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, keep comprehensive prevention & control on 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 the food and drug safety of the people.

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.

From July 12 to 13, 2012年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召开。会议回顾了今年上半年食品药品监管工作进展情况，分析了当前食品药品监管工作形势，就抓紧落实、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局长尹力在座谈会上讲话，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，始终高悬“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；二要着力做好相关的工作；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年）》，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来安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，总后卫生部监察局代表，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)
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)

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)
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.  

(Sep. 11, 2012)

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 shall still refer to those for new drugs.

(June 29, 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 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)
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 authentication and 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.

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)

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

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。

SFDA征求《药品生产企业现场检查风险评定原则》意见
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 incorporated 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 chemicals 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 the accomplished review tasks in the first half of 2012:

- **Traditional Chinese Medicine (TCM):** 432 tasks completed.
- **Chemicals:** 3277 tasks completed.
- **Biologics:** 336 tasks completed.

![Graph](image-url)
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)

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)

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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)