Volume V 2010

CHINA PHARMACEUTICAL NEWSLETTER

中国医药国际交流中心

SERVIER
施维雅(天津)制药有限公司

NEWS

SFDA Commissioner Shao Mingli met with U.S. Delegation led by Dr. Ira Kasoff, Assistant to Under Secretary of U.S. Department of Commerce on August 20, 2010 Both parties retrospectively reviewed China-US cooperative relationship under the framework of China-US Joint Commission on Commerce and Trade (JCCT). In depth discussions were held on issues concerning medicine, medical device and health-care foods.

(August 21, 2010)

SFDA Commissioner Shao Mingli met with Dr. John Lim, Chief Executive Officer of Singapore Health Sciences Authority on August 17, 2010 Discussions and talks were held concerning issues pertaining to the latest revision of China's GMP, developments of the informationization of Drug Administration in China, updates of Singapore's Drug Supervision and Administration, and exchanging views on strengthening and reinforcing international communication and cooperation between both parties.

(August 18, 2010)

SFDA Commissioner Shao Mingli met with Ms. Margaret Hamburg, the Director General of FDA of the United States in Beijing, on August 11, 2010 Reviewed the development of cooperation between the two nations since the signing of the Cooperation Agreement on the Safety of Drugs and Medical Devices in 2007. Both parties also had in-depth discussions about how to strengthen the safety supervision of drugs and medical devices and how to better ensure safe medication. (August 16, 2010)

SFDA Deputy Commissioner Wu Zhen met with Denmark Delegation led by Ms. Jytte Lyngvig, CEO of Danish Medicines Agency on September 9, 2010 Both parties exchanged views on issues of common interests about drugs and medical devices. (September 10, 2010)

SFDA Deputy Commissioner Bian Zhenjia supervises the specific rectification program addressing drug safety On September 9, SFDA Deputy Commissioner Bian Zhenjia visited Beijing Drug Administration to inspect developments to rectify specific drug related issues on drug safety. He praised the achievements made by Beijing Drug Administration since the rectification process commenced. He pointed out that local Food and Drug Adiministration should work under the unified arrangement of SFDA, pay greater attention to rectify drug safety concerns, overcome difficulties, ensure strict implementation of the drug safety and accountability system, strengthen supervision and guarantee the quality and safety of drugs.

(September 10, 2010)

SFDA Deputy Commissioner Bian Zhenjia attends the opening ceremony delivering a speech at China International Medical Device Regulatory Forum 2010 China International Medical Device Regulatory Forum 2010 was held by China Center for International Pharmaceutical Exchange from September 7 to 10, 2010. SFDA Deputy Commissioner Bian Zhenjia attended the opening ceremony giving a speech on the implementation of systematic rules and regulations concerning the supervision and management of China's medical device and to reinforce international communication and scientific administration in this sector.

(September 10, 2010)

Published by
China Center for Pharmaceutical International Exchange & Servier (Tianjin) Pharmaceutical Co., Ltd.

SFDA Departments no longer accept Applications on Accreditation and Approval of Drug Tendering Agencies

According to *State Councils Decision on Cancelling and Decentralizing Management Layers for the Fifth Batch of Administrative Approval Items*, "Qualification Accreditation of Drug Tendering Agencies" is now listed as cancelled administrative approval items. To ensure smooth transition of relative systems after the cancellation date of these administrative approval items, SFDA made specific regulations on correlating matters on September 8. From this date, the two notices, *Notice re Issuing Management Approach on Qualification Accreditation and the Administration of Drug Tendering Agencies and Notice concerning the processing work of Accreditation of Drug Tendering Agencies*, are abolished.

Local Food and Drug Adiministration in all provinces no longer Applications on Accreditation and Approval of Drug Tendering Agencies. Former qualifying certificate obtained by drug tendering agencies will be automatically cancelled from its expiry date. SFDA demanded that Local Food and Drug Adiministration in all provinces, autonomous regions and municipalities directly under the central government conscientiously implement drug administration functions under the leadership of local governments, actively cooperate with departments concerned to implement and synchronize centralized drug tendering and procurement.

(September 8, 2010)

食品药品监督管理部门不再受理药品招标代理机构资格认定工作

根据《国务院关于第五批取消和下放管理层级行政审批项目的决定》，“药品招标代理机构资格认定”被列为取消的行政审批项目。为了做好取消该行政审批后的相关工作，9月8日，国家食品药品监督管理局就有关事项做出明确规定：从发文即日起，《关于印发药品招标代理机构资格认定及监督管理办法的通知》、《关于药品招标代理机构认定工作的通知》予以废止；各省、自治区、直辖市食品药品监督管理部门不再受理药品招标代理机构资格认定工作，已取得《药品招标代理机构资格证》的，期满后自动作废。国家食品药品监督管理局要求各省、自治区、直辖市食品药品监督管理部门在当地政府的领导下，认真履行药品监管职能，积极配合有关部门继续做好药品集中招标采购工作。

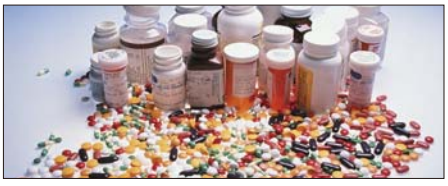
（2010年9月8日）

SFDA will conduct a national inspection to the supervision and administration of drug circulation

To further strengthen the supervision on drug circulation and get in touch with the status of China's pharmaceutical companies, from Aug.30 to Sep.10, 2010, SFDA organized a number of inspection teams to carry out nationwide investigations on the replacement of licenses of pharmaceutical companies and the work of categorized drugs management.

Through formal work reports, discussions, symposia and field investigations, the inspection teams shall listen the reports concerning the specifics of the inspections from the local Food and Drug Administration, and ideas and suggestions on drug administrative work from enterprises to continuously improve and enhance the level of administration and inspection.

(August 30, 2010)



国家食品药品监管局将组织检查调研全国药品流通环节监管工作情况

为进一步加强药品流通监管，全面了解我国药品经营企业现状，国家食品药品监督管理局于8月30日至9月10日，组织多个检查调研组就药品经营企业换证和药品分类管理工作等内容在全国范围内组织开展了检查调研工作。

检查调研组将采取听取工作汇报、召开座谈会及现场检查等方式，听取各省局关于检查主要内容的情况汇报，听取企业对药品经营监管工作的意见和建议，不断改进和提高监管工作水平。

（2010年8月30日）

Ministry of Health, State Administration of Traditional Chinese Medicine and State Food & Drug Administration issue *Opinions on Strengthening the Management of Traditional Chinese Medicinal Preparation in Medical Institutions*

In order to strengthen the management of traditional Chinese medicinal preparations and promoting the development of these preparations in medical institutions, MOH, SATCM and SFDA jointly issued Opinions on Strengthening the Management of

卫生部、国家中医药管理局、国家食品药品监督管理局发布《关于加强医疗机构中药制剂管理的意见》

为加强医疗机构中药制剂管理，促进医疗机构中药制剂发展，8月24日卫生部、

Traditional Chinese Medicinal Preparation in Medical Institutions on Aug.24.

The joint opinions elaborated the principles and measures for strengthening the management of traditional Chinese medicinal preparation in medical institutions through five aspects: (1) Become aware of the significance in developing traditional Chinese medicinal preparation in medical institutions. (2) The basic principles in developing traditional Chinese medicinal preparation in medical institutions. (3) Strengthen drug registration management of traditional Chinese medicinal preparation in medical institutions. (4) Improve the management of making up of traditional Chinese medicinal preparations in medical institutions. (5) Strengthen the management of the utilization of traditional Chinese medicinal preparations In medical institutions,

The MOH, SATCM and SFDA stipulated that traditional Chinese medicinal preparation made in medical institution can only be used under the direct supervision of physicians inside the medical institution and that open-market distribution or any disguised forms of marketing, e.g. covert dealing via Internet or mail-order systems is strictly forbidden. (August 30, 2010)

国家中医药管理局和国家食品药品监督管理局发布了共同组织制定的《关于加强医疗机构中药制剂管理的意见》。

《意见》主要有以下五个方面的内容：一是深刻认识发展医疗机构中药制剂的重要意义；二是发展医疗机构中药制剂的基本原则；三是加强医疗机构中药制剂注册管理；四是完善医疗机构中药制剂的配制管理；五是加强医疗机构中药制剂的使用管理，阐述了加强医疗机构中药制剂管理的原则和措施，其中，明确规定医疗机构中药制剂只能在本医疗机构内凭医师处方使用，不得在市场上销售或者通过互联网、邮购等变相销售。

（2010年8月30日）

Launching Ceremony of the 2010 Version of Chinese Pharmacopoeia----Promoting education and training for better drug administration and inspection

On September 15, the launching ceremony of the 2010 Version of Chinese Pharmacopoeia was held in Beijing. Vice-chairman of the NPC Standing Committee, Sang Guowei stated that the new version of Chinese Pharmacopoeia not only recorded 40% more of drug species but also improved or raised the standards of 70% of the former recorded species. The promotion and implementation of the new Pharmacopoeia will inevitably impact the pharmaceutical market as more and more low-quantity drugs are weeded out of the market place. The new Pharmacopoeia is of great significance in enhancing the safety level of people's drug safty, boost the international competitiveness of Chinese medical products, and further promote the restructuring of China's pharmaceutical industry.

The 2010 Version of Chinese Pharmacopoeia will come into effect as of August 1, 2010. SFDA Deputy Commissioner Wu Zhen put forward requests on how to implement the 2010 Version of Chinese Pharmacopoeia:

1. Strive for better popularization and training for the new Pharmacopoeia;

2. Strengthen the supervision and inspection of the implementation of new Pharmacopoeia.

R & D institutions, drug manufacturers and distributors are all required to be fully aware of the technical renovations and adjustments prescribed by the new Pharmacopoeia, actively organize and carry out equipment renovation and technological innovation, to secure the development and production of qualified products within the standards set forth by the new Pharmacopoeia. local Food and Drug Adiministration at all levels should resolve administrative approval items applied for by enterprises according to the requests of the new Pharmacopoeia and reinforce supervision and inspection on its implementation. Local Health administrative departments at all levels should motivate all medical institutions to be crystal clear of the standards set forth by the recorded species in the new Pharmacopoeia so as to regulate the clinical application of drugs.

3. Further propel consistent development work of national drug standards. SFDA shall put on the agenda the compilation of the 2015 Version of Chinese Pharmacopoeia To let the work scientificly arranged and actively promoted. (September 16, 2010)

2010年版《中国药典》宣传贯彻大会要求——做好宣传培训 加强监督检查

9月15日，2010年版《中国药典》宣传贯彻大会在京召开。出席会议的全国人大常委会副委员长桑国卫指出，新版药典不仅收载品种增加了40%以上，而且对70%的原有标准进行了完善或者提高。新版药典的推广执行，必将给医药市场带来冲击，更多低质量的药品将被市场淘汰。新版药典对于提高公众用药安全水平，提升我国医药产品国际竞争力，进一步推动我国医药产业结构调整具有重大意义。

2010年版《中国药典》将于今年10月1日开始执行。国家食品药品监督管理局副局长吴浈在会上对就如何贯彻实施2010年版《中国药典》提出了要求：一是认真做好新版药典的宣传和培训工作；二是要加强对新版药典执行情况的监督检查，科研单位、药品生产经营企业要充分了解新版药典在技术要求上的更新和变化，积极组织开展设备改造及工艺革新，确保研制、生产出符合新版药典标准的合格产品；各级药品监管部门要及时办理企业根据新版药典要求提出的行政许可事项，加大新版药典执行的监督检查力度；各级卫生行政部门要动员广大医疗机构，明确使用新版药典收载药品的要求，规范药品临床应用；三是继续推进国家药品标准工作不断发展。国家食品药品监督管理局将把2015年版药典的编制工作摆上工作日程，科学安排，积极推进。（2010年9月16日）

Center for Drug Certification of SFDA issued the Application Guide for *On-site Inspection of the Manufacturing of Registered Drugs*

To improve the work quality and efficiency of on-site inspections in the manufacturing of registered drugs, Center for Drug Certification of SFDA issued an application guide for On-site Inspection for the Manufacturing of Registered Drugs. This guide was issued on August 8. The contents are:

1. Applicant should present an On-site Inspection Application to Center for Drug Evaluation of SFDA within six months after receiving Drug Evaluation's Notice of a pending On-site Inspection for Drug Manufacturing.

2. The application for inspection must be submitted in both paper and electronic file formats. After receiving, from the Center for Drug Evaluation of SFDA, the notice of an on-site inspection, the applicant should log into the website of the Center for Drug Certification of SFDA (http//www.ccd.org.cn) click on the button "On-site Inspection for the manufacturing of Registered Drugs" (abr. System) complete the forms and submit online.

3. After the Center for Drug Certification of SFDA has received SFDA Center for Drug Evaluation's Notice of On-site Inspection for Drug Manufacturing and has registered and confirmed the Information of the respective applicant, relative drug applicant and the serial number of acceptance will be listed in an online application from for On-site inspection of New Drug Manufacturing thereby opening the User Interface of electronic application forms automatically.

4. Applicant is required to check correlating information of their drugs in the "public notification section of application" for On-site Inspection of New Drug Manufacturing". Click "create electronic application form", then fill in the serial number of acceptance, name of the manufacturing unit, acceptance date of new drugs, the serial number of on-site inspection and the verification code

temporarily distributed by the online system. Once all these procedures are completed, the interface shall be gained for online form completion for the relevant drug.

5. The applicant shall complete and fill in accurate and true information on the Application Form for On-site Inspection of the Manufacturing of Registered Drugs (hereafter referred to as Application Form) and to include the manufacturing information of three (3) batches of product samples applying for registration and manufacturing. No incomplete grid in the application form is allowed to be void of information. If there is no relevant information required in a particular grid, insert the word None. Unauthorized modification on the format and content of the Application Form is forbidden. For more detail, review the Instructions in the Application Form.

6. The applicant can temporarily save their edited data by clicking the "save" button at any stage during the application procedure on the form. Prior to formal submission, the Application Form can only be printed in test print format without the bar code data. The test printed format cannot be used as a formal submission version.

7. After completing and confirming the accuracy of the relative information, applicant can click the "submit" button to dispatch the electronic information to the. Center for Drug Certification of SFDA.

国家食品药品监督管理局药品认证管理中心发布《药品注册生产现场检查申请指南》

为提高药品注册生产现场检查工作质量和工作效率，国家食品药品监督管理局药品认证管理中心（以下简称认证中心）于8月18日发布了《药品注册生产现场检查申请指南》。内容如下：

1. 申请人应当自收到国家食品药品监督管理局药品审评中心（以下简称药品审评中心）发出的药品生产现场检查通知之日起，6个月内向认证中心提出现场检查申请。

2. 检查申请需以电子及纸质二种方式进行提交。申请人应在收到药品审评中心发出的现场检查通知后，登录认证中心网站（http//www.ccd.org.cn），点击“药品注册生产现场检查”系统（简称系统）进行网络填报、提交。

3. 认证中心收到药品审评中心《药品生产现场检查告知书》及相关材料并经登记确认后，注册检查填报系统中的“新药生产现场检查申请公示列表”显示相应品种申请人和注册受理号信息，同时系统自动开放申请生产单位电子《申请表》填报界面。

4. 申请人需在“新药生产现场检查申请公示列表”中查询到品种相关信息，点击“创建电子申请表”，并经填写核对受理号、申请生产单位名称、新药受理日期、现场检查通知流水号以及系统临时分配的验证码后，方可进入到相应品种网络填报界面。

5. 申请人应按照界面提示如实填报《药品注册生产现场检查申请表》（以下简称“《申请表》”），包括申报注册生产时三批样品生产信息等，不得有空项。如遇表格项下要求相关信息确实没有，则应填写“无”。《申请表》的格式和内容不得擅自更改，详见《填表说明》。

6. 在填写申请表信息过程中，申请人可以点击（保存）按钮进行临时保存。在正式提交前打印的申请书，均为测试打印版，没有条码信息，不可作为正式纸质提交版本使用。

7. 经确认相关信息已填写完整无误后，申请人通过点击（提交）按钮，将申请书电子信息提交至认证中心，并在提交完成后打印三份《申请表》（正式提交版本应在首页左上角显示条码），分别加

Next, print three (3) copies of Application Form (the formal submission version with bar codes on upper left corner) -- Mail the all three copies with official seal and the perforation seal plus one (1) photocopy (4 copies in total) to the Second Inspection Division of the Center for Drug Certification at the following address: F3, Building No.11, Fa Hua Nan Li Residence, Chongwen District, Beijing. Zip code 100061.

8. Paper-copy Application Forms must be submitted via mail. If special circumstances occur when the forms are sent via secure courier services, the authorized delivery trustee (courier) has to present a valid Letter of Authorization submitted by the Applicant and a photocopy of his/her personal ID. Without the Letter of Authorization and photocopy of courier's ID, the Application Forms shall not be accepted.

9. After receipt of both the electronic and paper copy Application Forms, the Center for Drug Certification will initiate official work procedures on the inspection of the drug. While official procedures are being worked through, the electronic application system will send feedback to applicants notifying them of their application status.

10. The electronic application system has a six-month time limit for the drug applied manufacturing unit. The online application interface will terminate after the 6 months if no Application Form is submitted. Then the Center for Drug Certification will terminate inspection work procedures forthwith.

11. Should applicants not be able to submit the inspection application within the six-month time limit as prescribed by the Regulations on Administration of Pharmaceutical Registration due to specific reasons i.e. laboratories are undergoing technological renovation etc., the Applicant is required to submit a postponement application completed in written form and submit this to the Center for Drug Certification before expiry of the deadline date. The postponement application should include information of the applicant, name of the drug, acceptance serial number, reason for postponement, time limit for postponement etc and include confirmed statements issued by the Local Food and Drug Adiministration. A carbon copy of the Postponement Application should then be sent to The Center for Drug Evaluation for putting on record. (August 19, 2010)

盖申请人公章及骑缝章，并一份复印件共四份邮寄至认证中心检查二处（地址：北京市崇文区法华南里小区11号楼三层；邮编：100061）。

8．纸质《申请表》提交采取邮寄形式，如遇特殊情况当面送达，须附申请人委托书以及受托人身份证复印件，如无委托书和受托人身份证复印件的材料应予以拒绝或退回。

9．电子和纸质《申请表》均收到后，认证中心正式启动品种检查工作程序，同时电子申报系统将向申请人反馈接收状态。

10．电子申报系统对该品种申请生产单位开放时限为6个月。6个月期满如不提交申请，系统将关闭该受理号品种申请界面，认证中心将启动终结该品种在认证中心的检查工作程序。

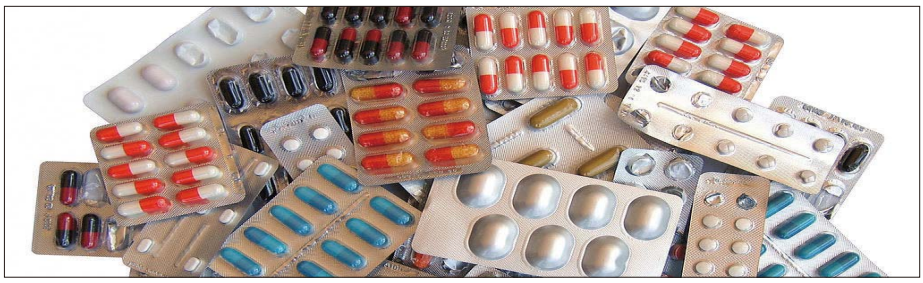
11．如遇该品种生产车间正在技术改造或其他特殊原因，申请人无法在《药品注册管理办法》规定时限内提交检查申请的，申请人应在满六个月前向认证中心提交正式的书面延迟申请，延期申请中应至少包括申请人、品种及受理号名称、延期原因、延期时限等，并有该品种生产申请人所在省局注册处出具的确认意见。另外，延期申请应同时抄送药品审评中心备案。（2010年 8月19日）

Application Material Requirements for the Conversion of Prescription Drugs to Non-prescription Drugs

In order to guide drug registration applicants in the preparation of application material for the conversion of prescription drugs to non-prescription drugs, in light of the *Notice on the Evaluation of the Conversion of Prescription Drugs to Non-prescription Drugs* (Guo Shi Yao Jian An [2004] No.101), the Eveluator of the Center for Grug Eveluation of SFDA has provided the following recommendations.

I. COMPREHENSIVE REQUIREMENTS

1. The appraisal of the conversion of prescription drugs to non-prescription drugs belongs to the scope of reeveluation of marketed drug, in which retrospective study is the major concern. Hence, an overall retrospection and analysis should be performed on the relevant research data



处方药转换非处方药申请资料要求

6月30日国家食品药品监督管理局发布了《关于做好处方药转换为非处方药有关事宜的通知》，为指导药品注册申请人准备处方药转换非处方药申请资料，国家食品药品监督管理局药品审评中心提出如下建议：

一、综合要求

1．处方药与非处方药转换评价属药品上市后评价范畴，以回顾性研究为主，故在开展本项工作中应对品种相关研究资料进行全面回顾和分析。文献检索范围应包括国内外主要医药学文献及期刊，并保证相关文献均纳入综述中，主要文献资料应附文献全文，所报外文资料必须提供相应中文译文。如相关文献较多可以电子文档方式提供（光盘）。

2．申报资料项目1、3、4须提供电子文档。

of the drug. The literature survey should be done in the major medical literature and journals at home and abroad and it should be ensured that the relevant literature has been included in the review. The full text of the main documents should be attached and Chinese translations must be provided for literatures involving foreign languages. If relevant literatures are more, the electronic version (CD) should be provided.

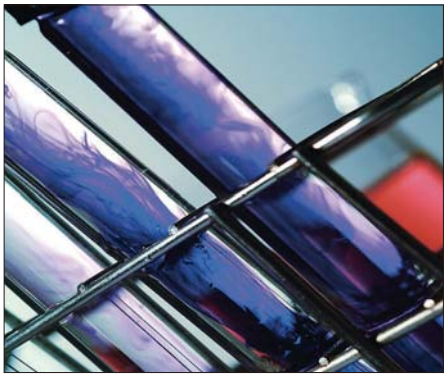
2. The items 1, 3 and 4 of the application material must be provided as electronic documents.

3. The public literature references quoted should indicate the literature source. Non-public literature should specify the research institution, research date and proof of research institution (such as the seal stamp, available in form of a copy).

4. If the relevant research data is not available, for the traditional Chinese medicine brlonging to category I or the chemical drug belonging to category I, an explanation is required indicating why this research could not be performed. If the relevant literature cannot be searched, an explanation and the scope of the literature searching is required.

5. The summarized data required in the application material indicate that the applicant should provide a summarization of the related data specifically relevant for this conversion of a prescription drug to an non-prescription drug, rather than summarized literatures.

6. The application material should be printed (or copied) on A4 paper and be bookbound .



II. DATA REQUIREMENTS

(i) Summarized Data

1. Application form for the conversion of a prescription drug to an non-prescription drug

The application form should be filled in strictly according to the Notice on the Evaluation of the Conversion of Prescription Drugs to Non-prescription Drugs (Guo Shi Yao Jian An [2004] No.101). The names of toxic traditional Chinese herbal materials should refer to the list of toxic herbal materials in the Management Principles for the Conversion of Traditional Chinese Patent Medicines Containing Toxic Materials to Non-prescription Drugs.

2. Catalog of application material

The names and number of page of all data or documents provided in all items must be listed on the catalog, such as the names of all documents in the item "Proof Documents", the standard names of every ingredient in the item "The Legal Quality Standards of Pharmaceutical Preparations, Medical Materials and Excipients", the titles of summarization and testing data as well as the names of the publications in the item "Toxicological Research Data", etc.

3. Application explanation

1) The R&D section should include the production development institution and date, the major research projects conducted, the marketing date of the product, the marketing date of the researched original product, and the original research institution, as well as the changing condition of drug names and document approval numbers, etc.

2) The section on production and sale should include the approximate numbers for production, annual sales, estimated usage per person, etc.

3) The summarization of safety and effectiveness should be a conclusive summaries of toxicological research data, research data of adverse reactions or events, efficacy research data and clinical research data.

4) The overview of the literature survey should explain the scope of all the

3．引用的公开文献应说明文献来源；非公开文献应注明研究机构、研究时间，并应有研究机构的证明（如公章等，复印有效）。

4．中药一类、化药一类品种必须提供的资料中，如无相关研究资料，应予以说明，并说明可不开展此项研究的理由；如未检索到相关文献，应予以说明，并说明文献检索范围。

5．资料要求中所要求提供的综述资料是指申请人针对此次处方药转换非处方药申请相关资料的综述，不应只提供综述性文献。

6．申报资料使用A4纸打（复）印并装订。

二、各项资料要求

（一）综述资料

1．处方药转换非处方药申请表

申请类别应严格按《关于开展处方药与非处方药转换评价工作的通知》（国食药监安〔2004〕101号）所规定的类别填报。有毒中药材名称可参照《含毒性药材中成药转换评价非处方药处理原则》中所列毒性药材名单。

2．申报资料目录

应包括所有项目中所提供的所有资料名称和文件页数。如“证明性文件”项中的各证明文件名称、“药品制剂及药材、辅料的法定质量标准”项中的各成份标准名称、“毒理研究资料”项中的综述及试验资料名称、文献名称等。

3．申报说明

（1）研发情况中应包括如本品研制时间、机构，所开展的主要研究项目，本品上市时间，原研品上市时间、原研机构，以及药品名称、批准文号的变更情况等；

（2）生产、销售情况中应包括：大约有多少企业生产、每年销售数量、使用人次估算等；

（3）安全性、有效性综述应为“毒理研究资料、不良反应（事件）研究资料、药效学研究资料、临床研究资料”项目中综述内容的结论性内容综述；

（4）文献检索范围中应说明全部申报资料检索了多大范围内的文献，如检索的数据库名称、检索策略、检索时间范围等，并承诺未隐匿安全性信息；

（5）化学药品应说明其在世界主要国家和地区是否为非处方药。

4．拟使用的非处方药说明书样稿

application data searched, such as the names of databases searched, the searching strategy and time ranges. Additionally, it is required to give an assurance that no hidden safety information is involved.

5) It is required to explain whether the chemical drug is an non-prescription drug or not in the main countries and regions of the world.

4. The draft of the planned non-prescription drug leaflet

"The original leaflet" means the formal leaflet currently used in the market, which should be consistent with the leaflet in the samples. It is not allowed simply to enclose a print or a copy of the leaflet. If there have been any changes in the main contents of the current leaflet as compared with the original one, it is required to explain the reasons for the changes and provide relevant documents showing proof. "The draft of the non-prescription drug leaflet" means the draft of the non-prescription drug leaflet planned to be used in future, and only the printed text needs to be provided. If the main contents in the "draft" are different with the original one, it is required to explain the reasons in detail.

5. One sample of the minimum current sales unit

It is required to use a sample of the minimum sales unit on the current domestic market. If the product is not officially on the market, relevant explanations should be provided.

6. Proof documents

It is required to include the drug production license or import registration certificate. The authorization agent should also provide the original authorization document of the manufacturer.

(ii) Pharmacology Data

7. The legal quality standards of pharmaceutical preparation, medicinal materials and auxiliary materials

Firstly, it is required to list the names of the preparations, medicinal materials (ingredients) and auxiliary materials and to explain, by listing tables, the sources of the standards (such as the Pharmacopoeia of XX version, the Ministerial Standard of XX volume, the XX Provincial Standard and New Drugs in XXXX year), the standard No., as well as to enclose duplicates of the quality standards in sequence.

8. Drug quality data

The quality report should explain the drug quality record for the previous three years, such as whether there were any quality problems or whether the drug was notified because of quality issues. The stability research report should provide a long-term stability research report for the same period of validity.

(iii) Drug Safety Study

9. Toxicology research data

For traditional Chinese medicines, the toxicology research data of the preparation and the toxic medicinal materials should be included. For chemical drugs, the toxicology research data of the preparation and its active ingredients should be included. It is required to indicate the source of the data, its searched scope and the searching strategy. For traditional Chinese patent medicines containing toxic medicinal materials, the relevant research data of such materials should be provided.

The active components of the published non-prescription drugs refer to published non-prescription drug component lists in the form of active ingredients. Those which have been listed in non-prescription drug catalogs but have not been listed as active components in non-prescription drugs are not included.

10. Research data on adverse reactions or events

It is required to include a research summary of any adverse reactions or events of the preparation and every component, as well as relevant clinical trials, data from the literature and the searching report of adverse reactions from the inspection institution on or higher than provincial level. The period searched should be within 3 months before the application.

1) The summarized data should indicate the source of the data and the scope searched, a comprehensive analysis of all the data,

“原说明书”是指正在市场上销售使用的正式说明书，应与样品中的说明书一致，不能只附说明书打印件或复印件；如现使用说明书内容与最早上市时间使用说明书主要内容发生变化的，应说明变化原因及相关证明性文件；“非处方药说明书样稿”为拟今后使用的非处方药说明书样稿，只需提供打印文本；“样稿”与原说明书主要内容存在不同的，需要逐条说明理由。

5．现销售的最小销售单位样品一份

应使用目前正在国内市场销售的最小销售单位样品。如未正式上市销售，应对此进行说明。

6．证明性文件

应包括药品生产批件或进口注册证，代理商还应提供生产企业授权书原件。

（二）药学资料

7．药品制剂及药材、辅料的法定质量标准

首先应列出制剂、药材（成份）、辅料的名称，列表说明标准来源（如xx版药典、部标xx册、xx省标、xx年新药等）、标准号，其后按顺序附上质量标准复印件。

8．药品质量资料

质量情况报告应说明近三年来药品质量情况，如是否出现过质量问题，是否因质量问题被通报；稳定性研究报告应提供与有效期时间一致的长期稳定性研究报告。

（三）药品安全性研究

9．毒理研究资料

中药应包括制剂毒理和有毒药材毒理研究资料，化药应包括制剂和活性成分毒理研究资料。应说明资料的来源和检索范围、检索策略；含有毒药材中成药应提供该药材的相关研究资料；

已公布非处方药活性成分是指以活性成分方式公布的非处方药成份名单，已列入非处方药目录但未作为非处方药活性成分公布的不包括在内。

10．不良反应（事件）研究资料

应包括制剂及各成分药品不良反应（事件）研究综述和相关临床试验及文献资料、省级以上药品不良反应监测机构检索报告（检索时间应截止到申报前3个月内）。

（1）综述资料中应说明资料的来源和检索范围，对所有资料进行综合分析，说明所有相关研究资料中不良反应（事件）发生情况，分析每种不良反应（事件）的发生率、原因；

and the occurrence of adverse reactions or events with all relevant data, as well as the incidence and reasons of each adverse reaction or event.

2) The relevant clinical trial and literature data should include the clinical trial data for the product involved. The clinical trial, in which this product is used for comparison should also be included (the data for traditional Chinese medicines category I, chemical drugs category I and chemical drugs category II can be simplified appropriately).

3) If there is a great deal of literature, the catalogs and sources of all the literature should be provided, with the full text of the main literatures attached. Additionally, electronic version (CD) are also permissible.

4) The searching report of adverse reactions should be provided by the state drug adverse reaction inspection center or provincial drug adverse reaction inspection center. Moreover. And the scope searched and searching strategy should be explained.

11. Dependence research data

The summarized data should indicate the sources of the data and scope searched, and provide a comprehensive analysis of all the data.

12. Tolerance research data

The summarized data should indicate the sources of the data and scope searched, and provide a comprehensive analysis of all the data.

13. Interaction with other drugs and food

The summarized data should indicate the sources of the data and scope searched, and provide a comprehensive analysis of all the data.

14. Safety research data for self-diagnosis and self-medication by the consumer

It is required in the application to highlight whether the patient can self-diagnose the indications, whether he/she needs the professional help, and whether he/she can master the usage and dosage correctly.

15. Safety research data under extended use

It is required to highlight whether more unreasonable uses of the drug may occur when the drug is extensively used and the extent of the harm caused.

(iv) Drug Effectiveness Study

16. Pharmacodynamics research data

The summarized data should indicate the sources of the data and scope searched, and provide a comprehensive analysis of all the data.

17. Clinical research data on drug effectiveness

The diseases in the clinical research should be consistent with the indications of the non-prescription drug applied. (July 16, 2010)

（2）相关临床试验及文献资料中应包括所有涉及本品的临床试验资料，以本品为对照品进行的临床试验也应纳入（中药一类、化药一类、化药二类可适当从简）；

（3）如文献内容较多，应提供所有文献目录和来源，并附主要文献全文，也可以电子文档方式提供（光盘）；

（4）不良反应检索报告应由国家药品不良反应监测中心或各省药品不良反应监测中心提供，并应说明检索范围和检索策略。

11．依赖性研究资料

综述资料中应说明资料的来源和检索范围，并对所有资料进行综合分析。

12．耐受性研究资料

综述资料中应说明资料的来源和检索范围，并对所有资料进行综合分析。

13．与其它药物和食物相互作用情况

综述资料中应说明资料的来源和检索范围，并对所有资料进行综合分析。

14．消费者进行自我诊断、自我药疗情况下的安全性研究资料

重点说明患者是否可自我诊断所申报的适应症，是否需要专业人员帮助，用法用量是否可以正确掌握。

15．广泛使用情况下的安全性研究资料

重点说明在广泛使用情况下是否会出现较多的不合理用药情况及其产生的危害程度。

（四）药品有效性研究

16．药效学研究资料

综述资料中应说明资料的来源和检索范围，并对所有资料进行综合分析。

17．药品有效性临床研究资料

临床研究所针对疾病应与拟申请非处方药适应症相一致。

（2010年7月16日）

Nationwide Institutions for the Control of Drugs to carry out Cyber-monitoring on the quality of Essentials Drugs

The project platform of Quality Information for essential drugs initiated by National Institute for the Control of Pharmaceutical and Biological Products (NICPBP) recently began a construction network. This project will build an exclusive network dedicated to monitoring the quality of essential drugs covering Institutions for Drug Control nationwide to achieve universal exchange, sharing and inspection of data pertaining to essential drug controls.

According to news released at the National Symposium of Information-Construction in China's Drug Control System held from 20 to 21st August in Shenzhen, NICPBP

全国药品检验所将联网监督基本药物质量

由中国药品生物制品检定所牵头组织的“基本药物质量信息平台”项目日前进入网络建设阶段，该项目将建设覆盖全国各级药品检验所的基本药物质量监督专网，以实现基本药物检验数据的交流和共享。

据8月20～21日在深圳召开的全国药品检验系统信息化建设工作座谈会消息，中国

has understood the condition of basic equipment, staff, network construction, IT development level of the Institutions for the Control of drugs in all levels through the preliminary investigation to the construction of national drug control information system. And accoding to the result of this investigation, NICPBP has organized to compile Implementing Plans for Construction Project of Essential Drugs Quality Information Platform. To date, all work procedures are in smooth operation with the project now entering the stage of network construction. It is anticipated that network integration, preliminary monitoring, commissioning and final monitoring on the Quality Information platform for Essential Drugs will be accomplished by the first half of next year.

The completion of the platform will not only strengthen quality monitoring work of essential drugs, but unifying the office network platform of all the Institutions for the control of drugs in China, achieving the share of information and business application platform, which will promote information sharing and constructive communication of the Drug Control System, thereby improving and increasing the level of Drug Control Management.

(August 24, 2010)

药品生物制品检定所通过对全国药品检验系统信息化建设情况的前期调研，掌握了各级药品检验所的设备、人员、网络建设、信息化发展水平等基本情况，根据调研结果组织编写了《基本药物质量信息平台建设项目实施方案》，目前各项工作顺利推进，该项目已进入网络建设阶段，预计将于明年上半年前完成“基本药物质量信息平台”的网络集成、初验、试运行与终验。

平台建设完成后，不仅可以加强基本药物质量监督工作，还将统一全国药品检验系统的办公网络平台，实现药品检验数据资源和业务应用平台共享，推动药品检验系统的信息化建设，提高药品检验业务管理的质量和水平。（2010年8月24日）

Special Focus

China’s Foreign Trade in Pharmaceuticals in the First Half of 2010

China’s foreign trade in pharmaceuticals continued to grow during the first half of 2010, up 28.8% compared with the same period last year.

According to data provided by the customs, the import and export of medicines and health products totaled 28.3 billion dollars in the first six months, 28.8% grew up compared with the same period last year and 2.1% of the total amount of the whole country, including 18.89 billion dollars in exports and 9.42 billion dollars in imports, increases of 31.2% and 24.3% respectively compared with the same period last year. The increase in exports over the same period led to a jump of 38.8% in the trade surplus, which reached 9.47 billion dollars.

Western medicines are the main force in China’s growth in exports. The exports amounted to 11.78 billion dollars, 33.9% increased compared with last year, accounting for 62.4% of the total medicine exports. The runners-up were medical devices and traditional Chinese medicines whose exports reached 6.19 billion dollars and 910 million dollars respectively, 27.0% and 26.0% increased compared with last year, accounting for 32.8% and 4.83% of total exports. (See Figure 1)

业界专题

2010年上半年我国医药外贸运行情况

上半年，我国医药对外贸易整体延续了2009年以来的增长势头，同比增幅达28.8%。

海关数据显示，1~6月，我国医药保健品进出口额累计达283.0亿美元，同比增长28.8%，占全国外贸总额的2.1%。其中，出口188.9亿美元，同比增长31.2%；进口额94.2亿美元，同比增长24.3%；由于出口额较去年同期有较大幅度的提升，导致贸易顺差同比大幅增长38.8%，达94.7亿美元。

西药类产品仍为我国出口增长的主力，出口金额达117.8亿美元，同比增长达33.9%，占我国医药总出口额的62.4%；医疗器械和中药类产品紧随其后，出口额分别为61.9亿美元和9.1亿美元，同比增长27.0%和26.0%，分别占总出口额的32.8%和4.83%（见图1）。

The import structure is similar to that of exports, with western medicines being the main component. Import were up to 5.86 billion dollars, an increase of 22.5%, making up 62.3% of total imports. Medical devices and traditional Chinese medicines realized imports of 3.24 billion dollars and 310 million dollars respectively, 28.7% and 16.3% grew up over the same period as last year, accounting for 34.5% and 3.3% of total imports. Specifically, health and rehabilitation products experienced the biggest increase, up to 56.5%. The import of biochemical medicines rose by 41.6%. Raw materials for western medicines overtook western patent medicines to rank third in import growth. (See Figure 2)

(1) All foreign trade indexes rose distinctly over the same period as last year, but were still lower than before the crisis.

The pharmaceutical foreign trade kept growing rapidly in the first half-year. The imports and exports of all kinds of commodities experienced different degrees of year-on-year increase; more than 85% of them achieving two-digit growth. The average growth exceeded 25%.

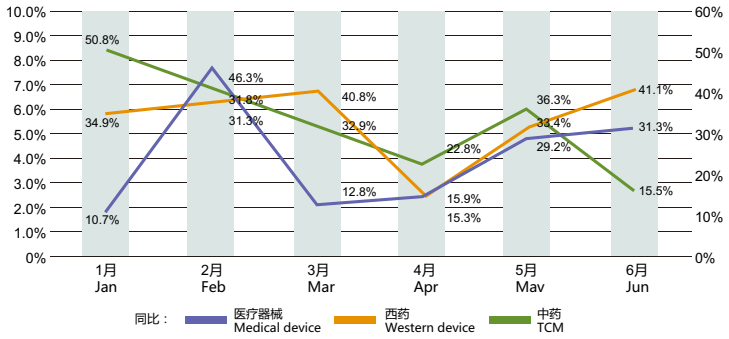
(2) Monthly imports and exports showed a V-shaped fluctuation, similar to that prior to the crisis

In terms of a monthly trend, the import and export volume of all kinds of commodities experienced a V-shaped fluctuation, which is now rebounding steadily, with the turning point appearing in February and March.

(3) Commodity exports rose in volume, but dropped in price

Despite the general stabilizing of exports, many competitive commodities reported rose in volume and dropped in price in the first 6 months. Influenced by factors like capacity surpluses in the domestic industry, an excess of supply

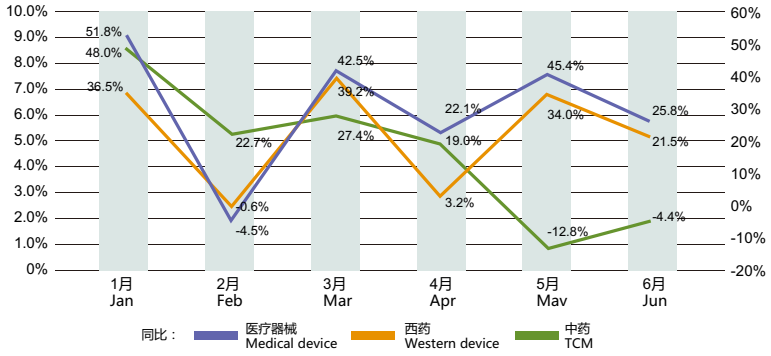
图1. 2010年1~6月西药、中药和医疗器械产品出口占比及同比
Figure 1. Export ratios and year-on-year growth rates of western medicine, TCM and medical device (Jan-June, 2010)



over demand in the world market and intensified competition from emerging countries. The monthly export volumes of medical dressings, which accounts for a big part of China's exports, reported over 60% in year-on-year growth, except for March, in which exports were affected by holidays. The prices, however, went down by 10% to 40% for 6 months in a row. The unit price fell to 2.33 dollars from 3.52 dollars

在进口方面，三大类产品的比重与出口格局大致相同，西药类产品仍为主要进口产品，进口额达58.6亿美元，同比实现22.5%的增长，占总进口额的62.3%；医疗器械和中药类产品的进口额分别达32.4亿美元和3.1亿美元，同比增长28.7%和16.3%，占进口总额的34.5%和3.3%。就单项大类产品而言，保健康复用品增幅居首，达56.5%；生化药次之，增幅为41.6%；西药原料超过西成药，以27.1%的增幅位列第三（见图2）。

图2. 2010年1~6月西药、中药和医疗器械产品进口占比及同比
Figure 2. Import ratios and year-on-year growth rates of western medicine, TCM and medical device (Jan-June, 2010)



in the first half of 2008. The export amounts of another commodity, vitamin API, amounted to 1.27 billion dollars in the first half of this year, a year-on-year increase of 29.5%. Despite the 37.4% jump in export volumes over the same period last year, the export prices dropped by 5.8 percentage points.

外贸呈现五大特点

（一）各项外贸指标同比增长明显，但尚未恢复到危机前水平

上半年，医药外贸行业持续走强，各类商品进出口同比呈现不同幅度的增长态势，85%以上商品实现两位数正增长，且平均涨幅超过25%。

（二）单月进出口呈现“V”型振颤，

(4) Foreign trade distribution pattern remains stable

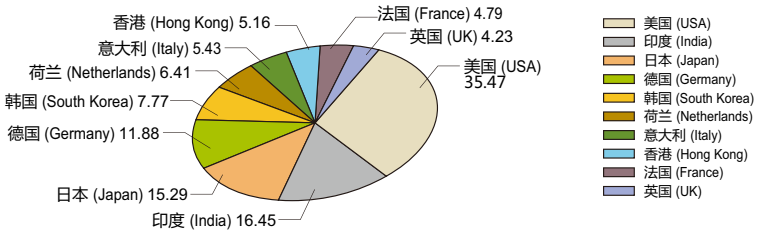
No big changes have taken place in the existing foreign trade distribution pattern. Big provinces have maintained their substantial advantages. The top five provinces and cities are Shanghai, Jiangsu, Zhejiang, Guangdong and Beijing. Their foreign trade amounted to 19.59 billion dollars, making up 69.2% of the total amount of foreign trade.

(5) The foreign trade volume to major international markets rebounded steadily and the trade surplus continued to grow

Our trade with the major trading countries all showed surpluses in the first half-year and the surpluses are increasing. Asia, Europe and North America remain the major areas for foreign trade, accounting for 90.9% of the total trade amount. Asia and Europe ranked first and second, with trade amounts of 10.11 billion dollars and 10.07 billion dollars respectively. North America ranked third with a trade amount of 5.554 billion dollars. Their year-on-year increases in imports and exports were 31.0%, 26.5% and 28.4% respectively. Furthermore, our imports and exports to ASEAN grew distinctly by 39.5%.

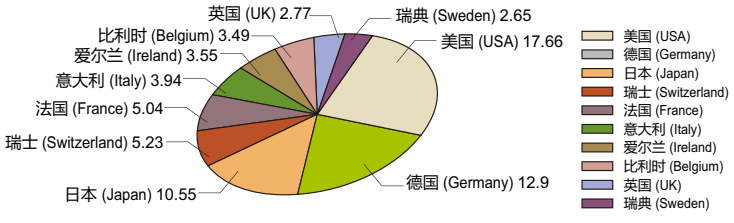
The United States, India, Japan, Germany and South Korea were the first five export target nations for China, making up 46.0% of total exports. Our exports to the United States were up to 3.55 billion dollars, accounting for 18.8% of the total export amount. (See Figure 3)

图3. 2010年1~6月出口额前十的国家（地区）
Figure 3. TOP 10 Countries Regions in Export Volume (Jan-June, 2010)



China's imports of pharmaceutical products come mainly from developed countries. The first five are the United States, Germany, Japan, Switzerland and France; 54.6% of imports are from these nations. America continued to hold the first place with imports of 1.77 billion dollars. (See Figure 4)

图4. 2010年1-6月进口额前十的国家（地区）
Figure 4. TOP 10 Countries Regions in Import Volume (Jan-June, 2010)



(From: China Pharmaceutical News Aug.12, 2010)

波动曲线与危机前相仿

从单月走势来看，上半年，各大类商品进出口额大都经历“V”型振颤稳步回升，其拐点出现在2～3月。

（三）大宗商品出口量涨价跌

上半年，尽管整体出口形势趋于平稳，但很多优势品种都出现了量涨价跌的局面。受国内行业产能过剩、国际市场供过于求、新兴国家竞争加剧等因素影响，上半年，占我国出口比重较大的医用敷料除3月份受节假日影响外，单月出口数量同比增幅均稳定在60%以上，但价格却连续6个月出现下跌，跌幅在10%～40%不等，单价已从2008年上半年的3.52美元跌至目前的2.33美元。另一大宗商品维生素类原料药，今年上半年出口额12.7亿美元，同比增长29.5%，在实现出口数量较去年同期上涨37.4%的同时，出口价格也回落了5.8个百分点。

（四）出口区位格局依旧稳定

2010年，我国医药外贸行业既有格局未出现明显变化，传统大省优势依然明显。进出口排名前五位分别是上海、江苏、浙江、广东、北京，五省市外贸额合计195.9亿美元，占外贸总额的69.2%。

（五）对主要国际市场贸易额稳步回升，贸易顺差进一步扩大

上半年，我国对主要贸易国家均呈现顺差，且顺差持续扩大。亚洲、欧洲和北美洲三足鼎立的局面继续得以保持，共占据了90.9%的份额。其中，亚洲、欧洲平分秋色，分别以101.1亿美元和100.7亿美元位列前两名，北美洲稍逊，以55.53亿美元位居第三，进出口同比分别增长31.0%、26.5%和28.4%。此外，我国对东盟进出口额增幅显著，高达39.5%。

从出口目的国或地区看，美国、印度、日本、德国和韩国依次为我国前五大出口地，占我国对外出口46.0%的市场份额，其中对美国出口35.5亿美元，占我国出口贸易的18.8%（见图3）。

从进口国家或地区看，我国医药产品进口仍来自于发达国家，其中前五位分别为美国、德国、日本、瑞士、法国，五国合计占我国医药类进口份额的54.6%。其中，美国以17.7亿美元的进口额继续稳坐我国对单一国别进口第一位置（见图4）。

（2010年8月12日）

Meeting Brief

International Forum on Generic Drugs Held in Beijing

Entrusted by the Department of Drug Registration of SFDA, China Center for Pharmaceutical International Exchange (CCPIE), held International Forum on Generic Drugs in Beijing from 6-7th Sept 2010 In order to promote the progress of generic drugs in China and to provide an exchange platform for drug supervision departments, technical test departments and drug production enterprises.

The Forum introduced, through four aspects, the development of generic drugs in USA, Europe, Japan and China and the requirements of regulations., ICH GUide, the quality requirements of the generic drugs, and the bioequivalence and clinical trial. It has an active fanction to promote the supervision and tactics study of generic drugs in China. There are nearly 300 participants took part in the Forum. (September 10, 2010)

The 4th Sino-US Pharmacopoeia Forum to be held in Hangzhou on October 20 to 22

The 4th Sino-US Pharmacopoeia Forum is scheduled to be held in Hangzhou on October 20 to 22, 2010. It is sponsored by the State Pharmacopoeia Commission of China, The theme of the forum is "Drug Standards and Quality Control in Drug Production".

Participants will be selected by each provincial, regional and municipal drug control institute, including representatives of drug makers and people from drug testing, scientific research, education and supervision institutions.

(August 3, 2010)

会议简讯

仿制药国际论坛在北京召开

为促进中国仿制药发展，为药品监管部门、技术检测部门、药品生产企业等提供一个互动交流与沟通的平台，扩大中外医药界的交流与合作，受国家食品药品监督管理局药品注册司委托，中国医药国际交流中心于2010年9月6～7日在北京举办了"仿制药国际论坛"。

论坛分仿制药在美国、欧洲、日本、中国的发展情况和法规要求；ICH指南；仿制药的质量要求；生物等效性和临床实验等四个板块，介绍了国内外仿制药的现状及发展前景，对我国仿制药监管和策略研究起到了积极的促进作用，近300人参加了论坛。（2010年9月10日）

第四届中美药典论坛
将于10月20～22日在杭州召开

论坛由中国国家药典委员会主办，主题为"药品标准与药品生产质量控制"。

参加论坛的方式为由各省、区、市药品检验所（院）负责统一组团参加，应主要包括药品生产企业的代表，药品检验、科研、教学、监管等部门和单位的代表。

（2010年8月3日）

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

China Center for Pharmaceutical International Exchange (CCPIE)
中国医药国际交流中心
Address: Room 1106, 11th Floor, Office Building B, Maples International Center, No. 32, Xizhimen North Street, Haidian District, Beijing, 100082, P.R.C.
中国北京市海淀区西直门北大街32号枫蓝国际中心B座写字楼11层1106室
邮编：100082
Tel: 010-8221 2866 ext.6006
Fax: 010-8221 2857
Email: zr@ccpie.org
Website: www.ccpie.org

Servier (Tianjin) Pharmaceutical Co., Ltd.
施维雅（天津）制药有限公司
Address: Unit 2001, 20 Floor, Tower 2, Prosper Center, No. 5 Guanghua Road, Chaoyang District, Beijing, 100020, P.R.C.
北京市朝阳区光华路5号院世纪财富中心2号楼20层2001单元
邮编：100020
Tel: 010-6561 0341
Fax: 010-6561 0348
E-mail: julie.zhang@cn.netgrs.com
Website: www.servier.com.cn