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中国食品药品国际交流中心
SERVIER 施维雅（天津）制药有限公司

Issuance of *Administrative Measures for the Monitoring and Re-evaluation on the Adverse Events of Medical Devices*

To strengthen the monitoring and re-evaluation on medical device adverse events, so as to timely and effectively control the risks of post-marketed medical devices, recently, the State Administration for Market Regulation and the National Health Commission of the People's Republic of China jointly issued the Administrative Measures for the Monitoring and Re-evaluation on the *Adverse Events of Medical Devices* (SAMR Decree No. 1, hereinafter referred to as the Measures), which shall come into force as from January 1, 2019.

The *Measures* clarified the principal responsibilities of holders of marketing license for medical device; separately defined the time limits, procedures, and work requirements for reporting and evaluation in light of the essential requirements, individual adverse events, group adverse events, and periodic risk assessment reports; detailed the requirements for the holders' risk control; and stipulated that the holders should perform re-evaluation actively, strengthen the supervision and inspection of the drug regulatory authorities, and increase the punishment for violations of laws and regulations.

The *Measures* have improved the monitoring system for adverse events and strengthened the obligation of holders to report adverse events directly. The risk control requirements have also been consolidated. It is stipulated that where the product has been spotted with unreasonable risks that may endanger human health and life safety during the monitoring, the holder should take the corresponding measures, such as stopping production, implementing recall, and modifying the Instructions for Use, etc., and should timely publicize the risks related to the safe use of medical devices and corresponding disposals.

The *Measures* established the Intensive Monitoring System, which stipulates that the drug regulatory authorities at or above the provincial level can designate qualified units as the monitoring sites to actively collect the data of products being monitored. The drug regulatory authorities shall take necessary administrative measures in a timely manner against the risks found during the monitoring.

The *Measures* improved the re-evaluation system, clarified the principal responsibility of the holders to carry out re-evaluation on their own accord, and required the holders to carry out re-evaluation actively. Where the results of re-evaluation indicate that the products have defects that endanger personal safety, or the risk-benefit ratio is unacceptable, the holders shall proactively apply for cancellation of the marketing license, and make the public informed in a timely manner.

The *Measures* strengthened the supervision and inspection to severely investigate and deal with illegal acts of nonperformance of responsibilities of direct reporting. It also required that provincial drug regulatory authorities shall formulate inspection plans, clarify inspection priorities, and supervise and inspect the system construction and implementation status of adverse event monitoring performed by the holders.

(August 31, 2018)

《医疗器械不良事件监测和再评价管理办法》发布

为加强医疗器械不良事件监测与再评价，及时有效控制医疗器械上市后风险，近日，国家市场监督管理总局和国家卫生健康委员会联合发布《医疗器械不良事件监测和再评价管理办法》（总局令第1号，以下简称《办法》）。《办法》2019年1月1日起施行。

《办法》明确了医疗器械上市许可持有人的主体责任，按基本要求、个例不良事件、群体不良事件、定期风险评价报告，分别规定了报告与评价的时限、流程和工作要求，细化持有人风险控制要求，规定持有人应当主动开展再评价，并强化药品监管部门的监督检查，加大对违法违规行为的惩处力度。

《办法》完善了不良事件监测制度，强化持有人直接报告不良事件的义务。强化了风险控制要求，规定持有人在监测中发现产品存在可能危及人体健康和生命安全的不合理风险时，应当采取停止生产、实施召回、修改说明书等相应措施，并及时公布与用械安全相关的风险及处置情况。

《办法》建立了重点监测制度，明确省级以上药品监管部门可以指定具备一定条件的单位作为监测哨点，主动收集重点监测品种监测数据。药品监管部门根据监测中发现的风险及时采取必要的管理措施。

《办法》完善了再评价制度，明确持有人主动开展再评价的主体责任，要求持有人主动开展再评价，再评价结果表明产品存在危及人身安全的缺陷或者风险获益比不可接受的，持有人应当主动申请注销上市许可，并及时向社会公布。

《办法》强化了监督检查，严厉查处不履行直接报告责任的违法行为，要求省级药品监管部门制定检查计划，明确检查重点，对持有人不良事件监测制度建设和工作开展情况进行监督检查。

（2018-08-31）

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NMPA Issued the *Announcement on Adjusting the Requirements for Application Dossiers of Long-term Stability Studies of Chemical Generics*

To advance the improvement of connection of requirements for application dossiers of long-term stability studies of chemical generics to the international technical requirements, accelerate the progress of generics conformance evaluation, and encourage application of new generics, on September 4, 2018, National Medical Products Administration (NMPA) issued the *Announcement on Adjusting the Requirements for Application Dossiers of Long-term Stability Studies of Chemical Generics, which adjusted the requirements set forth in the Requirements for Application Dossiers of New Registration Classification of Chemicals (Interim)* (CFDA Announcement [2016] No. 80) and the *Requirements for Application Dossiers of Quality & Efficacy Conformance Evaluation for Chemical Generics with Oral Solid Dosage Forms (Interim)* (CFDA Announcement [2016] No. 120). Specific requirements regarding the application dossiers of stability trials are as follows:

While applying for chemical generics marketing and conformance evaluation on the quality and efficacy of generic drugs, the application dossiers shall at least include the long-term stability trial data of 6 months for three registered batch samples on the premise that the registered batch production scale meets the requirements.

(September 4, 2018)

国家药品监督管理局发布《关于调整化学仿制药长期稳定性研究申报资料要求的通告》

为加快推进化学仿制药长期稳定性研究申报资料要求与国际技术要求接轨，加快仿制药一致性评价工作进度，鼓励新仿制药申报，2018年9月4日，国家药品监督管理局发布《关于调整化学仿制药长期稳定性研究申报资料要求的通告》，调整《化学药品新注册分类申报资料要求（试行）》（国家食品药品监督管理总局通告2016年第80号）和《化学药品仿制药口服固体制剂质量和疗效一致性评价申报资料要求（试行）》（国家食品药品监督管理总局通告2016年第120号）关于稳定性试验的申报资料要求，具体如下：

化学仿制药上市申请及仿制药质量和疗效一致性评价申请时，在注册批生产规模符合要求的前提下，申报资料至少需要包括三个注册批样品6个月长期稳定性试验数据。

（2018-09-04）

NMPA Issued the *Announcement on Adjusting the Review & Approval Procedures of Drug Clinical Trials*

On July 27, 2018, NMPA issued the *Announcement on Adjusting the Review & Approval Procedures of Drug Clinical Trials*, and the content is as follows:

To encourage innovation, accelerate new drug R & D, meet the public demand for medicine, and implement the principal responsibilities of applicants in drug R&D, in accordance with the *Opinions on Deepening the Reform of Review and Approval System to Encourage the Innovation of Drugs and Medical Devices* jointly issued by the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council (General Office No. 42 [2017]), the matters related to the review & approval of drug clinical trials shall be adjusted as follows: For applications of drug clinical trials in China, an applicant can conduct the drug clinical trial as per the submitted protocols should the Center for Drug Evaluation (hereinafter referred to as CDE) of the former CFDA failed to issue an opinion of rejection or questioning within 60 days as from its acceptance of the application and the receipt of corresponding administrative fees.

The specific matters are hereby announced as follows:

I. Preparation and application of Communication Session

(I) Before application of the first drug clinical trial for the new investigational drug, an applicant shall submit an application for the Communication Session to CDE to determine the completeness of the clinical

国家药品监督管理局发布《关于调整药物临床试验审评审批程序的公告》

2018年7月27日，国家药品监督管理局发布《关于调整药物临床试验审评审批程序的公告》，内容如下：

为鼓励创新，加快新药创制，满足公众用药需求，落实申请人研发主体责任，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），对药物临床试验审评审批的有关事项作出调整：在我国申报药物临床试验的，自申请受理并缴费之日起60日内，申请人未收到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）否定或质疑意见的，可按照提交的方案开展药物临床试验。

现就具体事宜公告如下：

一、沟通交流会议的准备与申请

（一）申请人在提出新药首次药物临床试验申请之前，应向药审中心提出沟通交流会议申请，并在确保受试者安全的基础上，确定临床试验申请资料的完整性、实施临床试验的可行性。

（二）申请人准备的沟通交流会议资料应包括临床试验方案或草案、对已有的药学

trial application dossiers and the feasibility of the trial on the basis of guaranteeing the safety of subjects.

(II) The dossiers of Communication Session prepared by an applicant shall cover clinical trial protocol or draft protocol, and a complete summary of existing pharmaceutical and non-clinical study data and other research data.The applicant shall, on his/her own, evaluate the compliance of the existing study with the postulates for the application of clinical trial to be implemented, and identify the issues to be discussed with CDE.

(III) An applicant shall submit the Application Form for Communication Session (Annex 1) in term of the Administrative Measures for Communication between Drug R&D and Technical Review (Interim) (hereinafter referred to as the Measures for Communication). CDE shall timely notify the applicant of its approval of the Communication Session and negotiate with the applicant on the timetable. The applicant shall submit in a timely manner the complete dossiers (see Annex 2) for the Communication Session in accordance with the relevant requirements for communication. CDE shall conduct preliminary review on the dossiers for Communication Session and notify the applicant of the corresponding opinions and Q&A via the "Applicant Window" at least two days before the convening of Communication Session. Upon receipt of the preliminary review opinions and Q&A, the applicant shall feedback as soon as possible whether the questions thereof have been addressed. Where the applicant deems that the questions have been addressed and there is no need for a Communication Session, it shall, through the "Applicant Window" on CDE website, notify CDE to cancel the application for Communication Session; otherwise, the applicant shall continue to organize the Session as scheduled.

II. Convening of Communication Session

(IV) The Session shall be presided over by CDE. The two parties shall discuss the key technical questions raised by the applicant as per the drug clinical trial protocol, whether the existing dossiers and data support the implementation of a clinical trial and whether the subject safety risks are controllable, and propose requirements and suggestions for follow-up studies.

(V) For the Communication Session, conference minutes shall be formed in term of the "Measures for Communication". Where the existing dossiers and data or supplemented and improved dossiers and data can support the implementation of clinical trials, the applicant can submit an application for clinical trials after the Communication Session or after supplementing dossiers and data. Where the existing dossiers and data have major defects and the clinical trial protocol is incomplete or the risk control measures are unable to guarantee the safety of subjects in clinical trials, the applicant shall analyze the reasons and carry out the relevant study. The conference minutes shall be filed as the review documents and shall be used as a reference for review and approval.

III. Acceptance, review & approval of clinical trial application

(VI) The applicant shall submit the application for the first clinical trial of new investigational drug and the application dossiers in accordance with the relevant requirements. For the application for Phase I clinical trial, the dossiers specified in Annex 3 of the Announcement shall also be submitted.

CDE shall complete the formal review within 5 days upon the receipt of application

和非临床研究数据及其他研究数据的完整总结资料。申请人应自行评估现有的研究是否符合申报拟实施临床试验的基本条件，并明确拟与药审中心讨论的问题。

（三）申请人应按照《药物研发与技术审评沟通管理办法（试行）》（以下简称《沟通交流办法》）要求，提交沟通交流会议申请表（附件1）。药审中心应及时通知申请人是否召开沟通交流会议，并与申请人商议会议时间。申请人应按沟通交流相关要求按时提交完整的沟通交流会议资料（附件2）。药审中心对沟通交流会议资料进行初步审评，在沟通交流会议召开至少2日前，通过“申请人之窗”将初步审评意见和对申请人所提出问题的解答意见告知申请人。申请人在收到初步审评意见和解答意见后，应尽快反馈问题是否已经得到解决。申请人认为问题已经解决不需要召开沟通交流会议的，应通过药审中心网站“申请人之窗”告知药审中心取消沟通交流会议申请；申请人认为申请沟通交流的问题仍未得到解决的，按原定计划继续组织会议召开。

二、沟通交流会议的召开

（四）会议由药审中心工作人员主持，双方围绕药物临床试验方案就申请人提出的关键技术问题，以及已有资料和数据是否支持实施临床试验开展和受试者安全风险是否可控进行讨论，并为后续研究提出要求和建议。

（五）沟通交流会议应按《沟通交流办法》要求形成会议纪要。现有资料、数据或补充完善后的资料、数据能够支持开展临床试验的，申请人即可在沟通交流会议之后或补充资料和数据后提出临床试验申请。现有资料和数据存在重大缺陷，临床试验方案不完整或风险控制措施无法保障临床试验受试者安全的，申请人应分析原因并开展相关研究工作。会议纪要作为审评文档存档，并作为审评和审批的参考。

三、临床试验申请的受理与审评审批

（六）申请人应按照相关要求提交新药首次临床试验申请和申报资料。其中对于I期临床试验申请，还应提交本公告附件3中载明的资料。

药审中心在收到申报资料后5日内完成形式审查。符合要求或按照规定补正后符合要求的，发出受理通知书。

受理通知书应载明：自受理缴费之日起60日内，未收到药审中心否定或质疑意见的，申请人可以按照提交的方案开展临床试验。

dossiers. Where the application dossiers or those after supplementation and revision as required meet the requirements, a Notice of Acceptance shall be issued.

Notice of Acceptance shall state that: An applicant can conduct the drug clinical trial as per the submitted protocol should the CDE failed to issue an opinion of rejection or questioning within 60 days as from its acceptance of the application and receipt of the corresponding administrative fees.

Upon commencement of a clinical trial, the applicant shall log on the website of CDE and register the relevant information on the "Registration and Information Disclosure Platform for Drug Clinical Trials".

(VII) Where the application dossiers meet the review requirements, but there is relevant information that needs to remind the applicant, CDE shall notify the applicant within 60 days upon the acceptance and payment, stating the relevant requirements and precautions. The applicant shall inquire and download the notice or reminder related to clinical trial application through the portal website of CDE.

(VIII) Where the accepted application dossiers do not meet the technical review requirements, CDE may give a one-time notification to the applicant of all the content that needs to be supplemented and revised through communication session or supplementary dossiers. The applicant shall submit in the one-time manner the supplementary dossiers within 5 days upon the receipt of such notification. An applicant can conduct the drug clinical trial as per the improved protocol should CDE failed to issue an opinion of rejection or questioning within 60 days as from its acceptance of the application and receipt of the corresponding administrative fees. Where the applicant fails to supplement dossiers within the time limit or the supplementary dossiers still cannot meet the review requirements, CDE may notify the applicant via a Notice of Pending Clinical Trial with a list of corresponding reasons.

(IX) Where there are major defects in application dossiers, or the clinical trial protocol is incomplete, or the safety of subjects in clinical trials cannot be guaranteed due to the lack of reliable risk control measures, or there are potential clinical risks, CDE may notify the applicant via a Notice of Pending Clinical Trial with a list of corresponding reasons. Before making such a decision, CDE shall communicate with the applicant. The applicant can inquire and down the Notice of Pending Clinical Trial on the portal website of CDE.

(X) Once the problems listed in the Notice of Pending Clinical Trial are resolved, the applicant can submit a written application to CDE for reply and resumption of clinical trial application. CDE shall provide, within 60 days upon the receipt of application, reply of its consent or rejection. The replies shall include the decision to approve the resumption of clinical trials or continue the implementation of suspended clinical trials, and the reasons thereof. The applicant shall not conduct the clinical trials until receiving such a written reply from CDE. Should any objection to the Notice of Pending Clinical Trial arise and it cannot be solved through communication, the applicant may apply for holding an Expert Consultation Conference or an open expert argumentation.

IV. Other relevant issues

(XI) For an application for international multicenter clinical trial with clear technical guidance, mature research experience in drug clinical trials, the applicant's guarantee of the quality of application dossiers, or synchronous R&D across countries, and approvals for implementation in countries and regions with developed regulatory system, the applicant may directly submit the application for clinical trials without the communication session.

临床试验开始时，申请人应登陆药审中心门户网站，在“药物临床试验登记与信息公示平台”进行相关信息登记。

（七）对于申报资料符合审评要求，但有相关信息需要提醒申请人的，药审中心应在受理缴费后60日内通知申请人，列明相关要求和注意事项。申请人应通过药审中心门户网站查询和下载临床试验申请相关通知或提醒。

（八）对于已受理的申报资料不符合审评技术要求的，药审中心可通过沟通交流或补充资料方式一次性告知申请人需要补正的全部内容，申请人应在收到补充资料通知之日起5日内一次性提交补充资料。申请人补充资料后在该申请受理缴费之日起60日内未收到药审中心其他否定或质疑意见的，可按照完善后的方案开展临床试验。申请人未按时限补充资料或补充资料仍不能满足审评要求的，药审中心以暂停临床试验通知书方式通知申请人，并列明目前尚不具备开展临床试验的原因。

（九）对于申报资料存在重大缺陷，或临床试验方案不完整的，或缺乏可靠的风险控制措施、存在潜在的临床风险而无法保障临床试验受试者安全的，药审中心以暂停临床试验通知书方式通知申请人，说明目前不支持开展临床试验的理由。药审中心在作出暂停临床试验决定前，应与申请人沟通交流。申请人可通过药审中心门户网站查询和下载暂停临床试验通知书。

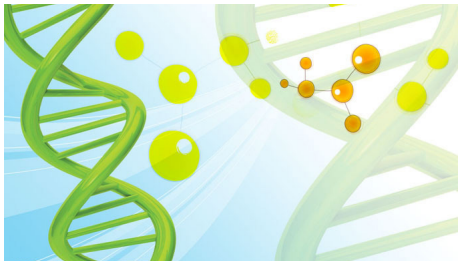
（十）申请人在解决了暂停临床试验通知书中所列问题后，可向药审中心书面提出答复和恢复临床试验申请。药审中心在收到申请之日起60日内提出是否同意的答复意见。答复意见包括同意恢复临床试验或继续执行暂停临床试验决定，并说明理由。申请人应在收到药审中心书面答复同意恢复意见后方可开展临床试验。申请人对暂停临床试验通知书有异议且无法通过沟通交流解决的，可申请召开专家咨询会或专家公开论证会。

四、其他有关事项

（十一）对于技术指南明确、药物临床试验有成熟研究经验，申请人能够保障申报资料质量的，或国际同步研发的国际多中心临床试验申请，在监管体系完善的国家和地区已经获准实施临床试验的，申请人可不经沟通交流直接提出临床试验申请。

（十二）已获准开展新药临床试验的，在完成Ⅰ期、Ⅱ期临床试验后、开展Ⅲ期临床试验之前，申请人应向药审中心提出沟通交流会议申请，就包括Ⅲ期临床试验方案设

(XII) Where the application for clinical trial of new investigational drug has been approved, upon the completion of Phases I and II clinical trials and prior to Phase III clinical trial, the applicant shall submit the application for Communication Session to CDE to discuss with CDE the key technical questions including the design of Phase III clinical trial protocol. The applicant may also submit application for communication on key technical questions at different phases of clinical R&D.



(XIII) Where there is an application for adding new indications during the period of approved clinical trials, the applicant may either submit a new application for clinical trial, or submit application for communication in accordance with the Measures before a decision is made. In case of submitting a new application for clinical trial, the dossiers that are duplicated with the first submission may be exempted from this submission, but the number of relevant dossiers in the first submission shall be indicated in the application dossiers.

(XIV) In case of any changes, such as the change of clinical trial protocol and major pharmaceutical changes, and significant safety discoveries in non-clinical studies, that may increase the safety risks of subjects, the applicant shall submit with the least delay possible a supplementary application as required. CDE shall complete the technical review within the specified time limit and notify, as fit, the applicant to revise the clinical trial protocol, suspend or terminate the clinical trial.

(XV) After obtaining the approval for the first clinical trial, an applicant shall submit periodic safety update report to CDE during drug R&D, including global R&D and marketing status, the ongoing and completed clinical trials, the new safety consequences, major production changes, overall safety assessment, summaries of significant risks, benefit-risk assessment and overall research plans for the next year (usually once a year, within two months of each full year after the approval of the drug clinical trial). CDE may require the applicant to adjust the reporting period as per the review. Where the report fails to be submitted within the time limit, the applicant shall suspend the drug clinical trial.

(XVI) In case of any suspected and unexpected serious adverse reactions and significant safety risk signals suggested by toxicological studies during drug clinical trials, the applicant shall submit (case by case) safety reports to CDE pursuant to relevant requirements in the Standards and Procedures for Expedited Reporting of Safety Data during Drug Clinical Trials. As per the review, CDE may require that the applicant revise clinical trial protocol, and if necessary, suspend clinical trials.

(XVII) The applicant shall submit the dossiers and data required for the review on time, ensure their quality, and accept the supervision and inspection on the R&D process by the regulatory authorities.

(XVIII) The time limit specified in the Announcement shall be calculated on the weekday basis.

(XIX) The Announcement shall come into effect on the date of promulgation, and shall prevail where inconsistencies arise with former Announcements. (July 27, 2018)

计在内的关键技术问题与药审中心进行讨论。申请人也可在临床研发不同阶段就关键技术问题提出沟通交流申请。

（十三）在已获准开展的临床试验期间，申请增加新适应症的，可提出新的临床试验申请，也可按此办法先提出沟通交流申请后决定。提出新的临床试验申请的，申请时与首次申请重复的资料可免于提交，但应当在申报资料中列出首次申请中相关资料的编号。

（十四）对于变更临床试验方案、重大药学变更、非临床研究重要安全性发现等可能增加受试者安全性风险的，申请人应按相关规定及时递交补充申请。药审中心应在规定时限内完成技术审评，并可视技术审评情况通知申请人修改临床试验方案、暂停或终止临床试验。

（十五）申请人在获得首次临床试验许可后，应定期向药审中心提供药物研发期间安全性更新报告，包括全球研发和上市状况、正在进行中和已完成的临床试验、新增的安全性结果、重大生产变更、整体安全性评估、重要风险总结、获益-风险评估和下一年总体研究计划等内容。一般每年一次，于药物临床试验许可后每满一年后的二个月内提交。药审中心可以根据审查情况，要求申请人调整报告周期。逾期未提交的，申请人应暂停药物临床试验。

（十六）对于药物临床试验期间出现的可疑且非预期严重不良反应和毒理研究提示重大安全性风险信号，申请人应按照《药物临床试验期间安全性数据快速报告标准和程序》中相关要求向药审中心递交（个例）安全性报告。药审中心可以根据审查需要，要求申请人修改临床试验方案，必要时暂停临床试验。

（十七）申请人应按时递交审评需要的资料与数据，保证质量，并接受监管部门对研发过程的监督检查。

（十八）本公告中规定的期限以工作日计算。

（十九）本公告自发布之日起实施，此前与本公告不一致的以本公告为准。

（2018-07-27）

Medical Devices

NMPA Issued the Guidance for Technical Review of Three Registrations of Nasal Feeding Nutritional Catheters and Others

To strength the supervision and guidance over the registration of medical device products and further improve the quality of registration review, NMPA formulated and released on September 4, 2018 the *Guidance for Technical Review on the Registration of Nasal Feeding Nutritional Catheters (2018 Revision), Guidance for Technical Review on the Registration of Disposable Sterile Catheters (2018 Revision),* and the *Guidance for Technical Review on the Registration of Customized Denture (2018 Revision).*

(September 4, 2018)

NMPA Issued the Announcement on Revising the Requirements for Application Dossiers of Medical Device Registration Renewal and Others

To implement 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 (General Office [2017] No. 42), and the State Council's requirements for deepening the reform of "Streamlining Administration, Delegating More Powers to Lower-level Governments and Society, Improving Regulation and Optimizing Services", further simplify and optimize the registration renewal for medical devices and review and approval of clinical trials, improve the review & approval efficiency, NMPA has organized revisions of the requirements for application dossiers of medical device registration renewal, etc., and issued an Announcement on August 23, 2018, which shall be implemented as from the date of issuance. (August 23, 2018)

NMPA Office Issued the *Notice on Strengthening the Management of Medical Device Production & Distribution Licensing (Record-filling) Information*

To continuously improve the medical device production & distribution licensing (record-filling), strengthen the management of information thereof, and facilitate regulatory authorities and enterprises to use the "Medical Device Production & Distribution Licensing (Record-filling) Information System", so as to adapt to the provisions for medical device administration, on August 2, 2018, NMPA Office issued the above Notice, requiring the food and drug administrations of all provinces, autonomous regions and municipalities directly under the Central Government, the Xinjiang Production and Construction Corps to effectively adjust, disclose and upload the information of medical device production & distribution (record-filling). (August 2, 2018)

医疗器械

国家药品监督管理局发布鼻饲营养导管等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《鼻饲营养导管注册技术审查指导原则（2018年修订）》《一次性使用无菌导尿管注册技术审查指导原则（2018年修订）》《定制式义齿注册技术审查指导原则（2018年修订）》，于2018年9月4日发布。 (2018-09-04)

国家药品监督管理局发布《关于修改医疗器械延续注册等部分申报资料要求的公告》

为贯彻中共中央办公厅、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），贯彻实施国务院深化“放管服”改革要求，进一步简化、优化医疗器械延续注册、临床试验审批，提高审评审批效率，国家药品监督管理局组织修改了医疗器械延续注册等部分申报资料要求，于2018年8月23日发布，自发布之日起施行。 (2018-08-23)

国家药品监督管理局办公室发布《关于加强医疗器械生产经营许可（备案）信息管理有关工作的通知》

为不断完善医疗器械生产经营许可（备案）工作，加强医疗器械生产经营许可（备案）信息管理，方便监管部门和企业使用“医疗器械生产经营许可（备案）信息系统”，适应医疗器械有关管理工作的要求，2018年8月2日，国家药品监督管理局办公室发布《关于加强医疗器械生产经营许可（备案）信息管理有关工作的通知》，要求各省、自治区、直辖市食品药品监督管理局，新疆生产建设兵团食品药品监督管理局做好医疗器械经营许可（备案）信息有关内容调整工作；做好医疗器械生产经营许可（备案）信息公开工作；做好医疗器械生产经营许可（备案）信息上传工作。 (2018-08-02)

Plan on ICH Guideline Worshops for the Second Half of 2018

《2018年下半年ICH指导原则培训和技术研讨会计划》

序号 NO.	会议名称 Meeting Name	时间 Time	地点 Venue	主办单位 Organizer	参加人员 Attendee
1	ICH M4通用技术文件(CTD)指南 Workshop on Common Technical Document (ICH M4)	2018.09.07–09.08 Sep 7-8, 2018	烟台 Yantai	中国药学会 Chinese Pharmaceutical Association	社会相关从业人员 Industry
2	ICH Q8-Q11专题研讨会 Workshop on ICH Q8-Q11	2018.09.15–09.17 Sep 15-17, 2018	北京 Beijing	ICH工作办公室；美国东北大学 Office of ICH Affairs; Northeastern University of the United States	监管机构相关人员 Regulatory Authority
3	ICH产品生命周期管理的技术和法规考虑指南（Q12）研讨会 Workshop on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management (ICH Q12)	2018.09.19 Sep 19, 2018	北京 Beijing	中国食品药品国际交流中心 China Center for Food and Drug International Exchange	社会相关从业人员 Industry
4	E2系列研讨会 A Series of Workshops on E2	2018.09.27–09.28 Sep 27-28, 2018	南京 Nanjing	中国药学会 Chinese Pharmaceutical Association	社会相关从业人员 Industry
5	ICH 通用技术文件（M4）指南研讨会 Workshop on Common Technical Document (ICH M4)	2018.09.27–09.28 Sep 27-28, 2018	泰州 Taizhou	中国食品药品国际交流中心 China Center for Food and Drug International Exchange	社会相关从业人员 Industry
6	ICH活性药物成分的GMP（Q7）指南研讨会 Workshop on Good Manufacturing Practice（GMP） Guide for Active Pharmaceutical Ingredients (ICH Q7)	2018.10.18 Oct 18, 2018	南京 Nanjing	中国食品药品国际交流中心；核查中心 China Center for Food and Drug International Exchange; Center for Food and Drug Inspection	社会相关从业人员 Industry
7	ICH M4通用技术文件(CTD)指南研讨会 Workshop on Common Technical Document (ICH M4)	2018.10.26–10.27 Oct 26-27, 2018	北京 Beijing	ICH工作办公室；中国药学会 Office of ICH Affairs; Chinese Pharmaceutical Association	监管机构相关人员 Regulatory Authority
8	ICH药典内容的评估（Q4B）指南研讨会 Workshop on Evaluation of Pharmacopoeial Texts (ICH Q4B)	2018.10.27–10.28 Oct 27-28, 2018	北京 Beijing	CH工作办公室；中国食品药品国际交流中心；国家药典委员会 Office of ICH Affairs; China Center for Food and Drug International Exchange；Chinese Pharmacopoeia Commission	监管机构相关人员 Regulatory Authority
9	ICH临床试验的一般考虑（E8）、临床试验的统计学原则（E9）指南研讨会 Workshop on General Considerations for Clinical Trails (ICH E8) and Statistical Principles for Clinical Trails (ICH E9)	2018.11.17-11.18 Nov 17-18, 2018	北京 Beijing	中国食品药品国际交流中心 China Center for Food and Drug International Exchange	社会相关从业人员 Industry
10	ICH伦理因素、临床实验质量管理规范、国际多中心临床试验（E5、E6、E17）指南研讨会 Workshop on Ethnic Factors, Good Clinical Practice (GCP) and Multi-Regional Clinical Trails (ICH E5, E6, E17)	2018.12.08–12.09 Dec 8-9, 2018	Beijing 北京	中国食品药品国际交流中心 China Center for Food and Drug International Exchange	社会相关从业人员 Industry
11	与ICH E2B（R3）相关的药物警戒（PV）数据管理研讨会（一） Workshop on Pharmacovigilance Data Management related to ICH E2B (R3) (I)	待定 TBD	北京 Beijing	药物信息协会（DIA）；ICH工作办公室 DIA; Office of ICH Affairs	社会相关从业人员 监管机构相关人员 Industry; Regulatory Authority
12	与ICH E2B（R3）相关的药物警戒（PV）数据管理研讨会（二） Workshop on Pharmacovigilance Data Management related to ICH E2B (R3) (2)	待定 TBD	北京 Beijing	药物信息协会（DIA）；ICH工作办公室 DIA; Office of ICH Affairs	社会相关从业人员 监管机构相关人员 Industry; Regulatory Authority

(September 5, 2018)

（2018-09-05）

Notes:
- All Chinese information in the Newsletter is extracted from newspapers and the Internet. All English articles are translations from the Chinese version.
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