The quality of national essential drugs and commonly used clinical drugs of the generic drugs approved for production prior to the implementation of the Provisions for Drug Registration revised in 2007 shall reach international advanced levels. 3. Pharmaceutical production shall ensure 100% compliance with the “Good Manufacturing Practice for Drugs” as revised in 2010; the production of sterile and implantable medical devices shall ensure 100% compliance with the “Good Manufacturing Practice for Medical Devices”. 4. Drug Supply shall ensure 100% compliance with the “Good Supply Practice for Drugs”. 5. All newly opened retail pharmacies and hospital pharmacies must have a licensed pharmacist. By 2015, all retail pharmacies and hospital pharmacies must have licensed pharmacists to guide the rational use of drugs.

The nine major tasks of the "Plan" are: 1. Improve the overall national drug standards. 2. Strengthen the Whole Process Quality supervision of drugs. 3. Improve drug inspection and testing system. 4. Improve drug safety monitor and vigilance levels. 5. Crack down on the manufacturing and sales of counterfeit and substandard drugs in accordance with the law. 6. Improve drug safety emergency treatment system. 7. Strengthen the infrastructure construction for drug administration. 8. Accelerate the construction of drug administration information system. 9. Enhance the quality of human resources. (February 14, 2012)
SFDA Releases the “Notice on Enabling New Official Seals for Administrative Licensing Acceptance, Document sign-receiving and Cosmetics Licensing”

On February 7, 2012, SFDA issued a Notice to enable, since February 9, 2012, the new SFDA Administrative Licensing Acceptance Official Seals (30 Seals), the Administrative Licensing Document sign-receiving Official Seals (30 Seals), and Cosmetics Licensing Official Seals (1 Seal), the pattern of the Seals was announced in the meantime. The original Official Seals for Administrative Licensing Acceptance, Document sign-receiving and Cosmetics Licensing shall be repealed simultaneously.  

(February 7, 2012)

State Food and Drug Administration Further Strengthened the Management of Clenbuterol Hydrochloride

On January 9, 2012, the State Food and Drug Administration issued a notice requiring food and drug administrations at all levels to further strengthen the management of clenbuterol hydrochloride, perform focused monitoring on enterprises in production (distribution) of clenbuterol hydrochloride APIs. Manufacturers having ceased production of clenbuterol APIs should be supervised and prohibited from unauthorized resuming of production.

In September 2011, the State Food and Drug Administration issued a notice to halt the production, sales and application of clenbuterol hydrochloride tablets in China. To further enhance the management of clenbuterol hydrochloride APIs, aerosols, and compound preparations etc., on January 9, 2012, the State Food and Drug Administration once again issued a notice requiring the regulation of the production, distribution channels and diagnosis & treatment behavior of clenbuterol hydrochloride.

The notice requires to regulate clenbuterol production and strengthen the management of the production and application of APIs; regulate the distribution channels to ensure the traceability of drug circulation; regulate diagnosis & treatment behavior, and conduct strict prescription management; reinforce supervision and inspection, implement regulatory responsibilities; strictly inspect and punish production and sales behaviors that violate laws and regulations.  

(January 19, 2012)

SFDA Requires Further Improving the Electronic Supervision of Certain Compound Preparations Containing Special Drugs

SFDA notice on the Implementation of Electronic Supervision of Certain Compound Preparations Containing Special Drugs (Guo Shi Yao Jian Ban [2010] No. 484) has clearly required the implementation of electronic supervision
on ephedrines-containing compound preparations (exclusive of Chinese patent medicine containing ephedra), codeine-containing compound oral solution, diphenoxylate-containing compound preparations and other compound preparations containing special drugs as of December 31, 2011. To effectively implement the electronic supervision of the above-mentioned products, on January 10, 2012, the State Food and Drug Administration issued the "Notice on Further Improving the Electronic Supervision of Certain Compound Preparations Containing Special Drugs," and the relevant affairs are notified as follows:

The aforementioned compound preparations containing special drugs produced as of January 1, 2012 must be encoded, registered or canceled after verification, and un-coded products shall not be permitted into market.

All Provincial (Automonomous regional, Municipal) Food and Drug Administrations should strengthen supervision and management, within their respective administrative areas urge pharmaceutical manufacturers to encode the above-stated compound preparations containing special drugs, drug distributors to verify the registration and sales of the encoded products, and to realize data upload through the electronic supervision network. If abnormal flow of drug sales is spotted, the sales must be suspended immediately, and the case must be reported to local food and drug administration departments. The Food and drug administration departments should immediately check the situation and invite food and drug administration in the destination areas of drugs to conduct a coordinated investigation, and the latter should cooperate actively. During the inspection, if the drugs were suspected to be distributed to illegal channels, the cases should also be immediately reported to public security department at the same level. (January 13, 2012)

Center for Complaint and Reporting, SFDA Enters into Formal Operation

On January 16, 2012, Center for Complaint and Reporting, SFDA (hereinafter referred to as the CCR) entered into formal operation, and formally initiate accepting Complaints & Reporting via mails and Internet.

SFDA requires all Provincial (Automonomous regional, Municipal) Food and Drug Administrations to pay great attention to the problems reflected through Complaint & Reporting, and provide strong support to CR in accordance with the “Provisions for Food and Drug Complaint and Reporting (interim)”, implement the work principles of territorial management, unified leadership and graded accountabilities, to speed up the construction of Complaint & Report institutions. Open as soon as possible the National Food and Drug Administration Complaint and Reporting Hotline “12331”, handle timely the complaints and reports within the administrative area, to further regulate food and drug production and distribution, strengthen the power to crack down on food and drug illegal activities, and protect food and drug safety for the public. Complaint Report URL: www.12331.org.cn

(October 16, 2012)
State Food and Drug Administration Calls for Strengthening the Implementation of the Revised Drug GMP

On January 6, 2012, the State Food and Drug Administration issued the "Notice on the Strengthening of the Implementation of Good Manufacturing Practice for Drugs (2010 Revision)," which called for strengthening the implementation of "Good Manufacturing Practice for Drugs (2010 Revision)" (hereinafter referred to as the newly revised Drug GMP), and adhering to the consistency of certification standards, and indicated that the cases of discrepancy and step-down of standards shall never be tolerated.

Since the newly revised Drug GMP came into force on March 1, 2011, food and drug administration at all levels and pharmaceutical manufacturers have actively organized its implementation, the overall work has been stable and orderly, but the progresses differ in different areas.

To promote the implementation of the newly revised Drug GMP, the State Food and Drug Administration issued a Notice requiring food and drug administration at all provincial levels to strengthen the construction of food and drug supervision & inspection teams, and drug certification & inspection institutions. Where conditions permit, explorations should be actively made on the professionalization of drug GMP inspectors, and certification should be performed by specially designated full-time staff. The State Food and Drug Administration shall gradually develop standards of professional inspectors and conduct specialized training for them, to ensure work quality and further enhance the effectiveness of drug inspection & certification. Food and drug administration at all levels should strengthen drug quality supervision in the process of technological upgrading of enterprises, reinforce supervision, verification and follow-up inspection efforts to prevent product quality problems as a result of the comitant production with technological upgrading in the transitional period.

The State Food and Drug Administration require urging the pharmaceutical manufacturers to improve their quality management system, and attach importance to technical upgrading. Meanwhile, in the implementation process of the newly revised Drug GMP, enterprises are encouraged to put into effect the "Guidance on Speeding up the Structure Adjustment of the Pharmaceutical Industry" jointly issued by the Ministry of Industry and Information Technology, Ministry of Health and State Food and Drug Administration, establish win-win partnership between enterprises, conduct mergers and acquisitions, adjust the industrial structure, eliminate backward production capacity, promote industrial upgrading and accelerate the development of advantageous enterprises. The manufacturers (plants), which produce blood products, vaccines, injection agents and other sterile drugs that fail the certification as of December 31, 2013, and others that fail the certification as of December 31, 2015 must stop production.

(January 6, 2012)
"Guideline on Management of Phase I Clinical Trial of Drugs (Interim)"

(To continue)

Chapter VII Contracts and Agreements

Article 27 Prior to the trial, the sponsor and investigators shall sign a commission contract with legal binding of Chinese law. The contract should clarify the content and progress of the trials, the responsibility and obligation of the two sides, the amount of commissioned research funding, and furthermore, special attention should be paid to confidentiality principle, subjects insurance, subjects’ compensation or redress principles, trial suspension and termination principles, accountability, definition of intellectual property rights, and thesis publication policies, etc.

Article 28 Research offices or laboratories should not subcontract the clinical trials; if part of the work cannot be completed, commission contract should be signed in advance between sponsor and other related institution(s).

Article 29 Research offices or laboratories should not add any contents or change the trial methods without authorization. If the Sponsor requires additional services, the two sides should sign additional agreements before the start of the trial under the premise that the additional work does not conflict with the clinical trial protocol, and does not damage the rights or safety of the subjects.

Chapter VIII The clinical trial protocol

Article 30 The clinical trial protocol should be developed prior to the start of Phase I trial, signed to confirm by the sponsor and the investigators upon consensus, and reported to the Ethics Committee for implementation after review and approval.

Article 31 Phase I trial protocol should be developed with reference to relevant technical guidelines based on a scientific nature and the protection of the subjects’ rights.

Article 32 During the trials, should the Phase I trial protocol need to be amended, the new one must be approved by the Ethics Committee or filed for record. In case of emergency medical event or serious adverse events, the investigators can take necessary emergency measures beyond the trial protocol to ensure the safety of the subjects.

Chapter IX Subjects Management

Article 33 Phase I trial must protect the rights and safety of the subjects, the recruitment methods of which should be reviewed by the Ethics Committee.

Article 34 The majority of the Phase I trial subjects should be healthy adults, if special populations are required for recruitment, such as children, the elderly, pregnant women, patients or other vulnerable groups, justifiable reasons should be provided, and appropriate security measures should be taken.

Article 35 Prior to the start of the trial, the subjects should be fully informed and sign an informed consent; during the implementation of the trials, good communication should be maintained...
with the subjects in order to enhance their compliance, and timely detect adverse events. During the trials, should the informed consent form need to be amended, the revised informed consent form must be approved by the Ethics Committee. A new informed consent should be obtained from the research subjects.

**Article 36** In Phase I trial, subjects often receive no significant treatment benefits, the sponsor should give the subjects reasonable economic compensation. For subjects experience damages due to participation in the trials, the sponsor should be liable for corresponding treatment costs and reasonable compensations.

**Chapter X Investigational drug administration**

**Article 37** The sponsor is responsible to provide investigational drugs, and should be liable for their quality.

**Article 38** Clinical trial institutions should set up clinical trial pharmacy, with qualified storage facilities and equipment for study drug.

**Article 39** An appropriate individual should be assigned to manage the investigational drugs, the receipt, storage, distribution, use, recovery, and return of the test drugs should be administered in accordance with Investigational Drugs Management System and SOP, and relevant records should be well kept. The preparation of investigational drugs should be in line with the requirements of trial protocol. The weighing, dilution and aseptic preparation of investigational drugs must comply with relevant regulations.

**Article 40** The investigators are responsible for the use of investigational drugs, they should use investigational drugs in light of the trial protocol and random table, ensure that the subjects receive drugs on scheduled time and dosage, and make good records.

**Article 41** The investigational drugs may not be used for other purposes, or sold publicly or covertly.

**Chapter XI Management and Analysis of Biological Samples**

**Article 42** The collection, processing and preservation of biological samples should be in accordance with the clinical trial protocol and SOP. The labelling of the sample containers should have sufficient information, identifiable and unique.

**Article 43** The transportation and preservation of biological samples should meet the requirements of the trial protocol and related SOP, to ensure that their integrity and activity are not affected, and records should be taken accordingly.

**Article 44** During the trial, the identification and traceability of biological samples should be ensured, the records of the labeling, transportation and preservation of samples should be well kept, the sample storage archive should be established.

**Article 45** Before the start of the analysis, a detailed test protocol for the analysis of biological samples should be developed according to the requirements of the trial protocol, which will enter into force with the signatures of laboratory directors, project leaders and the sponsor.

**Chapter XII Data Management and Statistical Analysis**

**Article 46** The original Phase I trial data (including electronic data) is the first-hand information collected during the
trials, whose authenticity, accuracy, and completeness should be ensured. The data-generating devices, equipment and methods must be validated.

**Article 47** The computer system refers to the information system that is used, directly or indirectly, for data reception, collection, processing, reporting and storage, or a system integrated in the automation equipment, including one or more hardware units and software. The computer system for clinical trial data management and statistical analysis must be validated, and have traceability automatically generated by the system, all changes to the data are automatically recorded; the original data should be saved timely during system upgrading, to prevent data loss or alteration. The application of computer systems should set strict log-in permissions and password management system.

**Article 48** The verification measures (such as double entry, automatic system logic checks, etc.) should be performed for data entry to avoid data entry errors. The data verification and lock process should be recorded in detail, and data modifications should have appropriate supportive documentations.

**Article 49** The statistical analysis staff shall develop statistical analysis protocol after the trial protocol is determined, refine and confirm the data before they are locked; the statistical analysis must adopt recognized statistical software and appropriate statistical methods; the statistical analysis procedures must be programmed, the program source code should be readable to facilitate verifications; and the results of statistical analysis should be expressed in professional, objective and standardized terms.

**Article 50** The statistical analysis of Phase I trials should focus on the impact of dosage on safety indicators, pharmacokinetic parameters, pharmacodynamic index and its variation patterns.

**Chapter XIII Summary Report**

**Article 51** After the Phase I trial completion, the Summary Report of Phase I trial (hereinafter referred to as the Summary Report) should be drafted integrating all the clinical trial data. The Summary Report shall be signed and confirmed by the sponsor and principal investigators, and stamped with the seals of sponsors and clinical trial institutions. The biological sample analysis report should be signed by the Laboratory Director and stamped with the seal of the research institution.

**Article 52** The structure and content of the Summary Report can refer to relevant technical guidelines, and reflect the characteristics of Phase I trial.

**Chapter XIV Miscellaneous**

**Article 53** The State Food and Drug Administration is responsible for the interpretation of this Guideline.

**Article 54** This Guideline shall enter into force as of the date of publication.

(December 5, 2011)
SFDA Center for Drug Evaluation’s 2012 Open Day Work Arrangements

SFDA Center for Drug Evaluation (CDE)’s Open Day Activities have provided an open window for government transparency, the 2012 Open Day Activities shall witness major adjustments: the former single pattern of activity shall be adjusted to diversified activities that integrate online registration with CDE invitation and give equal importance to popularity (Universal type) & professionalism (In-depth type). The online registration shall be enabled in the meantime.

2012年药品审评中心开放日活动安排
2012 Open Day Work Arrangements

<table>
<thead>
<tr>
<th>Time</th>
<th>Types of activities</th>
<th>Target attendees</th>
<th>Organization models</th>
<th>Overview of Activities</th>
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<tr>
<td></td>
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<td>活动类型</td>
<td>活动对象</td>
<td>组织方式</td>
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<tr>
<td>March 6</td>
<td>In-depth type</td>
<td>Veterans in registration and drug R&amp;D, know the ropes of CDE’s previous works, and familiar with relevant laws and regulations on Drug Administration (hereinafter inclusive).</td>
<td>Online registration, sequential arrangement, 20<del>25 one time. Timing: the afternoon of the second Tuesday of the month for the activities. 网上报名，按序安排，每期 20</del>25 名。时间安排为活动当月的第二个周二下午。</td>
<td>Introduce CDE’s recent important regulations, key work ideas and implementation status, site visits, reviewers’ site briefing, panel discussions. Duration: 3 hours. (hereinafter inclusive) 介绍审评中心近期实施的重要规范和重点工作的思路和执行情况，实地参观，审评工程师审评人员实地讲解; 组织座谈，时间 3 小时。（下同）</td>
</tr>
<tr>
<td>3 月 6 日</td>
<td>深入型</td>
<td>长期从事注册和药品研发工作，了解审评中心既往工作，且熟悉药品管理相关法规的有关人员（下同）。</td>
<td></td>
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</tr>
<tr>
<td>April 11</td>
<td>Universal type</td>
<td>Green hands in registration, or those who are unfamiliar with the basic information and works contents of CDE (hereinafter inclusive). 初涉注册事务或对药品审评中心基本情况和工作内容不甚了解的有关人员（下同）。</td>
<td>Online registration, sequential arrangement, 20 - 25 people one time. Timing: the afternoon of the second Wednesday of the month for the activities. 网上报名，按序安排，每期 20 - 25 名。时间安排为活动当月的第二个周三下午。</td>
<td>Introduce the basic situation of CDE, including the organization, the review process, tips (for dossier submission, documents submission, and consultation etc.). Organize onsite visits (mainly including the workplaces of Dossier Management and Review Departments). Duration: 1.5 hours. (hereinafter inclusive) 介绍审评中心基本情况，主要包括组织机构设置，审评流程，办事须知（资料提交，公文提交， 咨询等），组织现场参观（主要包括资料管理部门和审评工作场所）。时间 1.5 小时。（下同）</td>
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Scrip Releases 2011 List of Global Top 100 Pharmaceutical Companies

Scrip, the global authority of pharmaceutical news agencies recently announced the 2011 List of Global Top 100 Pharmaceutical Companies. Pfizer remained at the top, Sanofi-Aventis ranked second, Merck Sharp and Dohme rose from last year’s 7th to the 3rd place.

Judging from the List, European and American enterprises dominated the forefront of the ranking List. Of the Top 25 enterprises with sales exceeding five billion U.S. dollars, 10 enterprises are from the United States, 9 from Europe, 5 from Japan, and 1 from Israel.

排名 | 公司                        | 排名 | 公司                      | 排名 | 公司               |
---|----------------------------|---|----------------------------|---|---------------------|
1  | 辽瑞 Pfizer                 | 2  | 赛诺菲 Sanofi-Aventis      | 3  | 默沙东 Merck Sharp and Dohme |
4  | 诺华 Novartis               | 5  | 葛兰素史克 GlaxoSmith-Kline | 6  | 罗氏 Roche Group      |
7  | 阿斯利康 AstraZeneca        | 8  | 强生 Johnson&Johnson       | 9  | 礼来 Eli Lilly       |
10 | 雅培 Abbott Laboratories    | 11 | 百时美施贵宝 Bristol Myers Squibb | 12 | 楼瓦 Teva |
13 | 安进 Amgen                  | 14 | 拜耳 Bayer                 | 15 | 武田制药 Takeda     |
16 | 勃林格殷格翰 Boehringer Ingelheim | 17 | 安斯泰来 Astellas           | 18 | 诺和诺德 Novo Nordisk |
19 | 第一三共株式会社 Daiichi-Sankyo | 20 | 卫材 Eisai                  | 21 | 大冢控股 Otsuka     |
22 | 百特国际 Baxter International | 23 | 默克 Merck                  | 24 | 吉利德科技 Gilead   |
25 | 迈兰 Mylan                  | 26 | 施维雅 Servier              | 27 | 三菱田边 Mitsubishi Tanabe |
28 | 福雷斯特 Forest             | 29 | 奈科明 Nycomed              | 30 | 美国CSL制药公司 CSL |

Scrip公布2011全球百强制药企业名单

全球权威的全球制药新闻机构Scrip在近期公布了2011年最新的全球100百强制药企业排行榜。辉瑞继续位居榜首。赛诺菲排名第二，默沙东制药公司从去年的第7位跃居第3位。

从排名上看，百强药企排行榜中位居前列的以欧洲和美国的企业为主。前25名销售额超过50亿美元的企业，10家来自于美国，9家来自于欧洲，5家来自于日本，1家来自于以色列。
The Status of China’s Pharmaceutical Exports Remains Stable in 2011

China Chamber of Commerce for Import & Export of Medicines & Health Products recently released the 2011 statistics of China’s pharmaceutical foreign trade, the data has shown that China’s “tripartite confrontation (Asia, Europe and North America) of Major Pharmaceutical Foreign Trade Markets remains stable, accounting for more than 80% share of exports.

2011年中国医药保健品进出口统计
China’s Import and Export of Medicines & Health Products in 2011

单位，亿美元（100 million）

<table>
<thead>
<tr>
<th>商品分类 Category</th>
<th>出口额 Export Amount</th>
<th>出口额同比(%) Growth Rate in Equal Terms</th>
<th>出口额占比(%) Export Amount Proportion</th>
<th>进口额 Import Amount</th>
<th>进口额同比(%) Growth Rate in Equal Terms</th>
<th>进口额占比(%) Import Amount Proportion</th>
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### China’s Import and Export of Medicines & Health Products in 2011

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<th>Category</th>
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<td>Medical Device</td>
<td>265.98</td>
<td>54.43</td>
<td>36.29</td>
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</tbody>
</table>

#### Growth Rate of Export Amount in Equal Terms in 2011

- Traditional Chinese Medicine: 2011 34.67%, 2010 38.84%
- APIs of Western Medicine: 2011 25.93%, 2010 22.31%
- Western Patent Medicine: 2011 55.7%, 2010 54.96%
- Biochemical: 2011 22.14%, 2010 19.42%
- Medical Device: 2011 54.43%, 2010 53.59%

#### Growth Rate of Import Amount in Equal Terms in 2011

- Traditional Chinese Medicine: 2011 32.61%, 2010 33.26%
- APIs of Western Medicine: 2011 23.88%, 2010 21.34%
- Western Patent Medicine: 2011 51.02%, 2010 50.34%
- Biochemical: 2011 20.36%, 2010 19.82%
- Medical Device: 2011 51.34%, 2010 50.52%

#### Growth Rate of Import & Export Amount in Equal Terms in 2011

- Traditional Chinese Medicine: 2011 33.26%, 2010 33.26%
- APIs of Western Medicine: 2011 22.31%, 2010 20.36%
- Western Patent Medicine: 2011 54.96%, 2010 54.96%
- Biochemical: 2011 19.42%, 2010 19.42%
- Medical Device: 2011 53.59%, 2010 53.59%

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**France-Gidy** (法国-盖迪)  
**Spain-Madrid** (西班牙-马德里)  
**Russia-Moscow** (俄国-莫斯科)  
**Brazil-Rio de Janeiro** (巴西-里约热内卢)  

施维雅全球部分机构掠影  
Photos of Servier in the world
\textbf{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