SFDA Commissioner Shao Mingli meets Vice President Cabbrisas 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 Cabbrisas 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)
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

2011年12月20日，2012年全国食品药品监督管理工作会在北京召开。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。卫生部部长陈竺在会并作重要讲话。国家食品药品监督管理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大。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冒伪劣的整治打击力度，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。国家食品药品监督管理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、技术支持、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，也是推进新一轮医药卫生体制改革的重要之年，要着重抓好以下几项工作：一是完善监管体制机制。加强规范化建设、加强法规制度建设，加强政策理论研究，深化审评审批制度改革，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.

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 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)

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.

Fifth, strengthen the construction of cadre teams and honest government to ensure the implementation of the administration tasks.

(December 22, 2011)
**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)

**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)
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)

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 serious 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)

"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.
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 with the correct implementation of testing personnel.

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...
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)
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)

"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.
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 a-visor 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 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.
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.

VI. 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 advance, 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 and consensuses or mutual understanding of both participants etc., which are to be submitted to the applicants and CDE participants in written form within one month after the approval, and then to the review departments.

VII. Communication meetings proposed by the applicants:

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(B) The Minutes should accurately and comprehensively reflect the meeting procedures, major topics and consensuses or mutual understanding of both participants etc., which are to be submitted to the applicants and CDE participants in written form within one month after the approval, and then to the review departments.
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)

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**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)

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**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。

据国家食品药品监督管理局药品认证管理中心负责人介绍，境外药企纷纷表示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，牢固地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.

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