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NEWS

SFDA Commissioner Shao Mingli meets Vice President Cabrisas of the Council of Ministers of Cuba and his entourage On the afternoon of December 26, 2011, Shao Mingli, Commissioner of SFDA, met with the visiting Mr. Ricardo Cabrisas Ruiz, Vice President of the Council of Ministers of Cuba, and his entourage in Beijing. Both sides gladly reviewed the longtime and effective cooperation in the medicine and health field between both governments and discussed relevant issues on biomedicine. (December 28, 2011)

SFDA Commissioner Shao Mingli Meets with Vice President of the Legislative Institution of Indonesian Congress and her entourage On the afternoon of December, 7, 2011 SFDA Commissioner Shao Mingli met with the visiting Vice President of the Legislative Institution of Indonesian Congress and her entourage, the two sides exchanged views on the laws and regulations for food safety, the administration of drugs and medical devices etc. (December 9, 2011)

National Health Conference held in Beijing On January 5, 2012, the National Health Conference was held in Beijing. The meeting summarized the Health Work in 2011, and deployed the work tasks of 2012.

Health Minister Chen Zhu summarized and reviewed the Health Work in 2011. He pointed out that the year of 2011 has been an essential year to implement the recent Five Key Tasks of Healthcare Reform, and also the first year of the "12th Five-Year Plan" for health development. During this year, the smooth progress of healthcare reform and various health works have played an important role in safeguarding public health interests, and promoting the coordinated economic and social development.

Chen Zhu pointed out that in 2012, the health sector should focus on the deepening of healthcare reform, and promote the implementation of various health tasks. The annual tasks of reform should be implemented to construct a good beginning for the healthcare reform in the "12th Five-Year Plan" Period, which include: further improving the reimbursement level of new rural cooperative medical care system, reinforcing and improving the comprehensive reform of the grass-roots health institutions, further improving the national essential drug system, actively promoting the reform of public hospitals, and promoting the gradual equalization of basic public health services. (January 9, 2012)

2012 National Food and Drug Medical Device Inspection Teleconference held in Beijing On December 28, 2011, the 2012 National Food and Drug Medical Device Inspection Teleconference was held in Beijing, SFDA Deputy Commissioner Bian Zhenjia attended the meeting and delivered an important speech.

It was noted that in 2011, China National Institute for Food and Drug Control has conducted registration inspection, import inspection, supervision testing of 13,000 batches of test samples. In the evaluative testing of national drugs, a total of 211 species and nearly 30,000 batches of samples are extracted, with a pass rate of 96.82%; more than 25,000 batches of essential drugs samples are extracted, with a pass rate of 97%.

In 2011, the national drug testing system has completed the full- coverage sampling test of essential drugs, and provided scientific data supports to protect the quality of essential drugs and accurately evaluate the drug safety situation. At present, China has established a relatively complete pharmaceutical supply system, as well as a basic safety supervision system covering the whole process of drug research and development, production and circulation, drug safety status and drug safety assurance level are significantly improved.

Deputy Commissioner Bian Zhenjia fully affirmed the remarkable achievements of food and drug medical device inspection, and pointed out that the inspection work should actively seize the technology high ground in strategic emerging industries, and speed up the construction of food and drug medical device inspection system to keep abreast of the international standards. (January 4, 2012)

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National Food and Drug Regulatory Working Conference Held in Beijing

On December 20, 2011, the 2012 National Food and Drug Regulatory Working Conference was held in Beijing. Li Keqiang, Member of the Standing Committee of the Political Bureau of the Central Committee of the CPC, Vice Premier of State Council gave important instructions for the Conference. Health Minister Chen Zhu presented and made an important speech. Shao Mingli, SFDA Commissioner delivered the work report at the conference. The Conference summarized the work in 2011, analyzed the current regulatory situation, and deployed major tasks in 2012. The Conference urged the full implementation of the "12th Five-Year" Plan to accelerate the infrastructure building for long-term stability of food and drug safety.

The important instructions from Vice Premier Li Keqiang, Member of the Standing Committee of the Political Bureau of the Central Committee of the CPC, were announced at the Conference. Li Keqiang pointed out that in 2011, the national food and drug administration system has promoted the implementation of the special campaign on catering industry and food & drugs, protected the safety of essential drugs, improved the regulatory mechanism, performed a great deal of works and achieved positive progresses. Next year shall be a very important year for China's development process, the tasks for the deepening of healthcare reform and the strengthening of food and drug administration are very prominent. We shall thoroughly implement the scientific development outlook, vigorously practice the scientific administration concept, innovate institutional mechanisms to improve the integrity and effectiveness of the administration, and further reinforce the crackdown and punishment of illegal additives and counterfeit drugs, eliminate hidden dangers, prevent and control risks to ensure public food and drug safety, and ensure the continuous stability and improvement of food and drug safety situations.

Health Ministry Chen Zhu fully affirmed in his speech the remarkable achievements of food and drug administration in 2011, and raised requirements for food and drug administration tasks in 2012.

SFDA Commissioner Shao Mingli reviewed the 2011 food and drug administration works in his work report, pointed out that in 2011, the national food and drug administration system has actively promoted the implementation of the "12th Five-Year Plan", the quality control of essential drugs, the special campaign on food and drug safety and other major special works of national significance, and achieved remarkable results; strengthened the routine regulation on catering services, food and drugs, health foods, cosmetics and medical devices; improved food and drug regulatory levels; and achieved new progresses in legal system & responsibility system construction, technical support, internationalization of administration and other aspects. The various works proceeded solidly have further consolidated the stable improvement of food and drug safety situation.

Commissioner Shao Mingli stressed that the year of 2012 is of vital importance for the full implementation of the "12th Five-Year Plan", and the promotion of new phase of healthcare reform, we should concentrate on the following aspects: First, improve the regulatory systems and mechanisms to strengthen the standardized constructions. Strengthen the regulatory system construction and the research on policies and theories; deepen the evaluation & approval system reform; strictly implement the accountability system. Second, improve the level of scientific administration, prevent and control food and drug safety risks. Enhance the overall quality control levels for standards and technical specifications; improve quality management system; conscientiously implement the revised pharmaceutical GMP; strengthen the information technology construction. Third, severely crack down on behaviors breaking laws and regulations, and intensify efforts to

全国食品药品监督管理工作会议在京召开

2011年12月20日，2012年全国食品药品监督理工作会议在北京召开。中共中央政治局常委、国务院副总理李克强对会议的召开作出重要批示。卫生部部长陈竺到会并作重要讲话。国家食品药品监管局局长邵明立作工作报告。会议总结了2011年工作，分析了当前监管形势，部署了2012年重点任务。会议要求，全面实施“十二五”规划，加快夯实食品药品安全长治久安的基础。

会议宣读了中共中央政治局常委、国务院副总理李克强对会议召开作出的重要批示。李克强指出，2011年，全国食品药品监管系统深入推进餐饮食品和药品专项整治，保障基本药物安全，完善监管机制，做了大量工作，取得了积极进展。明年是我国发展进程中十分重要的一年，深化医改、加强食品药品监管的任务都很重。希望大家深入贯彻落实科学发展观，大力践行科学监管理念，创新体制机制，提高监管的系统性和有效性，进一步加大对非法添加和假药等的整治打击力度，排除隐患，防控风险，确保公众饮食用药安全，确保食品药品安全形势持续稳定好转。

卫生部陈竺部长在讲话中充分肯定了2011年食品药品监管工作取得的显著成效，并对2012年食品药品监管工作提出了要求。

国家食品药品监管局邵明立局长在工作报告中回顾了2011年食品药品监管工作，指出2011年全国食品药品监管系统积极推进“十二五”规划、基本药物质量监管、食品药品安全专项整治这些事关全局的重大专项工作，取得了明显成效。强化餐饮服务食品、药品、保健食品、化妆品、医疗器械日常监管工作，提升食品药品监管水平，在法制建设、责任体系建设、技术支撑、监管国际化等方面取得了新进展。各项工作扎实推进，进一步巩固了食品药品安全稳中向好的形势。

邵明立局长强调，2012年是全面实施“十二五”规划的关键之年，也是推进新一阶段医药卫生体制改革的重要之年，要着重抓好以下几项工作：一是完善监管制度机制，加强规范化建设。加强法规制度建设；加强政策理论研究；深化审评审批机制改革；严格责任追究。二是提高科学监管水平，防控食品药品安全风险。整体提

investigate such cases. Continue to combat illegal additives in catering services, health foods and cosmetics; maintain severe punishment measures against counterfeit drugs; regulate online drug transactions and information release; and continue to strengthen the review and management of advertisements. Fourth, strictly regulate essential drugs to ensure quality and safety. Lay emphasis on administration focuses; accelerate the promotion of electronic monitoring; and enhance the ability and level of adverse reactions monitoring. Fifth, strengthen the construction of cadre teams and honest government to ensure the implementation of the administration tasks.

(December 22, 2011)

升标准和技术规范的质量控制水平；健全质量管理体系；认真做好新修订药品GMP实施工作；加强信息化建设。三是严厉打击违法违规行为，加大案件查办力度。继续打击餐饮服务环节、保健食品、化妆品非法添加行为；保持打击假药高压态势；规范互联网药品交易和信息发布；继续加强广告审查管理。四是严格基本药物监管，确保质量安全。突出监管重点；加快推进电子监管；提升不良反应监测能力和水平。五是加强干部队伍和党风廉政建设，保障监管任务落实。 （2011年12月22日）

Food and Drug Administration Departments' special campaign on Drug Safety achieved remarkable results

On December 29, the National Teleconference on the Summarization of the Special Campaign on Drug Safety was held in Beijing, marking the successfully accomplishment of the Drug Safety Special Campaign for a period of two and a half years. SFDA Deputy Commissioner Bian Zhenjia reported the work status of the Food and Drug Administration Departments during the Drug Safety Special Campaign.

Deputy Commissioner Bian Zhenjia stated that, after two and a half years of Special Campaign, 1. The effect of cracking down on producing and selling fake drugs is obvious; 2. The strict prohibition of non-pharmaceutical drugs posing as pharmaceutical drugs has achieved good results; 3. Drug production supervision has been strengthened to protect the quality and safety of drugs; 4. New models have been explored for the evaluation and approval of drugs and medical devices; 5. The quality management standards for the production and distribution of drugs become more complete; 6. The management of the purchasing and distribution channels of drugs has been gradually standardized; 7. The monitoring of adverse drug reactions has been strengthened to strictly control drug safety risks; 8. The electronic monitoring system for drugs has been established to improve the level of supervision.

In the next stage, food and drug administration departments will further strengthen the close collaboration of Health, Public Security, Industry and Information Technology, Industry and Commerce, Traditional Chinese Medicine and other Departments, to give full play of the inter-ministerial coordination mechanism of 13 ministries and commissions on the fight against the production and sales of counterfeit drugs, continue to crack down with high intensity on the production and sales of counterfeit drugs; launch centralized special campaigns on the purchasing, consigning, and sales of drugs via the Internet; launch special campaigns on the illegal chemical additives of health foods, and prohibited or prescribed substance of cosmetics; launch special campaigns on illegal processing upon commissions and other illegal actions; and reinforce the regulation of illegal drug advertising. Further strengthen the supervision on the research and development, the production and distribution of drugs, improve the level of production and supply of national essential drugs and the quality assurance standards. Promote the credit system construction of pharmaceutical enterprises to further construct and improve the responsibility system of drug safety and long-term drug safety mechanism, to ensure public drug safety and effectiveness.

(December 31, 2011)

食品药品监管部门药品安全专项整治工作取得明显成效

12月29日，全国药品安全专项整治工作总结电视电话会议在京召开，为期两年半的药品安全专项整治工作圆满结束。国家食品药品监督管理局副局长边振甲向会议通报了食品药品监管系统在药品安全专项整治期间的工作情况。

边振甲副局长表示，经过两年半的专项整治，一是严厉打击生产销售假药行为效果明显；二是大力整治非药品冒充药品行为成果显现；三是加强药品生产监管，保障药品质量安全；四是探索药品和医疗器械审评审批工作新模式；五是药品生产经营质量管理规范更加完善；六是药品购销渠道管理逐步规范；七是加强药品不良反应监测，严密控制药品安全风险；八是建立药品电子监管制度，提高监管水平。

下一阶段，食品药品监管部门将进一步加强与卫生、公安、工信、工商、中医药部门密切协作，发挥13部门打击生产销售假药部际协调联席会议机制作用，继续保持打击制售假药高压态势，集中开展打击利用互联网收购药品、通过网络联系采用寄递形式销售药品的专项行动，开展打击保健食品非法添加化学药物成分及化妆品违法使用禁限用物质专项行动，开展打击非法委托加工等违法违规行动，继续加大药品违法广告整治力度。进一步加强药品研制生产流通环节监管，提高国家基本药物生产供应和质量保障水平。推进药品生产经营企业诚信体系建设，进一步建立健全药品安全责任体系及药品安全长效机制，确保公众用药安全有效。

（2011年12月31日）

National Drug Safety Supervision Working Conference convened

From January 12 to 13, 2012, the National Drug Safety Supervision Working Conference was held in Hefei, SFDA Deputy Commissioner Wu Zhen attended the meeting and delivered a speech.

Deputy Commissioner Wu Zhen stated that in 2011, the national drug safety supervision has made remarkable achievements, the tendency of frequent drug safety accidents in previous years has been effectively curbed, and the current drug safety situation is generally stable, showing a good momentum of continuous development.

Wu Zhen pointed out that the current drug safety supervision work is facing unprecedented opportunities and challenges, to address the major problems existing in the current drug production and distribution, SFDA had decided to launch a centralized special campaign on the regulation of drug production and distribution in the first half of 2012; this year we aim to improve relevant rules and regulations and lay a solid foundation for drug safety supervision system; SFDA shall further clarify the responsibilities of the 4-tier drug administration institutions, establish a joint-action system, organize the research on the division of responsibilities, the objectives and tasks of the 4-tier drug administration institutions, and earnestly implement the accountability system; the coordination and cooperation of the safety supervision departments with the registration and inspection departments etc. shall be strengthened to form a complete chain of supervision; the drug GMP certification and inspection system shall be improved, and a scientific and rational drug GMP inspector appointment and evaluation mechanism shall be established; the Major Events Reporting System and Regulatory Information Disclosure System shall be established and improved. In this year, we shall also seize the opportunity, focus on the promotion and implementation of drug GMP, drug circulation supervision, essential drugs' quality control, electronic monitoring and other work priorities.

At the meeting, principal leaders of SFDA Drug Safety Supervision Department deployed the key tasks of drug safety supervision in 2012. (January 16, 2012)

全国药品安全监管工作会议召开

2012年1月12至13日，全国药品安全监管工作会议在合肥召开，国家食品药品监管局副局长吴浈出席会议并讲话。

吴浈副局长表示，2011年，全国药品安全监管工作取得了显著成绩，有效遏制了前些年药品安全事故频发的势头，药品安全形势总体平稳，呈现稳中向好的良好势头。

吴浈指出，当前药品安全监管工作面临着前所未有的机遇和挑战，为解决当前药品生产流通领域存在的突出问题，国家食品药品监督管理局决定在今年上半年开展一次全国药品生产流通领域的集中整治行动；今年要夯实基础，完善药品安全监管规章制度：要进一步明确四级监管机构的职责并建立联动机制，国家食品药品监督管理局将组织研究全国四级药监机构的职责分工、目标任务，切实落实责任制；要加强安监与注册、稽查等部门的衔接配合，形成完整的监管链条；要完善药品GMP认证检查制度，建立科学合理的药品GMP检查员聘任及考评机制；要建立健全重大事项报告制度以及监管信息公开制度。另外，今年还要抓住机遇，着力推动药品GMP、流通领域监管、基本药物质量监管和电子监管等重点工作的贯彻落实。

会上，国家局药品安全监管司主要负责人部署了2012年药品安全监管工作。

（2012年1月16日）

State Food and Drug Administration issued the Notice on Further Regulating the Management on the Registration of API Mixed Powders

To further standardize the management on the registration of API mixed powders, and ensure product quality, on December 30, 2011, SFDA issued a notice on relevant requirements for the registration management of API mixed powders for preparations.

First, the manufacturers of API mixed powders must hold a drug approval number for APIs in mixed powder, and passed GMP certification, and the production process of mixed powders should also pass Drug GMP field inspections.

Second, the manufacturers of preparations using mixed powders should firstly perform supplier audit on the manufacturers of API mixed powders, in accordance with the "Provisions for Drug Registration", propose additional application for "change manufacturing processes that may affect the quality of drugs" and submit the relevant research data of mixed powder and supplier audit information for approval before application. (December 30, 2011)

国家食品药品监督管理局发布关于进一步规范原料药混合粉注册管理的通知

为进一步规范原料药混合粉注册管理，保证产品质量，2011年12月30日，国家食品药品监督管理局就制剂用原料药混合粉注册管理有关要求发布通知。

一、原料药混合粉生产企业必须持有混合粉所需原料药的批准文号并通过GMP认证，混合粉生产过程应通过药品GMP现场检查。

二、使用混合粉的制剂生产企业对原料药混合粉生产企业进行供应商审计后，按照《药品注册管理办法》的规定，提出“改变影响药品质量的生产工艺”补充申请，并提交混合粉相关研究资料和供应商审计资料，经批准后方可使用。（2011年12月30日）

State Food and Drug Administration revised the Packaging insert of three drugs including topical benzocaine

To ensure clinical drug safety, improve the contents of drug instructions, SFDA revised the Packaging insert of topical benzocaine, tiopronin injection and Compound Liquorice Oral Solution. The pharmaceutical manufacturers of the above-mentioned drugs should promptly notify relevant medical institutions, pharmaceutical enterprises and other units and departments the revised contents of all Packaging insert that needs to be modified accordingly, and replace as soon as possible the ex-factory Packaging insert of the above-stated drugs. (December 29, 2011)

国家食品药品监督管理局对外用药苯佐卡因等三种药品说明书进行修订

为保证临床用药安全，完善说明书内容，国家食品药品监督管理局对外用药苯佐卡因、硫普罗宁注射液和复方甘草口服溶液说明书进行了修订。凡需要根据修订内容修改说明书的，药品生产企业应当将修改内容及时通知到相关医疗机构、药品经营企业等单位和部门，并尽快对已出厂的上述药品说明书予以更换。（2011年12月29日）

State Food and Drug Administration released alert on the severe allergic reactions of vitamin K1 injections

Recently, SFDA released the Vol. 43 Adverse Drug Reaction Information Bulletin, which shows that from January 1, 2004 to May 31, 2011, the Case Reports Database of the National Center for Adverse Drug Reaction Monitoring has recorded 893 cases of servious adverse reactions / events of vitamin K1 injections, of which there are 328 cases of anaphylactic shock (36.7%), severe allergic reactions are the most prominent vitamin K1 adverse reactions. In-depth analysis of the data revealed some irrational phenomena in the clinical application of vitamin K1 injections, such as off-label use, drug overdose, inappropriate route of drug administration etc., which have aggravated the safety risks of vitamin K1 injections.

To this end, SFDA reminds the medical staff and patients to watch out the severe allergic reactions and risks of vitamin K1 injections.

(December 26, 2011)

国家食品药品监督管理局提醒关注维生素K1注射液的严重过敏反应

日前，国家食品药品监督管理局发布了第43期药品不良反应信息通报显示，2004年1月1日至2011年5月31日，国家药品不良反应监测中心病例报告数据库中有维生素K1注射液严重不良反应/事件报告893例，其中过敏性休克328例（占36.7%），严重过敏反应是维生素K1最为突出的不良反应。数据分析显示，维生素K1注射液临床使用中存在一些不合理现象，如超适应症用药、超剂量用药、不适宜的给药途径等，这些不合理使用加大了维生素K1注射液安全风险。

为此，国家食品药品监督管理局提醒医务人员和患者关注维生素K1注射液引起严重过敏反应的风险。（2011年12月26日）

"Guideline on Management of Phase I Clinical Trial of Drugs (Interim)"

(To continue)

Chapter IV Management system and standard operating procedures

Article 16 Phase I Clinical Trial laboratories should develop appropriate management systems and standard operating procedures (SOP) with prompt updates and improvement.

Article 17 The management system should at least include: contract management, personnel management, document management, test drugs management, testing sites and facilities management, equipment and facilities management.

Article 18 The SOP of Phase I trials includes at least the following categories: trial design, trial implementation, testing drug management, adverse event handling, data management, clinical trial report, document management, quality control etc.

《药物Ⅰ期临床试验管理指导原则（试行）》

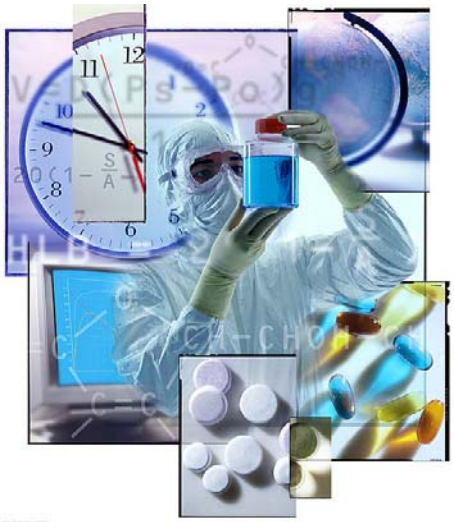
（接上期）

第四章　管理制度与标准操作规程

第十六条　Ⅰ期试验研究室应制订相应的管理制度和标准操作规程（SOP），并及时更新和完善。

第十七条　管理制度至少包括：合同管理、人员管理、文档管理、试验用药品管理、试验场所和设施管理、仪器和设备管理等。

第十八条　I期试验的SOP至少包括以



Article 19 The development, review and approval, implementation, revision and repeal of the management system and SOP.

(A) Development. The management systems and SOP should be developed with unified format and coding, the content should be in line with relevant laws and regulations, the management systems and SOP should be marked with the current version number and effective date, which are subject to timely updates.

(B) Review and approval. The draft of management system and SOP should be reviewed and discussed to ensure that the documents are concise, understandable, complete and clear, logical and feasible, and compatible with other documents already in force. The documents determined after review should provide effective date, and shall be approved and signed by the person in charge of the laboratory.

(C) Implementation. The management system and SOP should be executed immediately after entry into force, all staff must accept the training of management system and related SOP, when the management system and SOP are updated, targeted training is needed.

(D) Revision and repeal. The management system and SOP are subject to regular and irregular revision and repeal as required. The relevant information shall be recorded with timely updates of the versions and serial numbers. The management system and SOP to be repealed should be filed with void markers. It is to be ensured that the existing management system and SOP are the latest version, and the list of the latest version of the management system and the SOP should be retained.

Chapter V Quality Assurance

Article 20 Phase I trial laboratory should establish or be included into relatively independent, complete quality assurance system, which is implemented by personnel not directly involved in the clinical trials, all the observations and findings should be verified and promptly recorded. The Quality control personnel should be assigned by the person in charge of the laboratory.

Article 21 An internal quality control program should be developed in accordance with the test items to verify each procedure and stage of the trials, perform quality control in every stage of data processing, to ensure the testing process is in line with test programs and SOP requirements; the sponsors should periodically verify the test items to ensure data integrity, accuracy, authenticity and reliability. The frequency and nature of verification should be based on the actual situation of the trials. Accurately record the problems found during the inspection, supervise testing personnel to solve problems; on the issues identified propose improvement measures to ensure the correct implementation of testing personnel.

Chapter VI Risk Management

Article 22 Risk management is an important part of Phase I trial, the sponsors, principal investigators, Laboratory Directors, the Ethics Committee and other relevant parties should maintain timely communication and exchange. Before the start of the trial the risk factors should be assessed, and risk management plan should be developed; during the trials effective risk management measures should be taken, timely collect and analyze the new findings or information of test drugs, timely

下几大类：试验设计、试验实施过程、试验用药品管理、不良事件处置、数据管理、试验总结报告、文档管理、质量控制等。

第十九条 管理制度和SOP的制订、审核和批准、实施以及修订与废止。

（一）制定。应制定管理制度和SOP，保证所有管理制度与SOP有统一格式和编码，内容符合相关的法律法规，管理制度与SOP均应标明现行版本号码及生效日期，并及时更新。

（二）审核和批准。管理制度与SOP起草后，应对SOP草稿进行审阅和讨论，保证文件简练、易懂、完整和清晰，具有逻辑性和可行性，与已生效的其他文件具有兼容性。审核后确定的文件，应规定生效日期，并由研究室负责人签署批准。

（三）实施。管理制度与SOP生效后应立即执行，所有工作人员必须接受管理制度与相关SOP的培训，更新管理制度与SOP时，需进行针对性的培训。

（四）修订与废止。根据需要对管理制度和SOP进行定期和不定期修订与废止。将相关信息记录在案，并及时更新版本和版本序列号。需撤销的管理制度与SOP需归档保管并有作废标记。保证现行所用的管理制度与SOP为最新版本，并保留最新版本的管理制度与SOP清单。

第五章 质量保证

第二十条 I期试验研究室应建立或被纳入相对独立的、完整的质量保证体系，由不直接涉及该临床试验的人员实施，所有观察结果和发现都应及时核实并记录。质量控制人员应由研究室负责人指派。

第二十一条 应根据试验项目制订内部质量控制计划，对试验进行的每个阶段和程序进行核查，在数据处理的每一个阶段和程序进行质量控制，确保试验过程符合试验方案和SOP的要求；申办者应按监查计划定期对试验项目进行核查，保证数据完整、准确、真实、可靠。核查的频率和性质应根据试验的实际情况而定。如实记录核查过程中发现的问题，督促试验人员解决问题；对发现的问题提出改进措施，确保试验人员正确执行。

第六章 风险管理

第二十二条 风险管理是Ⅰ期试验的重要内容，申办者、主要研究者和实验室负责人、伦理委员会等各相关方应保持及时沟通与交流。试验开始前必须对风险要素进行评估，并制订风险控制计划；试验

modify protocol, suspend or terminate clinical trials, and ensure the effective implementation of risk management measures through surveillance and inspections.

Article 23 The risk assessment and risk management plan should be scientific and feasible, the risk assessment should include at least the following factors:

(A) The risk factors in the design of the trials;

(B) The test drugs' inherent risk factors;

(C) The subjects' inherent risk factors;

(D) Risk factors in the trial operation.

Article 24 The sponsors' role in risk management

(A) Before clinical trials, the sponsors should assess the potential risks in the trial process, provide the anticipative risk information, and reach a consensus with the investigators;

(B) The sponsors should be familiar with pre-clinical trial drug research data and information to fully assess the risks of clinical trials, and develop clinical trial protocol;

(C) The sponsors shall establish a communication mechanism between the test wards and laboratories researchers, timely and properly handle adverse events, develop data and safety monitoring plan, monitor and manage adverse events that may occur;

(D) The sponsors shall provide to investigators and the ethics committee in a timely manner important new trial-related

information (especially the new information on drug safety application and adverse drug reactions).

Article 25 Investigators' role in risk management:

(A) The investigators should hold discussions with the sponsors before the clinical trials to develop risk control measures that ought to be conscientiously implemented in the process of clinical trials.

(B) Before the start of clinical trials, the principal investigators should establish effective channels of communication between trial related wards and laboratory researchers, in particular, clarify the reporting procedures for outlier test data beyond the prescribed range of laboratories; for multi-center trial, the inter-laboratory communication procedures need to be set up.

(C) Any abnormal values or outliers beyond the specified range spotted during the analytical test process should be promptly reported to the principal investigator.

Article 26 Ethics committee's role in risk management:

The Ethics Committee should review the risk control measures and monitor their implementation; review the suspension and termination of clinical trials to protect the rights of subjects; may require the sponsor or investigator to provide relevant information of the adverse events in clinical trials, the disposal methods and results, and have the power to suspend or terminate clinical trials.

(To be continued) (December 5, 2011)

过程中应采取有效的风险控制措施，及时收集和分析试验用药品的新发现或信息，适时修改试验方案、暂停或终止临床试验，以及通过监查和稽查保障风险控制措施有效执行等。

第二十三条 风险评估和风险控制计划应具有科学性和可行性，风险评估内容至少应包括以下因素：

（一）试验设计中的风险要素；

（二）试验用药品本身存在的风险要素；

（三）受试者自身存在的风险要素；

（四）试验操作中的风险要素。

第二十四条 申办者在风险控制中的职责

（一）申办者在临床试验前应对试验过程中可能存在的风险进行评估，提供预期的风险信息，并与研究者达成共识；

（二）申办者应熟悉试验药物的临床前相关研究数据和资料，充分评估临床试验风险，制订临床试验方案；

（三）申办者应建立与试验病房和实验室研究者间的沟通机制，及时妥善处理不良事件，并制订数据和安全监查计划，监控并管理可能发生的不良事件；

（四）申办者应向研究者和伦理委员会及时提供与试验相关的重要新信息（尤其是关于药物安全使用和药物不良反应的新信息）。

第二十五条 研究者在风险管理中的职责：

（一）研究者应在临床试验开始前与申办者商讨制订风险控制措施，并在临床试验过程中认真执行。

（二）主要研究者应在试验开始前，建立与临床试验相关的试验病房和实验室研究者之间的有效沟通渠道，尤其要明确实验室超出规定范围的实验数值的报告方式；如果是多中心试验，需要对各研究室之间的交流程序作出规定。

（三）在分析实验过程中发现任何不正常或超出规定范围的数值时，应及时报告给主要研究者。

第二十六条 伦理委员会在风险管理中的职责：

伦理委员会应审查风险控制措施，并监督其实施；审查临床试验的暂停和终止，保障受试者权益；可以要求申办者或研究者提供药物临床试验的不良事件相关信息、处置方式及结果，并有权力暂停或终止临床试验。 （待续）

（2011年12月5日）

SFDA Center for Drug Evaluation issued "CDE Management Standards for Professional Review Meetings (Interim)" and six other standards and procedures

Since SFDA Center for Drug Evaluation (CDE) released the "Principles and Procedures for the Technical Review of Drugs" in March 2011, CDE has focused on three key areas of scientific decision-making, scientific management, and scientific review, actively carried out seminars system construction, and in October 2011, CDE issued the "CDE Review Task Management Standards (Interim)" and "Management Standards for CDE Technical Review Decision Making Pathways (Interim)."

As a refined supportive system of "Principles and Procedures for the Technical Review of Drugs", on December 30, 2011, CDE issued six standards and procedures covering the "CDE Management Standards for Professional Review Conferences (Interim)", "CDE Management Standards for Comprehensive Review Conferences (Interim)", "CDE Management Standards for Collaborative Review after the Inspection on Pharmaceutical Manufacturing Sites (Interim)", "CDE Management Standards for Ministerial Joint Conferences (Interim)", "CDE Management Standards for Communication Meetings with the Registration Applicants (Interim)" and "CDE Work Procedures Organizing Expert Consultation Conferences (Interim) ".

The Six Standards and Procedures have clarified the management requirements on the target, contents, procedures, decision-making system, determination of the results and other aspects for all internal CDE review meetings, and the various communication and consultation conferences held by SFDA Center for Drug Evaluation, the sponsors and external experts, which is of great significance to improve and systematically construct the CDE's decision-making mechanism and standardized system, and further enhance the quality and efficiency of CDE's review task management and review decision-making capabilities.

The health sector and business circles are welcome to supervise SFDA Center for Drug Evaluation's review works in light of the 6 management standards and procedures hereby released. (December 30, 2011)

国家食品药品监督管理局药品审评中心发布《药品审评中心专业审评会议管理规范（试行）》等六个规范和工作程序

国家食品药品监督管理局药品审评中心自2011年3月发布《药品技术审评原则和程序》后，即紧密围绕科学决策、科学管理、科学审评三个重点领域，积极开展规范化体系建设工作，并于2011年10月发布了《药品审评中心审评任务管理规范（试行）》和《药品审评中心技术审评决策路径管理规范（试行）》。

作为《药品技术审评原则和程序》的细化配套制度，2011年12月30日，药品审评中心发布了《药品审评中心专业审评会议管理规范（试行）》、《药品审评中心综合审评合议会议管理规范（试行）》、《药品审评中心药品生产现场检查后的合审会议管理规范（试行）》、《药品审评中心部长联席会议管理规范（试行）》、《药品审评中心与注册申请人沟通会议管理规范（试行）》和《药品审评中心专家咨询会议组织工作程序（试行）》等六个规范及工作程序。

六个规范及工作程序对药品审评中心内部的各级审评会议、国家食品药品监督管理局药品审评中心与申请人及外部专家召开的各种沟通、咨询会议等在会议目的、会议内容、会议程序、会议决策体系、会议结论的形成等方面提出了明确的管理要求，将对完善和系统构建中心的决策机制及规范化体系、进一步提高中心审评任务管理和审评决策的质量与效率具有重要意义。

欢迎业界依据本次公布的六个规范及工作程序对药品审评中心审评工作进行监督。

（2011年12月30日）

"SFDA Center for Drug Evaluation Management Standard for Communication Meetings with the Registration Applicants (Interim)"

I. To regulate the management of Center for Drug Evaluation's communication meeting with the registration applicants (hereinafter referred to as communication meeting), and to ensure the quality and efficiency of the communication meetings, we hereby develop this standard.

《药品审评中心与注册申请人沟通会议管理规范（试行）》

一、为规范药品审评中心与注册申请人沟通会议（以下简称沟通会议）管理，保证沟通会议质量与效率，制定本规范。

II. The communication meeting refers to discussions, exchanges and conferences organized by SFDA Center for Drug Evaluation (hereinafter referred to as CDE) and the applicant for registration (hereinafter referred to as applicant) regarding technical issues related to drug registration.

III. Relevant review departments are responsible for the management of communication meetings.

IV. The convening of communication meetings apply to the following three circumstances:

(A) According to the needs of technical review, CDE takes the initiative to communicate with the applicants;

(B) The applicants can take the initiative, in accordance with relevant regulations, to communicate with CDE. Generally include:

1. Registration application that is in line with special approval procedures, and needs communication regarding key technical issues involved in research and development, as well as registration application process;

2. Communication that is needed regarding major technical issues in the technical review of registered varieties, as well as the clinical research process;

(C) Other issues that call for conference communication.

V. The communication meetings are generally held in the manner of vis-a-vis meetings, video or telephone conferences.

VI. Communication meetings proposed by CDE:

1. Professional principal reviewer/ principal review reporter can propose communication meetings during the professional review period, principal reporter's comprehensive review period or technical review period (complete Annex 1: Approval Form for Communication Meeting with Registration Applicants (filled out by the personnel of review departments), which shall be reviewed and approved by relevant review department and submit to Administrative Management Department; the leaders of Administrative Management Departments, CDE leadership can also directly propose communication meetings (Coordinators are responsible for completing Annex 1). The Conference Application should clarify the issues to be discussed, the demands of the participants, the materials to be submitted and other related contents.

2. The Administrative Management Department is responsible for submitting the Conference Application to CDE leaders (authorized person) for approval.

3. The Administrative Management Department is responsible to organize and arrange communication meetings within 1 month after approval, and contact the applicant via telephone, fax, mail, etc., inform the applicant of the issues to be discussed in the meeting, the information to be submitted and the demands of the participants, and determine the time, place and other related matters of the meeting; and to notify relevant CDE personnel of the related arrangements prior to the meeting.

4. The review of the varieties involved (covered professions) in the meeting can be suspended according to the CDE prescribed procedures, and the review shall be restarted the day after the meeting.

二、沟通会议是指药品审评中心（以下简称药审中心）与注册申请人（以下简称申请人）之间就药品注册相关的技术问题组织的讨论交流会议。

三、沟通会议管理由相关审评部门负责。

四、召开沟通会议适用于以下三种情形：

（一）药审中心根据技术审评需要，主动提出需与申请人进行沟通交流的；

（二）申请人可根据相关管理规定，主动提出需与药审中心进行沟通交流的。一般包括：

1. 符合特殊审批程序的注册申请，就研发和注册申请过程中涉及的关键技术问题需要进行沟通交流的；

2. 针对在审注册品种技术审评或临床研究过程中的重大技术问题需要进行沟通交流的；

（三）其他需要会议沟通的。

五、沟通会议一般以面对面会议、视频或电话会议方式进行。

六、药审中心主动提出的沟通会议：

1. 专业主审人员/主审报告人可在专业审评阶段、主审报告人综合审评阶段或技术审核阶段提出（填写附件1：注册申请人沟通会议审批表（由审评部门人员填写）），由相应审评部门审核同意后，提交业务管理部；也可由业务管理部、中心领导直接提出（协调员负责填写附件1）。会议申请应明确会议拟讨论问题、参加人员需求、会议需提交资料等相关内容。

2. 业务管理部负责将会议申请提交中心领导（授权人）审批。

3. 业务管理部负责于批示后1个月内组织安排沟通会议，负责以电话、传真、邮件等方式联系申请人，告知申请人沟通会议需要讨论的问题、提交的资料以及参加人员需求，并确定会议时间、地点等相关事宜；负责会前将相关会议安排通知中心相关人员。

4. 会议涉及的品种可按中心规定的程序暂停审评（所涉专业），并应于会议召开后的次日重新启动审评。

5. 相关审评部门负责做好会议准备，明确会议讨论议题；会议期间与申请人进行充分的沟通交流，就会议讨论议题应达

5. Relevant review departments will see to that the meeting is well prepared, and the discussion topics of the meeting are clarified; fully communicate with the applicants during the meeting, reach a consensus or mutual understanding of each other's point of view on topics of the meeting, to ensure the quality and efficiency of the communication meeting; and propose treatment suggestions on related varieties after the meeting in light of the discussion opinions.

VII. Communication meetings proposed by the applicants:

1. The applicants must fill out the "Registration Applicant's Application Form for Communication Meetings" (Annex 2), and submit the issues to be discussed and relevant research data with reference to the requirements of "Special Approval Process for Communication and Exchanges".

2. The Administrative Management Department, in conjunction with the principal review and report department/ professional review department, is responsible to review the conference application submitted by applicants within a month, and propose suggestions on the necessity of the meeting, the issues be discussed at the meeting, the demands of the participants of both sides etc., which are to be submitted to CDE leaders (authorized person) for approval [see Annex 3: The Applicant's Application Form for Communication Meetings (completed by the Coordinators only)].

(1) The Administrative Management Department shall notify via telephone the applicants on disapproval of the convening of meetings, and make telephone records that are to be archived together with the documents received.

(2) The Administrative Management Department shall notify via telephone the review departments and the applicants the approved conference applications, and convene the meeting within one month after the approval, and send the specific arrangements of the meeting by phone, fax, mail etc. to the applicants and relevant CDE participants prior to the meeting.

3. The review department is responsible to inform the participants of the issues to be discussed at the meeting in advances, to ensure that the meeting is fully prepared, and the quality and efficiency of the communication conference. During the meeting, the review department should fully communicate with the applicants to reach a consensus on the issues of the meeting or to understand each other's point of view, to ensure the quality and efficiency of the communication meeting.

VIII. Requirements for the Minutes of the meeting

(A) Each meeting shall be recorded in a Meeting Minutes.

(B) The Minutes should accurately and comprehensively reflect the meeting procedures, major topics

成共识或互为理解对方观点，以保证沟通会议质量与效率；会后应及时根据会议讨论情况，形成相关品种的处理建议。

七、申请人主动提出的沟通会议：

1. 申请人需填写《注册申请人沟通会议申请表》（附件2），并参照“特殊审批程序沟通交流”相关要求，提交拟讨论问题和相应研究资料。

2. 业务管理部负责会同主审报告部门/专业审评部门在一个月内对申请人提交的会议申请进行审查，提出是否同意召开会议和会议拟讨论问题、双方参加会议人员需求等建议,报请中心领导(授权人)审批【见附件3：申请人沟通会议审批表（协调员填写）】。

（1）对于不同意召开会议的，业务管理部负责电话通知申请人，并做好电话记录，随来文一并存档。

（2）对于同意召开会议的，业务管理部负责将审批意见通知审评部门和申请人，并于正式审批后的一个月内组织召开沟通会议，负责会前将会议具体安排以电话、传真、邮件等方式反馈申请人和中心参加会议相关人员。

3. 负责组织会议的审评部门，应将会议拟讨论问题于会前发各参加会议人员，充分做好会前准备，以保证沟通会议的质量与效率。会议期间与申请人进行充分的沟通交流，就会议讨论议题达成共识或互为理解对方观点，保证沟通会议质量与效率。

八、会议纪要要求

（一）每次会议均应形成会议纪要。

（二）会议纪要应准确、全面地反映会议过程、主要讨论内容和会议预期目标的实现情况。

（三）由药审中心主动提出的沟通会议，由专业主审人/主审报告人负责起草会议纪要并在技术审评报告中予以体现，会

and the achievement of desired objectives.

(C) The Minutes of the communication meetings proposed by CDE shall be drafted by professional principal reviewer / principal review reporter and reflected in the technical review reports, the meeting minutes along with the technical review reports shall be submitted to the Department Director of the Review Department, the Minutes involving significant decisions should be reported in accordance with the requirements of the "Center for Drug Evaluation Management Standards for Decision-Making Pathways of Technical Review (Interim)". Other CDE participants can have access to the technical review report and meeting minutes through the online technical review system.

(D) The Minutes of the communication meetings proposed by the applicants shall be under the care of personnel (usually the principal review reporter / professional principal reviewer) designated by the meeting organization departments, or drafted in conjunction with the applicants, if necessary, seek the opinions of the participants. Once the Minutes are confirmed with a consensus, they are to be signed by both parties (the applicants and the department director of CDE organization department), and feedback to the applicant and CDE participants respectively.

(E) The Minutes shall be archived together with the applicants' conference application, the CDE's approval and other related documents, and filed timely in the CDE Minutes Management System for future reference and application in the follow-up study of new drug varieties and reviews.

IX. All relevant CDE personnel should implement this Management Standard accordingly.

X. This Management Standard shall enter into force as of the date of release.

(December 30, 2011)

议纪要随技术审评报告一起提交所在审评部部长，涉及重大决策的纪要还应按《药品审评中心技术审评决策路径管理规范（试行）》的要求进行报告。中心其他参加会议人员可通过技术审评系统查阅技术审评报告和会议纪要。

（四）由申请人主动提出的沟通会议，由负责组织会议部门指定人员（通常是主审报告人/专业主审人）负责，可会同申请人共同起草会议纪要，必要时征求参加会议人员的意见。会议纪要一经达成共识需经双方签字（中心为组织会议部门部长）确认后，分别反馈申请人和药审中心参加会议人员。

（五）会议纪要应随申请人会议申请和药审中心批示等相关文件一并存档，并及时在中心会议纪要管理系统中创建，以便在今后涉及在审新药品种的后续研究及审评工作中参考和利用。

九、药审中心各相关岗位工作人员均应执行本规范。

十、本规范自发布之日起施行。

（2011年12月30日）

Activity Brief

China's first inspections on the production sites of foreign pharmaceutical manufacturers in 2011

In 2011, 33 drug GMP inspectors have performed pharmaceutical inspections on Eli Lilly, Novartis, Roche, Sanofi, Mitsubishi Tanabe, Dr. Reddy, Daewoong Pharmaceutical and other foreign pharmaceutical manufacturers, and inspected the quality compliance standards of imported or to be imported drugs produced by these enterprises. This is the first time ever in the history of China's Food and Drug Administration.

According to the leaders of SFDA Drug Certification Center, foreign pharmaceutical manufacturers all welcomed China's pharmaceutical GMP inspection, and highly praised the professional standards and overall quality of China's pharmaceutical GMP inspectors. It is a good practice for China to perform inspections overseas, which has enhanced the regulatory capacity on imported drugs and laid a solid foundation to ensure the public drug safety of imported drugs.

(December 28, 2011)

特别报道

2011年我国首次开展境外企业药品生产现场检查

2011年，我国33名药品GMP检查员，对礼来、诺华、罗氏、赛诺菲、田边三菱、瑞迪博士、大熊等7家境外药品生产企业进行了药品检查，审核这些企业生产的进口或即将进口到我国的药品是否符合要求。这是我国首次开展的境外企业药品生产现场检查。

据国家食品药品监管局药品认证管理中心负责人介绍，境外药企非常欢迎我国对其开展药品GMP检查，并在药品检查工作中对我国的药品GMP检查员的专业水平和综合素质给予了高度赞扬。开展境外企业药品生产现场检查提高了对进口药品的监管能力，牢固了保证公众使用安全的进口药品的基础。

（2011年12月28日）

Notes: • All Chinese information in Newsletter extracted from Newspapers and Internet. All English articles are the translations from the Chinese version.

• Read the electronic version of the newsletter please visit http://www.ccpie.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.ccpie.org

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