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National Work Conference on Food and Drug Administration Convened

From July 12 to 13, the 2012 National Work Conference on Food and Drug Administration was held in Beijing. At the conference, the progress of key tasks of food and drug administration in the first half of this year was reviewed, the in-depth analysis was made on the current situation in food and drug administration, and work deployment was made to carry forward and complete the planned work for this year.

SFDA Commissioner Yin Li delivered an important speech at the conference, requiring the national food and drug administration system to focus upon the central task of protecting the People's food and drug safety, to remain “Alert” to and keep comprehensive prevention & control on safety risks, to reinforce overall regulation, and to build a consolidated defense line for food and drug safety of the people.

Commissioner Yin Li fully affirmed the progress of various works on food and drug administration in the first half of 2012, he stressed that this year is the year for the promulgation and implementation of the "12th Five-Year Plan" for National Drug Safety, and also a crucial year to consolidate and expand the three-year achievements of healthcare system reform. It is of vital importance to effectively implement the work tasks in the second half of this year to ensure the successful completion of various key tasks.

We must exert our efforts on: First, the subsequent disposal of chromium-excessive medicinal capsule events; Second, the work related to healthcare system reform; Third, the implementation of the "12th Five-Year Plan" for National Drug Safety, the consistency evaluation of generic drugs, the improvement of standards, and information network construction. We are to accelerate the introduction of Work Program for Generic Consistency Evaluation, the revision of the Management Measures for Drug Standards, the promulgation of the Work Plan to Improve Drug Standards (2012 ~ 2015), as well as the construction of Drug Electronic Supervision Platform, to further optimize the functions of electronic supervision system; Fourth, the improvement and reinforcement of daily supervision; Fifth, system-wide self-construction.

SFDA Deputy Commissioner Wu Zhen and Bian Zhenjia, and Chief of CCDI-accredited Discipline Inspection Group Yu Xiancheng attended the Conference and delivered keynote speeches on the status quo of food and drug administration, and the ideas for work in the next step.

The attendees of the Conference are representatives from food and drug administration of all provinces (autonomous regions and municipalities) and Xinjiang Production and Construction Corps, cities with independent planning, sub-provincial capital cities, the Health Department of PLA General Logistics Department, and SFDA departments and directly-affiliated units.

(Jul. 13, 2012)

全国食品药品监督管理工作座谈会召开

7月12至13日，2012年全国食品药品监督管理工作座谈会在京召开。会议回顾了今年上半年食品药品监管重点工作进展情况，深入分析了当前食品药品监管工作形势，就狠抓落实、确保今年各项工作圆满完成进行了部署。

国家食品药品监管局长尹力在座谈会上作重要讲话，要求全国食品药品监管系统必须紧紧围绕保障人民群众饮食用药安全这个中心任务，始终紧绷“安全”这根弦，全面防控风险，全面加强监管，牢牢筑起人民群众饮食用药安全防线。

尹力局长充分肯定了今年上半年食品药品监管各项工作进展，他强调，今年是《国家药品安全“十二五”规划》的颁布实施之年，也是巩固和扩大三年医改成果的关键一年。做好今年下半年的工作，确保各项重点工作圆满完成，意义重大。

一要着力抓好铬超标药用胶囊事件后期处置工作；二要着力做好医改的相关工作；三要着力推进《国家药品安全“十二五”规划》实施，做好仿制药一致性评价工作、标准提高工作和信息化建设等重点工作。要加快出台仿制药一致性评价工作方案，加快修订《药品标准管理办法》，尽快发布《药品标准提高工作计划（2012～2015）》，加快药品电子监管平台建设，进一步优化电子监管系统功能；四要着力改进和加强日常监管；五要着力抓好自身建设。

国家食品药品监管局副局长吴浈、边振甲、中央纪委驻局纪检组组长于贤成出席座谈会并分别围绕当前食品药品监管形势和下一步工作思路作了主题发言。

各省（区、市）及新疆生产建设兵团、计划单列市、副省级省会城市食品药品监管部门代表，总后卫生部药监局代表，国家食品药品监督管理局机关各司局及直属单位代表参加座谈会。

（2012年7月13日）

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China and the United States Established the Coordination Mechanism on Combating Illegal Websites Selling Counterfeit Drugs

In recent years, China's food and drug regulatory authorities have found, in supervision and inspection, that the servers of a large number of illegal websites publishing false information to sell counterfeit drugs are located overseas, particularly in the United States.

In order to investigate and crack down foreign-related illegal websites selling counterfeit drugs, and combat related illegal behaviors from the very beginning, SFDA has repeatedly communicated with the U.S. Food and Drug Administration (FDA) Office in China, to consult the joint establishment of coordination mechanism on combating illegal websites, and to hold regular meetings. The illegal website information and clues shall be provided by the Chinese side, while the U.S. FDA Criminal Investigations Office is responsible for the investigation, handling and website closure according to law. At present, SFDA has informed and transferred the clues of 107 suspected illegal websites to U.S. FDA, who has conducted investigations and verifications, by which six websites have been closed after being confirmed as illegal.

SFDA will further strengthen the communication with the U.S. FDA to urge the U.S. side to take initiatives to intensify the fight against foreign related websites selling counterfeit drugs, and curb the behavior of selling counterfeit drugs via the Internet. (Jul. 13, 2012)

中美建立打击销售假药非法网站协作机制

近年来，我国食品药品监管部门在监督检查中发现，大量发布虚假信息销售假药的非法网站服务器设在境外，其中以美国最多。

为了查处销售假药的涉外非法网站，从源头上打击网络销售假药违法行为，国家食品药品监督管理局和美国食品药品管理局（FDA）驻华办公室多次沟通，协商共同建立处理非法网站协作机制，定期举行例会，由中方提供非法网站信息线索，美国FDA刑事调查办公室负责调查处理并依法关闭。目前，国家食品药品监管局已向美国FDA移送了107个涉嫌违法网站的信息线索。美国FDA进行了调查核实，确认非法的6家网站均已被关闭。

国家食品药品监管局将进一步加强与美国FDA的沟通，敦促美方采取积极行动，加大力度打击销售假药的涉外网站，遏制网络销售假药行为。（2012年7月13日）

2012 National Pharmacoepidemiology Annual Conference Convened

From July 6 to 8, 2012, the “2012 National Pharmacoepidemiology Annual Conference" was held in Wenzhou City, Zhejiang province. Academician Sang Guowei, Vice Chairman of the 11th NPC Standing Committee and Chairman of the Chinese Pharmaceutical Association sent a special congratulatory message. About 200 attendees, including leaders, experts and scholars from the SFDA Center for Drug Evaluation, the Pharmacoepidemiology Professional Committee of China Pharmaceutical Association, and the Zhejiang Pharmaceutical Association presented. The theme of the meeting is to discuss “Promoting China’s Pharmacoepidemiological Studies to Promote Rational Clinical Drug Use”.

The attendees jointly discussed the status of research and practice of Pharmacoepidemiology at home and abroad, the adverse drug reactions and medication safety, drugs risk management, the policies and practice for drug safety supervision, the experience of Good Clinical Practice and reasonable drug use, and the ways to promote the development of Pharmacoepidemiology and the rational clinical use of drugs.

The exchanges and activities of this Conference, with academic reports of professional standards, had won good appraisal and full recognition of the participating experts and scholars, and shall play a very good role in broadening the ideas of the participants, and strengthening drug safety and rational drug use. (Jul. 11, 2012)

2012全国药物流行病学学术年会召开

2012年7月6至8日，“2012全国药物流行病学学术年会”在浙江省温州市召开。第十一届全国人大常委会副委员长、中国药学会理事长桑国卫院士专门发来贺辞，来自国家食品药品监管局药品评价中心、中国药学会药物流行病学专业委员会、浙江省药学会的领导和专家学者共200余人参加会议。会议主题是共同探讨“推进中国药物流行病学研究，促进临床合理用药”。

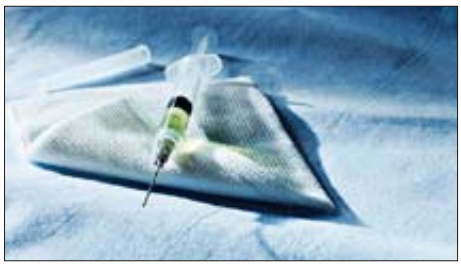
与会人员就国内外药物流行病学的研究与实践，药品不良反应与安全用药、药品风险管理、药品安全监管政策与实施，临床规范、合理用药的经验体会，以及推进药物流行病学学科发展，促进临床合理用药等内容进行了共同探讨。

专业水准的学术报告使此次交流活动得到了很好的评价，也赢得了众多与会专家学者的充分肯定，拓宽了参会者的工作研究思路，将对加强药物安全合理使用起到很好的推动作用。（2012年7月11日）

SFDA Organized the Inspection on the Packaging Insert of Benzene-Methanol-Containing Injection

Recently, SFDA detected, through Adverse Drug Reaction Monitoring reports, the cases of “gluteal muscle contracture” in some children under benzene-methanol intramuscular injection. To ensure pediatric medication safety, SFDA decided to organize the inspection on the packaging insert of benzene-methanol-containing injection.

SFDA requires the departments of food and drug administration of all provinces (autonomous regions, municipalities) to immediately organize the inspection on the packaging insert of relevant drugs produced by local enterprises. The enterprises under inspection should immediately implement related requirements for the revision of the packaging insert, if they are not labeled with the precaution of "This product contains benzene methanol and intramuscular injection for children is prohibited", and the products failed to comply are not allowed to be marketed. The marketed drugs that are not labeled with the above mentioned precaution should be, without exception, recalled without delay by the manufacturers, who shall also be investigated and punished in accordance with the relevant provisions of the “Drug Administration Law”. Serious adverse events, if any, should be reported promptly to SFDA. (Jul. 11, 2012)



国家食品药品监督管理局组织开展含苯甲醇的注射液说明书检查

近期，国家食品药品监督管理局通过药品不良反应监测，发现个别儿童使用含苯甲醇的注射液肌肉注射后出现“臀肌挛缩症”的病例报告。为保证儿童用药安全，国家食品药品监督管理局决定组织开展含苯甲醇的注射液说明书的检查。

国家食品药品监督管理局要求各省（区、市）药品监督管理部门立即组织对辖区内企业生产的相关药品说明书进行检查，发现未按规定在说明书中标注“本品含苯甲醇，禁止用于儿童肌肉注射”内容的，要监督企业立即落实说明书修订的相关要求，未按要求修订的，一律不得上市。未按规定标注上述内容的已上市药品，一律责令企业立即予以召回，并按《药品管理法》有关规定予以查处。如有重大情况，及时报告国家食品药品监督管理局。（2012年7月11日）

SFDA Issued the “Notice on the Adjustment of Production Site Inspection Procedures for In Vitro Diagnostic Reagents Managed As Drugs”

Currently the blood screening reagents and radiolabeled in vitro diagnostic reagents are subject to the registration management as drugs (biological products), according to relevant stipulations in the “Provisions for Drug Registration", the registration application for such products should be subject to the inspection of R&D site while being accepted, and subject to the inspection of production before approval. Taking into account the particularity of the in vitro diagnostic reagents, on June 29, 2012, SFDA issued a Notice to adjust the production site inspection procedures:

1. For in vitro diagnostic reagents with existing national drug standards, their application and approval procedures shall refer to those for generic drugs, after the acceptance of application, the R&D site inspection, production site inspection and the sampling test shall be performed, but the pre-marketing production site inspection is no longer required.

2. For in vitro diagnostic reagents without existing national drug standards, the application and approval procedures show still referred to those for new drugs.

(June 29, 2012)

国家食品药品监督管理局发布《关于调整按药品管理的体外诊断试剂生产现场检查程序的通知》

目前血源筛查试剂及采用放射性核素标记的体外诊断试剂按照药品（生物制品）进行注册管理，根据《药品注册管理办法》相关规定，此类产品在申报注册时均需进行受理时的研制现场核查和批准前的生产现场检查。考虑到体外诊断试剂的特殊性，2012年6月29日，国家食品药品监督管理局发布通知，对其生产现场检查工作程序作如下调整：

一、对于已有国家药品标准的体外诊断试剂，参照仿制药的申报与审批程序，在受理后进行研制现场核查、生产现场检查及抽样检验，不再进行批准上市前的生产现场检查。

二、对于非已有国家药品标准的体外诊断试剂，仍按照新药申请的程序申报与审批。（2012年6月29日）

SFDA Issued the Notice on Effectively Implement Electronic Supervision of Drugs in 2012

In order to conscientiously implement the "Notice on the Issuance of SFDA Major Tasks for Deepening the Healthcare System Reform in 2012" (SFDA Department of Policy and Regulations [2012] No. 120) and the "Notice on the Issuance of the Work Plan for Electronic Supervision of Drugs in 2011-2015" (SFDA General Office [2012] No. 64), and effectively implement electronic supervision of drugs in 2012, on June 28, 2012, SFDA issued a Notice on relevant matters.

The Notice requires that all varieties of related drugs shall be recorded into the network, and the network data entry of locally supplemented drug varieties and pharmaceutical precursor chemicals' prescribed preparations should be completed by February 28, 2013, in the future the new supplemented national and local essential drugs should be recorded in the network within eight months after the release of the Drug List. The manufacturers should print (paste) as required the electronic drug monitoring codes with unified identity on all levels of packaging of ex-factory products, and perform data collection and submission via Drug Admin Network. Food and drug administration departments of all provinces (autonomous regions and municipalities) shall submit prior to July 20, 2012, the text version and electronic version of the local supplemented essential drugs' catalog and manufacturer information (including business name, network entry, and implementation status) to SFDA Information Office.

The Notice requires the electronic supervision on some imported drugs, in 2012, electronic supervision has been applied to narcotic drugs, psychotropic drugs, blood products, vaccines, TCM injections and supplemented varieties of essential drugs. For imported varieties that are sub-packaged in China, the sub-packaging manufacturer shall print (paste) the electronic drug monitoring codes with unified identity on all levels of packaging before February 28, 2013; for imported varieties that are packaged out of China, the packaging manufacturer shall print (paste) the electronic drug monitoring codes with unified identity on bulk packaging before February 28 2013, and all levels of packaging before December 31, 2013. (paste) the electronic drug monitoring codes with unified identity on all levels of packaging before December 31, 2013. The above-mentioned enterprises shall perform the network data entry, code assignment, verification and conservation works as required by SFDA.

The Notice also requires to effectively strengthen the implementation of electronic supervision of drugs in related enterprises, to promote the pilots of electric supervision of drugs in retail pharmacies, actively cooperate with medical institutions to perform electronic supervision and further improve the supervision, inspection and technical guidance. (June 28, 2012)

国家食品药品监督管理局发布关于做好2012年度药品电子监管工作的通知

为认真贯彻《关于印发国家食品药品监管局深化医药卫生体制改革2012年度主要工作安排的通知》（国食药监法[2012]120号）和《关于印发2011—2015年药品电子监管工作规划的通知》(国食药监办[2012]64号)要求，切实做好2012年度药品电子监管工作，2012年6月28日国家食品药品监督管理局发布有关事宜的通知。

通知要求，全面实施有关药品品种入网，地方已增补的基本药物品种及药品类易制毒化学品单方制剂应于2013年2月28日前完成入网，今后新增补的国家和地方基本药物均应在目录发布后8个月内完成入网。产品出厂前，生产企业须按规定在其各级销售包装上加印（贴）统一标识的药品电子监管码，并通过药品电子监管网进行数据采集和报送。请各省（区、市）局于2012年7月20日前将地方基本药物增补品种目录及其生产企业信息（含企业名称、是否入网、是否已实施情况）文本版及电子版报国家局信息办。

通知指出，对部分进口药品实施电子监管，2012年度对进口药品中的麻醉药品、精神药品、血液制品、疫苗、中药注射剂及基本药物增补品种实施电子监管。在境内分包装的进口品种，分包装生产企业应于2013年2月28日前在各级销售包装上加印（贴）统一标识的药品电子监管码；在境外包装的进口品种，相关企业应于2013年2月28日前在大包装上加印（贴）统一标识的药品电子监管码，并于2013年12月31日前在其他各级销售包装上加印（贴）统一标识的药品电子监管码。上述企业应按照国家食品药品监督管理局要求做好入网、赋码和核注核销工作。

通知还对切实加强相关企业药品电子监管实施工作、推进零售药店药品电子监管试点、积极配合医疗机构实施药品电子监管以及进一步做好监督检查和技术指导工作提出了要求。（2012年6月28日）

SFDA seeks comments on the “Risk Assessment Principles for the Production Site Inspection of Pharmaceutical Manufacturing Enterprise"

To promote the implementation of “Good Manufacturing Practice for Drugs (2010 revised edition)", regulate inspection and certification, SFDA organized the drafting of the “Risk Assessment Principles for the Production Site Inspection of Pharmaceutical Manufacturing Enterprise" (draft for comment), which is open for public comments from June 29 to July 27, 2012. (Jun. 29, 2012)

国家食品药品监督管理局就《药品生产企业现场检查风险评定原则》征求意见

为推动《药品生产质量管理规范（2010年修订）》的贯彻实施，规范检查认证行为，国家食品药品监督管理局组织起草了《药品生产企业现场检查风险评定原则》（征求意见稿），于2012年6月29日至7月27日公开征求意见。（2012年6月29日）

Debut of New website of SFDA Center for Drug Evaluation

The new website for CDE was officially opened on July 9, 2012, under the premise of comprehensive security measures, it has achieved breakthroughs in the scope of information disclosure, the structure of the web interface and relevant functions, the new highlight is the "Applicants' Window" new channel (including seven sections: overview of applied varieties, progress inquiries, consultation appointment, improvement and submission of application information, electronic data submission, evaluation reports, conclusions of the evaluation), which provides services specifically tailored for the registration applicants, so as to carry out safe and effective information exchange, strengthen the transparency of review information, and promote communication with the applicants.

"Applicants' Window" channel shall adopt a double security mechanism featuring real-name authentication and CA unit digital certificate authentication

1. Tips for real-name authentication in the "Applicants' Window" Channel

The applicant for registration shall apply to the Center for Drug Evaluation for the real-name authentication accounts, which are divided into unit accounts and unit sub-accounts, the unit level account is able to apply, change or cancel the unit sub-accounts. Be it the unit accounts or unit sub-accounts, after successful registration, the account shall be granted to an independent legal entity and shall be kept administered

by designated personnel.

The Applicant can directly visit the "Applicants' Window" Channel, fill out the application form for registered accounts online, and submit the printed version along with other relevant supporting materials, on-site counter application and remote mail application are both alternative, and the application for registration account real name authentication is free of charge.

2. Tips for CA unit digital certificates application in the "Applicants' Window" Channel

CA unit digital certificate authentication is a further security measure on the basis of real-name authentication in the "Applicants' Window" Channel. Since CA unit digital certificate authentication system enhanced information security, the applicant can have more access to the information that is open to the applicants by CDE in the "Applicants' Window" Channel.

Users who passed the real-name

药品审评中心新版网站启用

药品审评中心新版网站于2012年7月9日正式启用，新版网站在全面采取安全保障措施的前提下，在信息公开范畴、网站界面结构、功能上均有所突破，并重点推出了“申请人之窗”新频道（下分申报品种一览、进度查询、预约咨询、申报信息完善与提交、电子资料提交、审评报告、审评结论7个栏目），专门为注册申请人提供针对性服务，以求安全、有效的开展信息交互工作，加强审评信息透明度，促进与申请人的沟通交流。

“申请人之窗”频道采用实名身份验证和CA单位数字证书认证双重安全机制

一、办理“申请人之窗”频道实名身份验证相关事宜

注册申请人向药品审评中心申请实名身份验证账户，实名身份验证注册的账号分为单位级账户和单位子账户两种，单位级账户对单位子账户具有申请、更新、注销等权限。无论是单位级账户还是单位子账户，账户注册成功后均发给独立法人单位，由单位指定人员负责保管和使用。

注册申请人可直接访问“申请人之窗”频道，网上填写、打印注册账号申请表，并随同其他相关证明材料一同提交，可采取现场柜台办理和远程邮寄两种方式进行办理，名身份验证注册的账号申请是免费的。

二、办理“申请人之窗”频道CA单位数字证书相关事宜

CA单位数字证书认证是在“申请人之窗”频道实名身份验证的基础上采取的进一步安全措施。由于CA单位数字证书的认证机制提升了信息安全保障，所以通过“申请人之窗”频道可获得更多药品审评中心对申请人公开的信息。

“申请人之窗”频道实名身份验证通

authentication in the "Applicants' Window" Channel can apply for the CA unit digital certificate in CDE-designated identity authentication institution: Beijing Digital Authentication Company, LTD (Beijing Certificate Authority). Counter application and online application are both viable, all expenses shall be settled directly by the registered user with Beijing Digital Authentication Company, Center for Drug Evaluation does not charge any fees.

(July 2, 2012)

过的用户方可办理CA单位数字证书，药品审评中心指定的身份认证办理机构为北京数字认证股份有限公司。办理方式有柜台办理和在在线办理两种方式，所有费用由注册用户直接与北京数字认证股份有限公司结算，药品审评中心不收取任何费用。

（2012年7月2日）

Center for Drug Evaluation Published the Accomplishments of Review Tasks and Review Conclusions in the First Half of 2012

To further enhance the openness and transparency, following the public notification of chemical drug review tasks at the beginning of this year, on July 10, 2012, the Center for Drug Evaluation (CDE) published the accomplishments of review tasks and review conclusions in the first half of 2012. Meanwhile, the accomplishments of review tasks for traditional Chinese medicine and biologicals are also incorporate in the public notification.

In the first half of 2012, CDE has accomplished a total of 4045 review tasks (counted by acceptance number, not by compounds, and supplementary documents are included), including 432 traditional Chinese medicine, 3277 chemical drugs, and 336 biological products. The TCM Review tasks include 56 new drug clinical trial applications, 56 new drug production applications, 23 applications for generics and formulation modifications, 272 supplementary applications, and 25 other applications (including imports re-registration, re-consideration, etc.); the review tasks for chemical drugs include 150 IND applications, 480 confirmatory clinical applications, 270 NDAs, 661 ANDAs, 1573 supplementary applications, and 143 other applications (including imports re-registration, re-consideration, etc.); the review tasks for biologicals include 121 new drug clinical trial applications, 49 new drug production applications, 160 supplementary applications, and 6 other applications (including imports re-registration, re-consideration, etc.).

The completion status of the review tasks shall be published by the corresponding review sequences for TCMs, chemical drugs and biological products, the statistics of task completion time points shall be based on the cut-off point of CDE-authorized issuance of accomplished technical reviews. The contents of the public notification cover

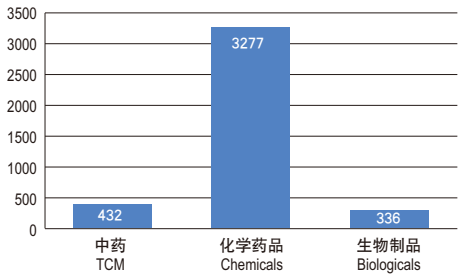
药品审评中心公示2012年1至6月审评任务完成情况及审评结论

为进一步加强公开透明力度，药品审评中心继年初公示化药月审评任务后，2012年7月10日，对上半年审评任务完成情况及其结论再予公示。同时，公示也增加了上半年中药和生物制品的完成情况。

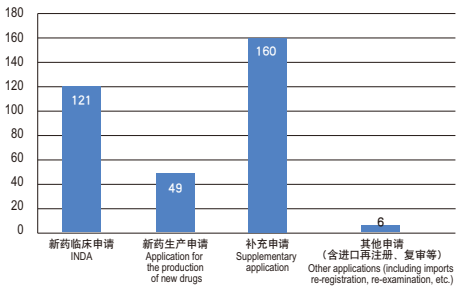
2012年1至6月，药品审评中心完成审评任务共计4045个（以受理号计，非化合物。完成任务中包括补充资料），其中中药432个，化药3277个，生物制品336个。中药审评任务中，新药临床申请56个、新药生产申请56个、仿制及改剂型申请23个、补充申请272个、其它申请（含进口再注册、复审等）25个；化药审评任务中，IND申请150个、验证性临床申请480个、NDA申请270个、ANDA申请661个、补充申请1573个、其它申请（含进口再注册、复审等）143个；生物制品审评任务中，新药临床申请121个、新药生产申请49个、补充申请160个、其它申请（含进口再注册、复审等）6个。

本次审评任务完成情况分别按照中药、化药和生物制品各审评序列进行公示，任务完成统计时间点以完成技术审

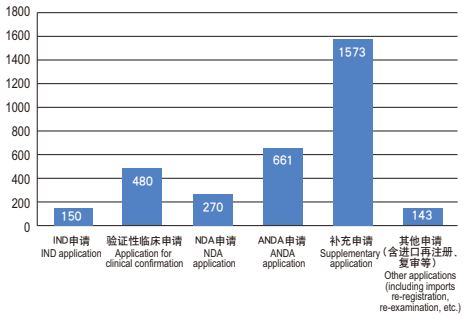
2012年1至6月完成审评任务数
The accomplished review tasks in the first half of 2012



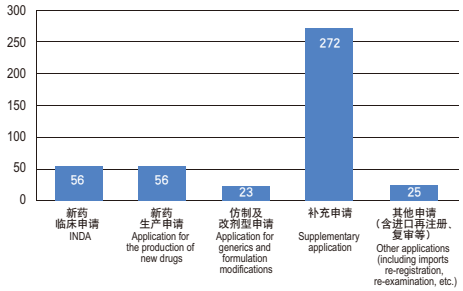
2012年1至6月完成生物制品审评任务数
The accomplished review tasks for biologicals in the first half of 2012



2012年1至6月完成化药审评任务数
The accomplished review tasks for chemicals in the first half of 2012



2012年1至6月完成中药审评任务数
The accomplished TCM review tasks in the first half of 2012



the month of the completion of specific varieties, the review task sequences, the acceptance number, the initiating time of task rounds, the time of the task being first accepted by CDE, and the conclusions of review tasks etc. In addition, the information of CDE communication with the registration applicants during the review process is also marked in the information of related varieties. (Jul. 10, 2012)

评、按照中心授权签发的时间为截止点。公示内容包括各具体品种的完成月份、审评任务序列、受理号、本轮任务启动时间、任务首次进入中心时间、本轮任务审评结论等。另外，在相关品种项下，标注了在审评过程中与注册申请人的沟通情况信息。（2012年7月10日）

Activity Brief

活动报道

SFDA Held Public Open Day Activities on Electronic Supervision

In the morning of July 5, 2012, SFDA held Public Open Day Activities on drug electronic supervision, a dozen of representatives of the public from Beijing attended the event.

In accordance with the principle of "overall planning, phased implementation and gradually impelling", in October 2007, SFDA established the monitoring information network for special drugs, and achieved dynamic control of anesthetic drugs and class I psychotropic drugs. By November 1, 2008, blood products, vaccines, TCM injections and class II psychotropic drugs are all subject to electronic supervision. As of the end of February this year, the national essential drugs realized electronic supervision. At present, the drug electronic supervision has covered one-third of drugs approved for marketing. After purchasing drugs that have been included in the electronic supervision, the public can inquire the electronic monitoring code on the package by telephone (95001111), SMS (106 695 001 111), online inquiry (www.drugadmin.com), phone image capture (download mobile phone software), and other ways so as to get related information at any time.

This year, SFDA plans to implement electronic supervision on imported anesthetic drugs, psychotropic drugs, blood products, vaccine, and the local supplementary varieties of essential drugs. Up to now, two-thirds of the pharmaceutical manufacturers and all pharmaceutical wholesale enterprises have been included in the electronic supervision system, at the same time, SFDA is promoting the pilots of electronic supervision of drugs in retail pharmacies, who shall actively cooperate with medical institutions in the implementation of pharmaceutical electronic supervision, and shall make great efforts to ensure that the work task of " realizing all-varieties and whole process electronic supervision on drugs before the end of 2015", which is proposed in the National Drug Safety "12th Five-Year Plan", come to fruition as scheduled. (Jul. 5, 2012)

国家食品药品监督管理局举办药品电子监管公众开放日活动

2012年7月5日上午，国家食品药品监管局举办药品电子监管公众开放日活动，来自北京市的十余名公众代表参加了活动。

按照“全面规划、分步实施、逐步推进”的原则，2007年10月，国家食品药品监督管理局建成特殊药品监控信息网络，实现了对麻醉药品和第一类精神药品的动态监控。2008年11月1日起，血液制品、疫苗、中药注射剂和第二类精神药品全部实施电子监管。截至今年2月底，国家基本药物实现了电子监管。目前，药品电子监管已覆盖三分之一已批准上市的药品。公众购买已纳入电子监管的药品后，可以通过电话（95001111）、手机短信（106695001111）、网上查询（www.drugadmin.com）、手机影像抓取（下载手机软件）等多种方式，查询每一个药品销售包装上的电子监管码，随时了解所购买药品的相关信息。

今年，国家食品药品监督管理局计划将麻醉药品、精神药品、血液制品、疫苗的进口药品以及基本药物地方增补品种实施电子监管。截至目前，全国三分之二的药品生产企业、所有药品批发企业已纳入电子监管系统，同时，国家食品药品监管局正在推进零售药店药品电子监管试点，积极配合医疗机构实施药品电子监管，努力确保《国家药品安全“十二五”规划》提出的“2015年年底前将实现药品全品种全过程电子监管”工作目标如期实现。（2012年7月5日）

Sales Value of China's 2011 Pharmaceutical Distribution Industry Grew by 23% Year-on-Year

According to the Statistical Analysis Report of the Operation of Pharmaceutical Distribution Industry in 2011, which was released by the Ministry of Commerce on June 21, 2012, the pharmaceutical distribution market demand was dynamic in 2011, the industry saw steady growth of purchase and sale. The full year sales value of pharmaceutical distribution industry reached 942.6 billion yuan, with the deduction of non-comparable factors, increasing 23% year-on-year. In segmentation, the sales volume of pharmaceutical retail market reached 188.5 billion yuan, with a growth rate stabilized at around 20%.

The report predicts that the size of the pharmaceutical distribution market will continue to expand. The pace of restructuring of the industry will be further accelerates. The pharmacies' alliance will be gradually developed to the standardization of pharmacy chains, and the rate of retail pharmacy chains will be further increased.

(June 21, 2012)

2011年我国药品流通行业销售总值同比增长23%

商务部2012年6月21日发布的《2011年药品流通行业运行统计分析报告》显示，2011年药品流通市场需求活跃，行业购销稳步增长。全年药品流通行业销售总值达到9426亿元，扣除不可比因素，同比增长23%。其中，药品零售市场销售规模达1885亿元，增幅稳定在20%左右。

报告预测，药品流通市场规模将继续扩大。行业结构调整步伐将进一步提速。药店联盟将逐渐向规范化连锁药店方向发展，零售药店连锁率将进一步提升。

（2012年6月21日）

图1. 2006~2011年药品流通行业销售趋势图

Figure 1. Sales trends of pharmaceutical distribution industry in 2006-2011

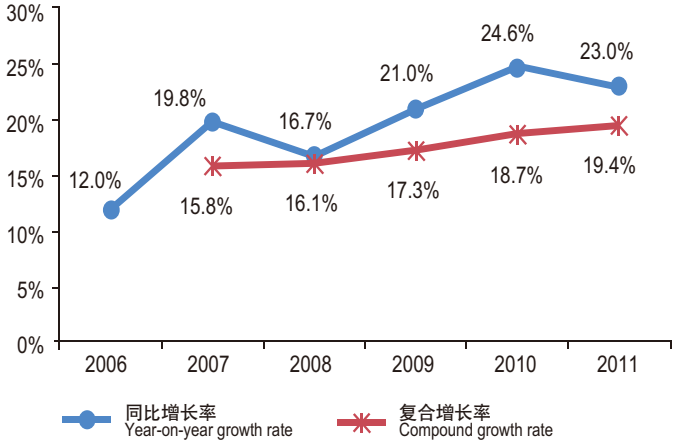
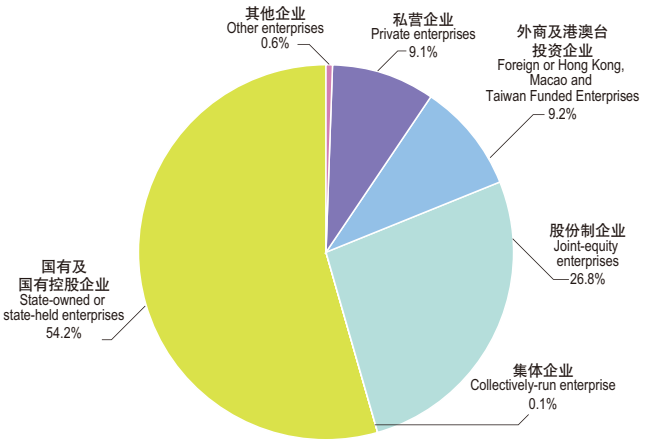


图2. 2011年规模以上药品流通直报企业利润总额所有制结构分布

Figure 2. Distribution of the ownership structure of pharmaceutical distribution enterprises above designated size in the directly reported corporate total profit



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

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

备 注： • Newsletter中所有中文信息摘自报刊及网络。英文均系中文翻译。

• 电子版Newsletter阅览请登录网站http://www.ccpie.org

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