National Work Conference Convened on Food and Drug Administration & Construction of Honest Party Conduct and Clean Government

From January 10 to the morning of January 11, 2013, the National Work Conference on Food and Drug Administration & Construction of Honest Party Conduct and Clean Government was held in Beijing. The Conference summarized the 2012 food and drug administration with analysis of the current and future regulatory situation, deployed the work tasks for Food and Drug Administration & Construction of Honest Party Conduct and Clean Government in 2013, and rewarded in recognition of the advanced collectives and workers in national food and drug administration system. Zhang Mao, Vice Minister of Health, attended the Conference and made a speech; SFDA Commissioner Yin Li delivered a work report; Yu Chengxian, Chief of SFDA Discipline Inspection Group accredited by CCID, member of SFDA Party Group, delivered a report on the Construction of Honest Party Conduct and Clean Government; SFDA Deputy Commissioner Wu Zhen delivered the conference summary. Vice minister Zhang Mao fully affirmed in his speech the achievements of 2012 food and drug administration, and stressed that the 18th Party Congress has deployed the overall goal of building a moderately prosperous society in 2020, in which the general requirements for health work: “to improve the health of the people”, has further pointed out the direction of the medical and health work for the current and future periods. Food and drug administration departments should act accordingly with comprehensive understanding and accurate grasp of the new requirements of the 18th Party Congress, to initiate new prospects for regulatory work.

In his work report, Commissioner Yin Li summarized the 2012 food and drug administration with objective analysis of the current work situation, and proposed the current and future goals for the reform and development of food and drug administration. Yin Li pointed out that this is the first year to fully implement the policies of the 18th Party Congress, to initiate new prospects for regulatory work. The whole system should comply with the general requirements of food and drug administration, and focus our efforts on eight areas: 1. Focus on in-depth study and implementation of policies of the 18th Party Congress, to continuously enhance our confidence and determination for effective food and drug administration. 2. Focus on the improvement of quality levels, to strengthen drug safety supervision. 3. Focus on laying a solid foundation to strengthen the safety regulation of medical devices. 4. Focus on improving the system to strengthen the supervision of health foods and cosmetics. 5. Focus on special rectification and comprehensive administration to strengthen the supervision of the catering industry. 6. Focus on improving the effectiveness of supervision, and speed up the construction of information technology. 7. Focus on promoting the transparency of government affairs, and strengthen
National Food and Drug Inspection Work Conference held in Kunming

The National Food and Drug Inspection Work Conference was held in Kunming City, Yunnan Province from January 24 to 25, 2013. In the Conference, the work of food and drug inspection in 2012 was summarized, the current situation was analyzed, and the corresponding work priorities in 2013 were deployed. SFDA Deputy Commissioner Sun Xianze attended the Conference and delivered a speech.

The Conference fully recognized the achievements in inspection of 2012. In accordance with the work deployment of inter-ministerial joint conference on combating production and sales of counterfeit drugs and the special action of “double-combats”, we carried on the system-wide combat to crack down with high-pressure on illegal activities, focused on the combat against infringement and counterfeiting, the purchases and sales of drugs via Internet and the counterfeit and substandard drugs in rural markets; besides, we also laid emphasize on the special rectifications of Chinese medicinal herbs market, health food, cosmetics and illegal additives, and the release of false drug information on the Internet. We have investigated and dealt with a batch of major cases, carried out supervision and sampling tests for drugs and medical devices, and achieved full coverage of sampling tests for essential drugs; we timely investigated and controlled problematic products, published quality announcements, continued to reinforce the supervision over advertising and Internet-based activities, and strengthened the system construction of national organizations, institutions and work mechanism for complaints and reports.

The Conference urged all regions to earnestly implement the SFDA works deployments according to their own situations, i.e., to reinforce the investigation and handling of the counterfeit-drug cases, focusing on outstanding problems and key links; effectively integrate the supervision and sampling tests of drugs and medical devices with new explorations, innovations and improved mechanisms; carry out special rectification, investigate and punish the illegal activities in the field of health foods and cosmetics; attach equal importance to guidance and prevention and muster up all internal and external forces to combat against the illegal and false drug advertisement, and false drug information on the Internet; upgrade information technology to enhance the efficiency and level of inspections; strengthen the legal and normative system construction for inspections, enhance the capacity and level of the inspection system; spare more efforts to the information and release; and strengthen the inspector team and the party construction and restrict corruption. The two normative documents of the "Guiding Opinions on Further Strengthening administration departments of all provinces (autonomous regions and municipalities) and Xinjiang Production and Construction Corps, municipalities with independent planning status, and sub-provincial capital cities, Drug Administration Bureau of the Health Department of PLA General Logistics Department, as well as relevant SFDA departments and directly affiliated units. (Jan. 12, 2013)

National Food and Drug Inspection Work Conference in Kunming

2013年1月24～25日，全国食品药品稽查工作会议在云南昆明召开。会议对2012年食品药品稽查工作做了总结，对当前稽查工作形势进行了分析。对2013年食品药品稽查重点工作进行了研究部署。国家食品药品监督管理局孙咸泽副局长出席会议并讲话。

会议充分肯定了2012年稽查工作取得的成绩。按照打击生产销售假药部际联席会议和“双打”专项行动的工作部署，全系统持续保持严厉打击各种违法违规行为的高压态势，集中开展打击侵权假冒、打击互联网售假药品、打击农村市场假劣药品、中药材专业市场专项整治、保健食品化妆品违法违规专项整治、互联网发布虚假药品信息专项整治工作。查处一批大案要案，开展药品医疗器械监督抽验和查处，完成基本药物全品种覆盖抽验，及时查处问题产品，发布质量公告，持续加大广告和互联网监管力度，加强全国投诉举报组织机构，工作机制制度建设。

会议要求，各地要结合本地实际，切实贯彻落实国家局工作部署。针对突出问题，重点环节，加大假药案件查办力度，开拓创新，完善机制，做好药械抽检的监管检查；开展专项整治，依法查处保健食品化妆品违法违规行为，疏堵结合，内外联控，打击发布虚假药品广告和互联网虚假药品信息，加强稽查信息化建设，提升稽查工作质量和水平，加强稽查法规制度建设，提升稽查系统能力和水平，加强新闻宣传和信息发布工作，加强稽查队伍能力建设和党风廉政建设。会议还对《关于进一步加强药品稽查工作的指导意见》（征求意见稿）和《重点案件稽查督办办法》（征求意见稿）进行了研究讨论。
Drug Inspection "(Exposure Draft), and "Measures for the Supervision and Handling of Major Cases "(Exposure Draft) were also deliberated and discussed in the Conference.

Attendees of the Conference are leaders of food and drug inspection and leaders of inspection departments in the food and drug administration of all provinces, autonomous regions, municipalities, Xinjiang Production and Construction Corps, municipalities with independent planning status, sub-provincial capital cities, the Health Department of the PLA General Logistics Department, as well as leaders of the concerned departments of SFDA and its directly affiliated units.

(2013-01-29)

The Institute for Biological Product Control of the National Institutes for Food and Drug Control designated as WHO Collaborating Center for Standardization and Evaluation of Biologicals

On January 1, 2013, the World Health Organization (WHO) officially approved the Institute for Biological Product Control (IBPC) of the National Institutes for Food and Drug Control (NIFDC) in China as WHO Collaborating Center for standardization and evaluation of biologicals, as the seventh in the world and the first in developing countries. This manifests that the testing and scientific research capabilities in China have attained first-class level internationally.

WHO Collaborating Center is most representative of the cooperation of WHO and its member states, its main role is to provide important technical support for WHO to enact technical regulations, to assist WHO in its realization of its functions and planning objectives, to enhance the scientific nature and effectiveness of global health work, as well as to develop and strengthen the research capabilities of the states and regions.

On January 28, 2013, a Summary Report Conference was held in Beijing for Celebration of the Designation of NIFDC (National Institutes for Food and Drug Control) as WHO Collaborating Center for Standardization and Evaluation of Biologicals & Qualification of NIFDC as WHO Drug Quality Control Laboratory. Dr. Michael O’Leary, WHO Representative in China, read the WHO Director-General Margaret Chan’s congratulatory letter to NIFDC and delivered a speech. Sang Guowei, Vice Chairman of the NPC Standing Committee, SFDA Commissioner Yin Li and Deputy Commissioner Sun Xianze, and leaders of the concerned SFDA departments attended the Conference. The Conference was presided over by NIFDC Director-General Li Yunlong.

Chairman Sang Guowei recalled in his speech the development progress of NIFDC over the past six decades, and the cooperation and exchanges between WHO and NIFDC. He also stated that the close cooperation between WHO and NIFDC is of great significance for us to accomplish the goals set forth in the 12th Five-Year Plan for National Drug Safety, to enhance the safety and efficacy of the drugs in China as the world’s largest developing country, and guide the transformation & upgrading, healthy development and internationalization of our pharmaceutical products.

Commissioner Yin Li expressed that the designation of NIFDC as WHO Collaborating Center for Standardization and Evaluation of Biologicals fully represents WHO’s recognition of NIFDC’s technical capacity, and fully embodies the continuous enhancement of China’s supervision level for biologicals, drug control technical

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(2013-01-29)

中检院生物制品检定所获批WHO生物制品标准化和评价合作中心——

2013年1月1日，世界卫生组织正式批准中国食品药品检定研究院生物制品检定所为WHO生物制品标准化和评价合作中心。这是全球第7个、也是发展中国家首个WHO生物制品标准化和评价合作中心。中检院成功申请WHO生物制品标准化和评价合作中心，标志着我国在生物制品领域内的检验、科研能力达到国际一流水平。

WHO合作中心是WHO与其成员国开展合作的最具代表性的形式，其主要作用是为WHO颁布技术法规提供重要技术支持，以协助WHO实现其职能和规划目标，增强全球卫生工作的科学性和有效性，同时使国家和区间的研究能力得到发展和加强。

2013年1月28日，中检院获批WHO生物制品标准化和评价合作中心暨通过WHO药品质量控制实验室认证总结汇报会在京举行。WHO驻华代表盖瑞明博士宣读了WHO陈冯富珍总干事给中检院的贺信并致辞。全国人大常委会桑国卫副主任、国家食品药品监督管理局尹力局长、孙咸泽副局长及相关司局负责人出席了当天的会议，会议由中检院李云龙院长主持。

桑国卫副主任在讲话中回顾了中检院六十年来的发展历程以及中检院与WHO之间的合作与交流。桑国卫表示，中检院与WHO高度合作的格局，对完成我国《国家药品安全“十二五”规划》、推动中国这个世界上最大发展中国家的药物质量安全和有效，引导我国医药产品转型升级、健康发展并走向世界具有重要意义。

尹力局长表示，中检院成为WHO生物制品标准化和评价合作中心，是WHO对中检院技术能力的认可，也是我国生物制品监管水平、药品检验技术和质量管理水平不断提高的结果，希望中检院以此为
capacity and quality management levels. It is expected that NIFDC shall take this as an opportunity to strengthen capacity building and development of professional talent teams, further improve the level of drug quality assurance and scientific drug control, continue to enhance China’s regulatory standards and status in the control of drugs and biological products, so as to play a more important role in international affairs.

(2013-01-29)

**NIFDC Deputy Director General Wang Junzhi Won Bethune Medal**

On January 7, 2012, NIFDC Deputy Director General & Researcher Wang Junzhi was awarded the Bethune Medal among 10 medalists on the 2013 National Health Conference held in Beijing. This is the first time for China’s health system to award such a Medal to a non-clinical expert, and also the first time for an expert in the field of drug control to win such an honor.

Being an honorary title set forth in the "Interim Provisions for Honorary Titles of National Health System" released under No. 14 Minister Decree of the Ministry of Health in 1991, the Bethune Medal is jointly awarded by the Ministry of Human Resources and Social Security and the Ministry of Health. It is the noblest administrative reward for model individuals of the national health system, from 1994 to 2008, only 38 medical workers in total have received this honor. (Jan. 07, 2013)

**State Food and Drug Administration and the Ministry of Finance jointly issued the "Incentive Measures for Reports of Food and Drug Illegal Acts"**

In order to encourage the public to report illegal acts pertaining to food and drug safety, to timely detect, control and eliminate food and drug safety hazards, crack down on illegal and criminal activities involving food and drugs, and ensure food and drug safety, on January 15, 2013, the State Food and Drug Administration (SFDA) and the Ministry of Finance jointly issued the "Incentive Measures for Reports of Food and Drug Illegal Acts" (hereinafter referred to as "Measures"). The "Measures" apply to food and drug administration departments at all levels, who shall provide corresponding material and spiritual rewards upon application to the informers (natural persons, legal persons and other organizations) who report via letters, visits, network, telephone and other channels, the illegal acts in the R&D, production, distribution and application of drugs, medical devices, health foods and cosmetics that fall within the scope of their regulatory responsibilities and have been verified and dealt with according to law.

The incentive measures for complaints and reports of food safety in catering service industry shall be implemented in light of the regulations for rewarding reports of food safety hazards in various provinces (autonomous regions and municipalities).

The rewards shall be, in principle, limited to real-name reports, whereas rewards shall also be provided to anonymous informers with willingness to receive the reward, whose real identity can be verified after the investigation and settlement of the cases.

According to the verification results of reported evidence and illegal facts, the
rewards for reports shall be classified into three levels. Level I reward applies to informers who provide concrete details of illegal facts, clues, and direct evidence of the party being reported, assist the investigations, and whose reported contents are entirely consistent with the illegal facts. Level II reward applies to informers who provide the illegal facts, clues and partial evidence of the party being reported, but do not directly assist the investigations, and whose reported contents are consistent with the illegal facts. Level III reward applies to informers who provide the illegal facts or clues of the party being reported, but cannot provide relevant evidence or assist the investigations, and whose reported contents are basically consistent with the illegal facts.

The "Measures" provided that the food and drug administration departments below the provincial levels (including provincial levels), as competent departments for rewarding reports, shall implement the notification, acceptance, evaluation and rewarding procedures in accordance with the principle of territorial management and graded responsibility. The necessary incentive funds shall be incorporated in the budget arrangements by the local financial departments, food and drug administration departments shall develop fund management measures in conjunction with the financial departments to strengthen management, and accept the supervision of the auditing and supervision departments.

The "Incentive Measures for Those Who Have Rendered Meritorious Services in Informing against the Production and Sales of Counterfeit and Substandard Drugs", which was jointly issued by the State Food and Drug Administration and the Ministry of Finance on November 27, 2003, shall be repealed simultaneously. (Jan. 15, 2013)

**Four Ministries and Commissions Jointly Promoting the Implementation of Newly Revised Drug GMP**

The Notice on Accelerating the Implementation of Newly Revised Drug GMP and Promoting Pharmaceutical Industry Upgrading was formally issued jointly by the State Food and Drug Administration, National Development and Reform Commission, Ministry of Industry and Information Technology and Ministry of Health. Under the original standard and schedule, the four government agencies advanced incentives in merger and reorganization, certification and inspection, examination and approval, commissioned production, price adjustment, bid procurement and technical transformation to encourage and guide drug manufacturing enterprises to meet the requirements of the newly revised Drug GMP.

Since the implementation of the newly revised "Good Manufacturing Practice for Drugs" (hereinafter referred to as the newly revised Drug GMP) from March 2011, all departments in various regions have closely cooperated and stepped up publicity and implementation efforts, some drug manufacturers have taken the lead to pass through certification and played a good exemplary role. But from the overall perspective, there is still a large gap from the target, especially, the task is particularly urgent for production of sterile preparations to achieve the desired goal by the end of 2013. In order to encourage and guide pharmaceutical manufacturing enterprises to achieve the newly revised drug GMP as soon as possible, the four ministries and commissions launched the following seven measures.

- **Level I Reward**: Applies to informers who provide complete and verifiable evidence of the party being reported, and whose reported contents are consistent with the illegal facts.
- **Level II Reward**: Applies to informers who provide partial evidence or clues of the party being reported, whose reported contents are consistent with the illegal facts, and cooperate with the investigation.
- **Level III Reward**: Applies to informers who provide evidence of the party being reported, but whose reported contents are not completely consistent with the illegal facts.

Four Ministries and Commissions Jointly Promoting the Implementation of Newly Revised Drug GMP

通知对加快实施新修订《药品生产质量管理规范》促进医药产业转型升级有关通知，正式印发。在坚持标准不降低、时间不放宽的要求下，四部委联合发布，引导和指导药品生产企业的实施。

2011年3月1日，修订《药品生产质量管理规范》（以下简称修订《药品生产GMP》）正式实施以来，各地区、各部门密切配合。加大宣传实施力度，部分药品生产企业已经率先通过认证，发挥了良好的示范带头作用。但总体来看，距离预期目标仍有较大差距。

特别是无菌制剂生产要在2013年底前实现预期目标，任务尤为紧迫。为此，四部委联合印发《关于加快实施新修订〈药品生产质量管理规范〉的通知》，明确提出以下7项措施。

一是鼓励和引导药品生产企业尽快达到新修订《药品生产GMP》，四部委联合发布。

2013年1月1日，修订《药品生产质量管理规范》（以下简称新修订《药品生产GMP》）正式实施。各地区、各部门密切配合，加大宣传实施力度，部分药品生产企业已经率先通过认证，发挥了良好的示范带动作用。但总体来看，距离预期目标仍有较大差距。

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一是鼓励和引导药品生产企业尽快达到新修订《药品生产GMP》，四部委联合发布。
1. Encourage the concentration of drug production to advanced enterprises. Support the upstream and downstream integration of enterprises for R & D and production, manufacturing and distribution, bulk drugs and formulations, herbal medicines and Chinese patent medicines and others, support enterprises to carry out merger, restructuring, and resource integration, to achieve economies of scale and intensive management, improve industrial concentration. Further improve the speed of review and approval of applications for pharmaceutical technology transfer registration in the wake of corporate mergers and acquisitions, or the optimization of resource allocation within enterprise groups, the provincial drug administration departments shall be responsible for the technical review, on-site inspection and quality assurance system auditing, and report the qualified applications to SFDA for approval. Pharmaceutical manufacturers who voluntarily give up the whole plant or part of the dosage form production transformation can transfer, in accordance with the above requirements, their existing pharmaceutical technology within the prescribed period to enterprises that have passed the newly revised drug GMP certification. However, the pharmaceutical technology one-time transfer for one dosage form is limited to only one enterprise. Production enterprises of injections and other sterile products, and manufacturers of other drug varieties should propose pharmaceutical technology transfer registration applications in accordance with the above requirements before December 31, 2014, and December 31, 2016, respectively, meanwhile applying for annulment of the corresponding drug production license and drug approval numbers.

2. Encourage advanced enterprises to obtain GMP certification with the least delay. Prioritized evaluations and other measures shall be applied to encourage one-off certification of the whole production lines of enterprises that have passed the drug GMP certification examination by member units of the World Health Organization or the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S), or other enterprises with better foundation and better quality assurance system, and without serious defects in past drug GMP certification examinations. Production lines that have passed the GMP certification inspection by member units of the WHO or PIC/S can be directly certified by Food and Drug Administration departments after inspection, review and confirmation of the compliance with the requirements of China’s newly revised drug GMP.

3. Restrict the drug registration applications of enterprises that failed to pass GMP certification in due time. Food and drug administration departments shall suspend the review and approval of drug registration of relevant dosage forms of manufacturers that failed to pass GMP certification in due time. New registration applications of production enterprises of injections and other sterile drugs, and manufacturers of other drug varieties shall be no longer accepted as from January 1, 2014, and January 1, 2016, respectively, if they cannot provide certificates of newly revised drug GMP certification of the appropriate dosage forms, and the review and approval for such applications that have been accepted shall be suspended and shall not be accepted or restarted until the above enterprises provided such GMP certificates, except for new pharmaceutical manufacturing enterprises (plants).

4. Strictly regulate the inspection and approval of commissioned drug production. Drug administration departments shall not approve any applications for commissioned drug production of injections and other sterile products since July 1, 2013, and other drugs varieties since January 1, 2015, if the trustees have not obtained the

游整合，支持企业发展兼并重组，资源整合，现规模较大，集约化经营，提高产业集中度，对企业兼并重组或企业集团内部优化资源配置而发生的药品技术转让注册等申请，进一步提高审评审批速度，由省级药品监督管理部门进行技术审评，生产现场检查以及质量保证体系审核。符合要求的，报国家药品监督管理部门审批。药品生产企业在被合并或部分剂型生产改变的，可按照上述要求，将其现有药品技术在规定期限内转让给通过新修订药品GMP认证的企业，但一个剂型的药品技术仅限于一次性转让给一家企业。注射剂等无菌药品生产企业应在2014年12月31日前，其他剂型药品生产企业应在2016年12月31日前按上述要求提出药品技术转让注册等申请，同时申请注销相应药品生产许可和药品批准文号。

二是鼓励优势企业尽快通过认证。对已经通过世界卫生组织或药品检验国际公约组织（PIC/S）成员国内药品GMP认证的企业或其他基础较好，质量保证体系完善，既往药品GMP认证检查中未发现严重缺陷项目的企业，通过优先安排检查等措施，鼓励其全部生产线一次性通过认证。对已经通过世界卫生组织或药品检验国际公约组织（PIC/S）成员国内药品GMP认证检查的生产线，药品监督管理部门对其检查工作复核认为符合我国新修订药品GMP要求后，可予直接通过认证。

三是限制未按期通过认证企业的药品注册。药品生产企业未在规定期限内通过新修订药品GMP认证的，药品监督管理部门将暂停其相应剂型的药品注册审批。注射剂等无菌药品生产企业自2014年1月1日起，其他剂型药品生产企业自2016年1月1日起，如不能提交相应剂型的新修订药品GMP认证证书，不受其新申报生产注册的申请注册，已经受理的此类申请暂停审评审批，待上述企业提交相应剂型的新修订药品GMP认证证书后，方可受理或重新启动审评审批程序，新药生产企业（车间）除外。

四是严格药品委托生产资质审查和审批。注射剂等无菌药品自2013年7月1日起，其他剂型自2015年1月1日起，受委托方未取得相应剂型新修订药品GMP认证证书的，药品检验管理机构一律不批准其药品委托生产许可。对已批准的委托生产，受委托方未相应剂型如在2013年底前或2015年底前未通过新修订药品GMP认证，逾期应停止委托生产。对于确已开展
certificate of newly revised drug GMP certification of the corresponding dosage forms. For commissioned productions that have been approved, the trustees should stop the production upon entrustment if their corresponding drug categories have not passed the certification of the newly revised drug GMP before the end of 2013 or before the end of 2015. Enterprises that have actually carried out restructuring for the newly revised drug GMP but have not yet passed the certification within the prescribed period can entrust enterprises that have passed such certification for production during their discontinued production and transformation, the commissioned production for injections & other sterile drugs, and other drug varieties can be conducted only before 12 May 31, 2014, and December 31, 2016, respectively. Biological products and TCM injections shall not be subject to entrusted production.

5. Give full play to the price leverage. Price departments shall fully consider the impact of the implementation of the newly revised drug GMP on production costs of enterprises while developing and adjusting drug prices. Preferential price policies shall be reasonably applied to products that have passed the certification of newly revised drug GMP and have been confirmed by food and drug administration departments as reaching the international levels.

6. Implement preferential policies for centralized drug procurement, which shall adhere to the principle of quality first and reasonable price. Further improve drug quality evaluation system, and take as an important indicator the attainment of newly revised drug GMP certification of the appropriate variety or dosage forms of manufacturers. In centralized procurement of essential drugs, if the products of manufacturers that have passed the newly revised drug GMP certification participate in the tender, similar products of other enterprises that failed to pass the newly revised drug GMP certification shall not enter the commercial bid review stage; in centralized procurement of non-essential drugs, researches shall be accurately made to explore the establishment of separate product categories, and further increase the evaluation weight of GMP certification. For drugs with uniform pricing, preferential procurement shall be applied to enterprises whose relevant varieties or dosage forms have passed the newly revised drug GMP certification.

7. Support drug GMP transformation projects of enterprises. Financial support shall be provided to newly revised drug GMP transformation projects of enterprises through special funds for industrial revitalization and technology transformation etc., to mobilize the enthusiasm of the enterprise to implement transformation. Support qualified enterprises to construct preparation production lines in compliance with international standards, organize and implement international certification for production quality system, to promote China’s pharmaceutical production and quality assurance level to gear to international standards.

In the Notice, the four government agencies require the food and drug administration, development and reform, industrial and information technology, health administrative departments to reinforce the harmonization and cooperation of various policies to form a policy synergy. At the same time, inter-departmental leadership team or coordination meeting mechanism shall be established. Sector management and operation supervision shall be strengthened to study, predict and timely solve the problems that may affect the normal supply of drugs to secure the needs of clinical medicine. The implementation status shall be reported to local governments in a timely manner, relevant policies shall be implemented under the uniform leadership of local governments for effective implementation of the newly revised drug GMP. For drug manufacturers with discontinued production or shut down due to the implementation of the newly revised drug GMP, preparations shall be made in advance to develop contingency plans for proper disposal, and effectively safeguard social stability. (Jan. 08, 2013)
SFDA Special Campaign on Severely Cracking Down on Illegal Release of False Drug Information for Sales of Drugs Achieved Significant Results

To ensure drug safety for the public, in February 2012, the State Food and Drug Administration (SFDA) launched a system-wide special campaign on “Strengthening the Supervision of Website Drug Information Services and Transaction Services, Severely Cracking down on Illegal Release of False Drug Information for Sales of Drugs”, over the past year, all areas have conscientiously and actively organized special campaign according to SFDA overall deployment, remarkable results have been achieved.

In this special campaign, the State Food and Drug Administration have listed all of the approved websites as key inspection objects, the whole system have inspected 3685 websites for online drug information service, 118 websites for online drug transaction services, the inspection rate is up to 100%. During the inspections, enterprises found with problems have been ordained for immediate corrections, those who refused to rectify have all been punished according to law. During the special campaign, notice for mandatory rectification has been issued to a total of 263 problematic enterprises, 102 qualification certificates for Internet drug information service have been canceled, 70 Internet drug information service qualification certificate have been withdrawn, 82 websites have been shut down, and 10 cases have been filed for investigation and punishment.

"Deepening the Reform of Drug Review and Approval "Solicits Public Comments"

Recently, the State Food and Drug Administration (SFDA) issued the "Opinions on Deepening the Reform of Drug Review and Approval, Further Encouraging Drug Innovation (Draft for Comment)” (hereinafter referred to as the "Draft ") for public comments. The "Draft" proposed to accelerate the approval of innovative drugs and generic drugs with clinical value, strengthen quality management of drug clinical trials, and to encourage the R&D of pediatric drugs.

The "Draft" proposed three measures to improve the review and approval mechanism and accelerate review of innovative drugs. First, encourage clinical value-oriented drug innovation. Second, adjust the technical requirements and specifications for review of innovative drugs. Third, optimize the review process to improve efficiency. The R&D and review of innovative drugs should be based on clinical value, which should be attached with more importance while paying attention to the pay more attention to the novelty and originality of the material basis. Accelerated review shall be given to drug R&D with the above characteristics, especially for registration applications of innovative drugs enlisted in the key special projects of China, for which expedited review, whole process tracking, and focused guiding shall be applied. A reviewer contact system shall be piloted to timely track review progress, strengthen supervision and inspection, encourage and support the R&D of high level innovative drugs with clinical value.

With respect to strengthening the management of generic drugs and speeding up the approval of priority varieties of generic drugs, the "draft" proposed to explore the establishment of a valuation system of marketed drugs. Through the evaluations, guidance can be provided for the R&D of generic drugs to reduce the waste of resources and duplication.
of applications, guide the applicants for rational applications, and improve the clinical value of generic drugs. Implement prioritized review system for registration applications of some generic drugs, such as those with insufficient clinical supply, inadequate competition in the market, those affecting the accessibility and affordability of public drug use, pediatric drugs, orphan drugs, and drugs for special populations, and other drugs that are confirmed as urgently needed in clinical applications, etc.

The "Draft" specifically proposed the encouragement of the R&D of pediatric drugs. Manufacturers are encouraged to actively develop the children-specific specifications and dosage forms for generic drugs, and the applications of innovative drugs are encouraged to apply simultaneously the dosage forms and specifications for children. The applications for children-specific specifications and dosage forms of generic drugs can enjoy preferential acceptance and review. At the same time, the determination models for the monitoring period of child medication shall be studied, and comprehensive incentives shall be researched in conjunction with relevant departments for pediatric drugs with respect to the bidding, pricing, medical insurance and other aspects. (Jan. 07, 2013)

Q & A

Center for Drug Evaluation Replies Common Questions for Generic Drug

(To continue)

To ensure the accuracy and reliability of impurity determination results, under normal circumstances, corrections need not to be made when the correction factors are within the 0.9-1.1 interval, self-control method without correction factors can be directly used for quantification; outside this interval, if principle component self-control method is adopted for quantification, correction factors must be added, the “principle component self-control method with correction factors” shall be employed to ensure the accuracy of impurity quantification; if the correction factor is outside the range of 0.2-5.0, indicating excessive difference of UV absorption of impurities and the principal components, the function of correction factors will be significantly affected, in this case the test conditions such as the detection wavelength should be changed to regress the correction factor within the above range, or we can reestablish the correction factors by taking as reference material by structural or UV absorption another standard substance (such as another specific impurity with readily available reference substance, and quantified standards determined by external reference method), which is similar to the impurity; if the correction factor still could not be adjusted to the appropriate range, external reference standard method for impurity reference substances and other appropriate methods shall be considered for quantification.

The application of the correction factor is similar to the use of the absorption coefficient, both need to have a certain preconditions, such as the same detection wavelength, analysis methods, and
original product, and their equivalence can be guaranteed by the establishment of a quality assurance system, the two will have the same clinical efficacy and safety. Thus, by comparative research of the marketed original drugs (control drugs), we can prove the consistency and equivalence of quality characteristics, and "bridge" the safety and efficacy of marketed drugs. Control drugs are the benchmark and basis for generic R & D, therefore the selection of controlled drugs is of great importance while seeking material consistency and quality equivalence with the marketed products, especially in our country, currently we still have no authoritative "Orange Book" directory for reference, even for the same variety, the quality levels of the commercially available products are quite different, if poor quality products are mistakenly selected for reference and control, the adverse factors of which may be passed and even superimposed and amplified in the generic R&D process, affecting the improvement of generic standards.

Control drug selection can refer to the following recommendations:

1. When selecting original R&D products as the first choice, is these products have been imported to China, we should select these imported original products.

2. If the original R&D products or imported original products are not available, we can choose the marketed same products of the ICH member states, i.e., the generic products marketed in the United States, the European Union, Japan or other countries. If the generic products of the above-mentioned countries have been imported to China, the imported products can be selected.

3. When the products of the above 1 and 2 cases are not available, if domestic enterprises applied the sterile APIs of the above origins to directly dispense and produce sterile injection powders, these products can also be used as a control drugs for impurity spectrum quality research, but relevant supporting documents must be provided to prove that the preparation is needed for material consistency and quality levels.

需要对相关特定杂质的色谱峰规定相对保留时间的限定。对于特定杂质的控制，校正因子的研究和测定非常必要。评估杂质定量是否需要采用校正因子校正，校正因子能否起到有效的校正作用，首先需要测出校正因子。按照相关技术指导原则的要求评估是否需要校正，并提供相应的对比研究资料。这些研究数据应包括杂质对照品，如校正因子的主成分自身对照法，不加校正因子的主成分对照对相同多批样品杂质定量测定结果的对比数据，作为是否需要校正或能否有效校正检测结果的支持与依据。

问题九：在仿制药研发中如何选择质量对比研究用对照药？

答：仿制药研发的目标是设计并生产出可以替代已上市产品的相同药品，已上市原研产品的安全性和有效性已经得到了系统的研究和验证，如果研制产品和已上市原研产品具有相同的物质基础和质量特征，建立的质量保障体系可以保障这种相同的情况下，则二者会具有相同的临床疗效和安全性。因此，通过与上市原研产品（对照药）的对比性研究，证明其物质基础的一致性和质量特征的等同性，来“桥接”上市药品的安全有效性，对照药是仿制药研发的标杆与基础，因此在求得与上市产品物质一致、质量等同时，对照药选择至关重要。尤其在我国，目前尚无权威《横皮书》目录可供参考，即使同一品种，市售品的质量水平也有较大差别，如误选较差产品为参比，其中的不良因素在仿制过程中可能被传递甚至叠加放大，影响到仿制水平的提高。

对照药选择可参照如下建议：

1. 首选原研品种，如果原研企业的产品已经进口我国，应采用原研进口品。

2. 如果无法获得原研产品或者原研进口品种，可以采用ICH成员国相同的上市品种，即美国，欧盟或日本等国上市的仿制品。如果上述产地仿制品已经进口我国，可采用其进口品。

3. 在无法获得1和2所述产品的条件下，如果国内企业采用上述产地的无菌原料药直接分装生产无菌粉针，也可采用该产品作为杂质谱等质量研究的对照药，但需提供相关证明性文件以说明该该制剂确为上述进口原料药直接分装获得，并说明原料药的生产厂、批号等产品信息。
of the impurity spectrum has indicated that the comparative study of the quality of the original R&D product can no longer be a mandatory requirement.

For simultaneous generic APIs and preparations R & D, when the original drugs are not available, if the APIs have no interferences, the comprehensive comparative study of impurities spectrum can be conducted by using preparations, i.e., to indirectly prove the consistency with the APIs impurities spectrum by comparing the Impurity spectrum and other quality characteristics of the generic preparations with the original preparation products.

5. If the generic drug is not marketed in the ICH member countries, the enterprise cannot obtain foreign or imported samples meeting the above requirements, such as Furbucillin Sodium, cefaliamidine etc., it is advisable to conduct the research and determine the limits according to the technical guidelines for impurity research and related ideas and technical requirements for impurity research of innovative drugs, and take a number of domestic marketed preparations as control to carry out in-depth impurity research and control, the quality of newly applied products shall not be lower than that of the domestic marketed products.

6. For drugs applied and registered as changed dosage forms, the target of the generic R&D is the product with changed dosage forms, but in order to avoid error propagation and superposition on R & D products, the control drug for quality comparison studies (especially the comparative study of the spectrum of impurities) should choose the original dosage forms of the original R & D enterprise products, rather than the other companies’ marketed products with changed dosage forms. For oral solid dosage forms, the comparative study of dissolution behavior should consider the difference of dosage forms, and conduct, when necessary, comparative study of the dissolution profiles of products with the same dosage form and good R&D basis in a variety of media.

(2012-08-08)

indeed directly dispensed from the imported APIs with elaborated manufacturers, batch numbers and other product information.

For other agents, due to the complexity of applied excipients, solvents, etc., or certain production processes that may generate heat, such as: fluidized bed granulation, drying, tableting, coating, etc., the impurity spectrum of the preparations, even if produced by imported APIs, may be different with that of the original products, such preparations cannot be used as control drugs for quality comparison.

4. When the generic drug is still marketed and applied in the above ICH member countries, if the applicant applied samples from the production origins (include domestic products) instead of the marketed product of ICH countries as control samples for impurities study, normally these generic drugs should not be recognized.

When the above-mentioned foreign marketed products (especially APIs) are not available, if these drugs have been recorded in BP, USPS, EP and the Pharmacopoeias of other ICH member states, with stringent control of impurities and other quality control items (such as azithromycin, clarithromycin etc.), and compliance with the existing technical guidelines for research of impurities, impurity analysis and research (including the effectiveness of the detection method, the use of impurity reference substance, the control of specific, non-specific and total impurities etc.) can be conducted in strict accordance with the standards and requirements of the Pharmacopoeias, and ensure the absence of abnormal impurities.

At the same time, if the comparative study of the impurity spectrum has indicated that its quality is not less than that of the domestic marketed products, the impurities can be considered as effectively controlled. The comparative study of the quality of the original R&D product can no longer be a mandatory requirement.

4. If the ICH member countries have recorded in BP, USPS, EP etc. ICH Pharmacopoeias have been available, and the corresponding quality control requirements have been recognized, the generic drug can be considered as effectively controlled.

5. If the generic drug is not marketed in the ICH member countries, the enterprise cannot obtain foreign or imported samples meeting the above requirements, such as Furbucillin Sodium, cefaliamidine etc., it is advisable to conduct the research and determine the limits according to the technical guidelines for impurity research and related ideas and technical requirements for impurity research of innovative drugs, and take a number of domestic marketed preparations as control to carry out in-depth impurity research and control, the quality of newly applied products shall not be lower than that of the domestic marketed products.

6. For drugs applied and registered as changed dosage forms, the target of the generic R&D is the product with changed dosage forms, but in order to avoid error propagation and superposition on R & D products, the control drug for quality comparison studies (especially the comparative study of the spectrum of impurities) should choose the original dosage forms of the original R & D enterprise products, rather than the other companies’ marketed products with changed dosage forms. For oral solid dosage forms, the comparative study of dissolution behavior should consider the difference of dosage forms, and conduct, when necessary, comparative study of the dissolution profiles of products with the same dosage form and good R&D basis in a variety of media.

(2012-08-08)
**Long-Term Development Plan Released for TCM Standardization**

The State Administration of Traditional Chinese Medicine has recently released the "Medium and Long-Term Development Plan for Standardization of Traditional Chinese Medicine" (2011 to 2020). In accordance with the specific objectives of the "Plan" in the "12th Five-Year Plan" period, the levels of TCM industry standards shall witness remarkable upgrades, and the industry standard construction shall be on the fast track.

The "Plan" put forward that by 2020, a TCM standard system with relatively reasonable structure shall be basically established to meet the needs of the industry development, the support system for TCM standardization shall be further improved to basically meet the demands; a TCM standard application & promotion and monitoring & evaluation system shall be preliminarily established; the construction of TCM standardization talent teams shall be significantly strengthened; the management system and operation mechanism of TCM standardization shall be more perfect, and China's capabilities for substantive participation in TCM international standardization activities shall be significantly enhanced.

The goals during the 12th Five-Year period include: 300 TCM standards shall be developed, revised and released, basically covering the clinical, teaching, research, pharmacy and other fields. The quality level of TCM standards shall be significantly improved, more than 90% of the TCM standard-age is less than five years, and the coordination of national, industrial and organizational standards shall be significantly enhanced. A batch of TCM standards research and promotion bases shall be constructed in grassroots areas, and the mechanism for TCM standards research and development, application and promotion, evaluation and feedback shall be basically established. China's capabilities for substantive participation in TCM international standardization activities shall be significantly enhanced.  

(Jan. 18, 2013)

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**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

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