测工作开展情况、医疗器械警戒快讯发布情况和报告质量评估工作等内容。报告比较全面地反映了2017年我国医疗器械不良事件监测工作情况。

总体来说，2017年全国医疗器械不良事件报告工作呈良好发展态势，报告数量持续增长，已超过37万份，平均百万人口报告数已达282份。其中，使用单位上报326,622份，占总报告数的86.83%；生产企业上报8655份，占总报告数的2.30%；经营企业上报40,754份，占总报告数的10.83%；还有120份报告来自于个人，占总报告数的0.03%。涉及Ⅲ类医疗器械的报告154,192份，占总报告数的40.99%；涉及Ⅱ类医疗器械的报告181,175份，占总报告数的48.16%；涉及Ⅰ类医疗器械的报告25,555份，占总报告数的6.79%；部分报告涉及的器械管理类别不详，共15,235份，占总报告数的4.05%。

2017年，全国共设立重点监测哨点1431家，开展各种形式的调研990次，组织培训会议143次，召开专家咨询会97次，主动收集监测数据229万余条。此外，国家药品不良反应监测中心共发布6期《医疗器械警戒快讯》，包括生物可吸收性血管支架系统、植入式心脏复律除颤器等32条产品安全性信息。 (2018-05-23)

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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