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## NEWS

**SFDA Commissioner Shao Mingli Met with Cuban Health Protection Agency Secretary Raphael and His Entourage** On August 3, 2011, SFDA Commissioner Shao Mingli met in Beijing with visiting Cuban Health Protection Agency Secretary Raphael and his entourage. The two sides reviewed the progress of bilateral cooperation since the two sides signed in 2010 the "State Food and Drug Administration & the Cuban Health Protection Agency/Drug Quality Control Center Memorandum of Understanding", and discussed in depth on further strengthening the cooperation in the field of safety regulation on traditional Chinese medicine and biological products. (August 3, 2011)

**SFDA Deputy Commissioner Bian Zhenjia Met with the Visiting Secretary Zhang Tiefu of the Social Work Department of LOCPG and President Zheng Yaotang of Hong Kong Federation of Trade Unions and Their Entourage** In the afternoon of July 11, 2011, SFDA Deputy Commissioner Bian Zhenjia met with the visiting Director General Zhang Tiefu of the Social Work Department of Central Government Liaison Office in Hong Kong S.A.R. (LOCPG), and President Zheng Yaotang of Hong Kong Federation of Trade Unions (FTU), and their entourage. The two sides exchanged views on the topics of the development of food safety work in the mainland as well as the SFDA's supervision of health food and regulatory functions of food safety in catering service and other sectors. (July 14, 2011)

**SFDA Foreign Affairs Work Conference Held** From July 28 to 29, 2011, the SFDA Foreign Affairs Work Conference was held in Yantai. SFDA Commissioner Shao Mingli attended the meeting and delivered a speech.

Commissioner Shao Mingli reviewed the achievements of foreign affairs works in the "Eleventh Five-Year Plan" Period, comprehensively analyzed the work situation of foreign affairs in food and drug administration, clarified the urgency of promoting the strategy of international administration and regulation, made clear requests on the Foreign Affairs works in the "Twelfth Five-Year Plan" Period, and highlighted the importance of the "construction of the Party conduct and of an honest and clean government" and anti-corruption work in foreign affairs.

The Conference pointed out that Foreign Affairs Work should proactively promote the strategy of international administration and make unremitting efforts to realize that China's overall food and drug administration is close to the international advanced levels.

(July 29, 2011)

**National Pharmaceutical Production Administration Work Conference Held** Recently, the National Pharmaceutical Production Administration Work Conference was Held in Guiyang, Guizhou Province. SFDA Deputy Commissioner Wu Zhen presented and delivered a speech. The Conference informed the implementation progress of the strengthening on supervision of national essential drugs and the new version of "Good Manufacturing Practice for Pharmaceutical Products (2010 revised edition)" (abbreviated as the new GMP), serious discussion and exchange were also made on the implementation of new GMP and supervision strengthening and management of essential drugs and other issues.

At the Conference, Deputy Commissioner Wu Zhen pointed out that the implementation of the new GMP shall focus on four aspects: First, enhance the management level of pharmaceutical production; Second, optimize the industrial structure, eliminate backward production capacity, and increase industrial concentration; Third, improve supervision and management capacity, strengthen administration; Fourth, improve drug quality and safety. Wu stressed that currently food and drug administration departments at all levels should attach great importance to superving the production of essential drugs, and introduce risk management in conjunction with the implementation of new GMP, to enhance management. The competent department shall also focus on the enhancement of sense of responsibility, establishment of overall concept, innovation of inspection methods, and actively carry out inter-provincial cooperation, so as to continuously improve the regulatory levels on the production of essential drugs.

(July 11, 201)

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## National Food and Drug Administration Work Conference Convened

On July 5, 2011 the National Food and Drug Administration Work Conference was held in Nanjing. SFDA Commissioner Shao Mingli delivered an important speech at the Conference.

Commissioner Shao Mingli pointed out that, in the next stage, the focus of food and drug administration on enhancing and innovating public administration should be placed on the innovative administration mechanism, the implementation of regulatory responsibility, and the improvement of regulatory efficiency. Efforts should be made to promote the formation of a benignant interaction with all levels of governments, related businesses, social organizations, public and media, enabling the convergence of more social forces to this common goal of ensuring food and drug safety. We must focus on the following tasks:

First, improve the responsibility implementation mechanisms to promote the formation of a work pattern of comprehensive regulation of Food and Drug Safety, urge the local governments, regulatory authorities, businesses to better perform their duties and responsibilities, to form a synergy of regulated, efficient, and orderly operation, and to form a comprehensive regulation to ensure safety through joint efforts; Second, improve the mechanism to safeguard the interests of the masses, to strengthen food and drug safety management from the very beginning, and timely investigate and resolve various food and drug safety issues reported by the people, to enhance people's trust in the regulatory works; Third, improve social participation mechanism, strengthen the integrated use of resources securing the food and drug safety, strengthen the cooperation with institutions of higher learning, research institutions, industry associations, enterprises and social organizations, unite all forces to safeguard food and drug safety and the market order; Fourth, improve the technology-oriented mechanism, give scope to the supporting role of science and technology in food and drug administration, and establish a technical support system catering to regulatory needs, national conditions and international regulatory trends; Fifth, improve the policy guidance mechanism, strengthen the industrial base for food and drug safety, implement more stringent regulatory measures and encourage explicit and innovation-oriented policies, to further promote the transition of industrial and economic growth patterns and the long-term stability of food and drug safety.

(July 7, 2011)

## 全国食品药品监管工作座谈会召开

2011年7月5日，全国食品药品监管工作座谈会在南京召开。国家食品药品监管局局长邵明立在座谈会上作重要讲话。

邵明立局长指出，下一步，食品药品监管工作要把加强和创新社会管理的重点放在创新监管机制、落实监管责任、提升监管效能上，努力推动形成与各级政府、相关企业、社会组织、公众以及媒体良性互动的局面，使更多社会力量汇聚到确保食品药品安全这一共同目标上来。重点要抓好以下几项工作：

一是完善责任落实机制，推动形成食品药品安全综合施治的工作格局，促使地方政府、监管部门、企业更好地履职尽责，形成规范高效、运转有序的工作合力，形成综合施治、共保安全的良好局面；二是健全群众利益维护机制，加强食品药品安全矛盾源头治理，及时排查解决人民群众反映的各种食品药品安全问题，增强人民群众对监管工作的信任感；三是完善社会参与机制，加强食品药品安全保障资源的综合运用，加强与高等院校、研究机构、行业协会、企事业单位以及社会组织的合作，凝聚各方力量，共同维护食品药品安全和市场秩序；四是完善科技保障机制，发挥科学技术在食品药品监管工作的支撑作用，建立适应监管需要、符合国情、顺应监管国际化趋势的技术支撑体系；五是健全政策引导机制，夯实食品药品安全的产业基础，实施更加严格的监管措施和导向明确的鼓励创新政策，在促进产业经济增长方式转变和食品药品安全长治久安上做更多努力。（2011年7月7日）

## "Measures for Drug GMP Certification" issued

To strengthen the management of drug GMP inspection and certification, further standardize GMP inspection and certification, advance the implementation of Good Manufacturing Practice for Pharmaceutical Products (2010 revised edition), the SFDA organized the revision of the Measures for Drug GMP Certification (hereinafter referred to as the Measures). The Measures has been issued on August 2, 2011, and shall go into effect from the date of promulgation.

The revised Measures has made elaborations on Drug GMP application, acceptance and review, site inspection, approval and certification, follow-up inspection, and management of " Drug GMP Certification " .

## 《药品生产质量管理规范认证管理办法》印发

为加强药品生产质量管理规范检查认证工作的管理，进一步规范检查认证行为，推动《药品生产质量管理规范（2010年修订）》的实施，国家食品药品监督管理局组织对《药品生产质量管理规范认证管理办法》进行了修订。2011年 8月2日，发布了《药品生产质量管理规范认证管理办法》，并于发布之日起施行。

The Measures defines that SFDA takes charge of the works of national drug GMP certification management, the GMP certification and follow-up inspection of injections, radioactive drugs, biological products; and the coordination of the offshore drug GMP inspection of imported drugs and the international or regional drug GMP inspection. Provincial drug administration authorities are responsible for the local GMP certification and follow-up inspection for drugs other than injections, radioactive drugs, biological products etc., and drug GMP inspections commissioned by the SFDA. The SFDA is responsible for the evaluation of the quality management system of drug certification & inspection institutions.

Newly start-up pharmaceutical manufacturers or pharmaceutical manufacturers with newly added production scope and new plants should apply for Drug GMP Certification in accordance with the "Regulations for the Implementation of Drug Administration Law of the People's Republic of China". Pharmaceutical manufacturers already obtained the "Drug GMP Certification" should re-apply for Drug GMP Certification 6 months prior to the expiry of the Certificate. Drug regulatory authorities should conduct at least one follow-up inspection on pharmaceutical manufacturers holding valid "Drug GMP Certifications". (August 8, 2011)

新修订的管理办法对药品GMP的申请，受理与审查，现场检查，审批与发证，跟踪检查，《药品GMP证书》管理等内容作出了明确规定。

管理办法指出，国家食品药品监督管理局主管全国药品GMP认证管理工作，负责注射剂、放射性药品、生物制品等药品GMP认证和跟踪检查工作；负责进口药品GMP境外检查和国家或地区间药品GMP检查的协调工作。省级药品监管部门负责本辖区内除注射剂、放射性药品、生物制品以外其他药品GMP认证和跟踪检查工作以及国家食品药品监督管理局委托开展的药品GMP检查工作。国家食品药品监督管理局负责对药品认证检查机构质量管理体系进行评估。

管理办法明确，新开办药品生产企业或药品生产企业新增生产范围、新建车间的，应当按照《药品管理法实施条例》的规定申请药品GMP认证。已取得《药品GMP证书》的药品生产企业应在证书有效期届满前6个月，重新申请药品GMP认证。药品监管部门应对持有《药品GMP证书》的药品生产企业进行跟踪检查。《药品GMP证书》有效期内至少进行一次跟踪检查。（2011年8月8日）

## The Interim Requirements for the Appointment and Evaluation of Drug GMP Inspectors " Issued

On August 2, 2011, the SFDA issued the "Interim Requirements for the Appointment and Evaluation of Drug GMP Inspectors" (hereinafter referred to as the "Interim Requirements"). The "Interim Requirements" requires the establishment of a unified national database for drug GMP inspectors, who are to be subjected to annual performance evaluation.

In accordance with the "Interim Requirements", the Center for Drug Certification of SFDA will establish a unified national database with respective archives covering drug GMP inspectors employed by the SFDA and provincial Food and Drug Administrations. An annual performance evaluation system shall be implemented for drug GMP inspectors. Those who cannot perform or correctly perform their corresponding duties, or fail to complete the inspection tasks, shall be evaluated as ineligible in the annual evaluation. The qualifications of drug GMP inspectors who cannot correctly perform their duties once or twice in a row shall be cancelled; and the qualifications of drug GMP inspectors who cannot perform their duties two times in accumulation shall be suspended. Drug GMP inspectors with suspended qualifications should be trained and qualified via examination to resume their eligibility. (August 8, 2011)

## 《药品生产质量管理规范检查员聘任及考评暂行规定》印发

2011年8月2日，国家食品药品监督管理局发布了《药品生产质量管理规范检查员聘任及考评暂行规定》（以下简称《暂行规定》）。《暂行规定》提出，要建立全国统一的药品GMP检查员库，药品GMP检查员实行年度考评制。

按照《暂行规定》，国家食品药品监督管理局药品认证管理中心将建立全国统一的药品GMP检查员库，建立药品GMP检查员管理档案。国家食品药品监督管理局和省级局分别聘任的药品GMP检查员均纳入药品GMP检查员库管理。药品GMP检查员实行年度考评制。药品GMP检查员不能履行或不能正确履行药品GMP检查员职责，不能完成检查任务的，年度考评为不合格。一次不能正确履行职责或连续两次不能履行职责的，注销其药品GMP检查员资格；累计两次不能履行职责的，暂停其药品GMP检查员资格。被暂停资格的药品GMP检查员，应经过培训、考核合格后方能恢复其资格。（2011年8月8日）

## SFDA Strengthen the Supervision and Administration of Commissioned Drug Processing upon the Entrustment of Foreign Pharmaceutical Manufacturers

In recent years, the situation of China's pharmaceutical manufacturers accepting foreign pharmaceutical manufacturers' commissioned pharmaceutical processing has been regulated to a certain extent along with its rather rapid development, but owing to the differences of drug regulatory systems in some countries, drug administration in this respect is rather complicated. Some individual enterprises in China blindly contract commissioned pharmaceutical processing and have been exploited by unscrupulous businessmen inside and outside China to produce counterfeit and shoddy products, and caused adverse international influences. To stand up for our country's image, we must strengthen the supervision over and administration of drug processing commissioned by foreign pharmaceutical manufacturers, and strictly regulate the behavior of accepting commissioned processing. SFDA issued a Notice on July 22, 2011, which requires that:

First, the provincial food and drug administration departments should attach great importance to this end, strengthen the record management of local pharmaceutical manufacturers' accepting foreign pharmaceutical manufacturers' commissioned pharmaceutical processing, extensively publicize the importance of enterprises' reporting for record, specifically guide and regulate the enterprises' behavior, prompting pharmaceutical companies to recognize the risk of blind contract of outsourced drug processing with foreign manufacturers, and consciously abide by the relevant regulations of record filing and drug processing.

Second, strictly examine the records of drug processing commissioned by foreign pharmaceutical manufacturers. The entrusting party must be foreign pharmaceutical manufacturers marketing authorization in overseas, and must sign the processing contract directly with China's pharmaceutical manufacturers. In case of any doubt upon the authenticity and legality of the documentary evidence of drug license for marketing, the entrusting party should be required to provide legalization documents issued by China's Embassy or Consulate in the country of the entrusting party. The outer labels and instructions of the drugs or preparations in commissioned production must be marked with the names and addresses of the enterprises entrusted, but should not contain such contents as China's drug approval number, imported drug registration certificate number, record number for commissioned processing, etc.

Drug manufacturers shall not accept foreign pharmaceutical manufacturers' commission for processing unpackaged preparations. The finished products after processing should be completed with primary packaging and labeled with the names of the drugs and the entrusted processing manufacturers. In the case of unpackaged preparations consigned for processing within multinational corporations and other enterprises, the relevant documents issued by foreign drug regulatory authorities should be provided.

Third, the provincial food and drug administration departments should strictly conduct record filing as required, and timely handle the filing applications that meet the requirements. While filling the "Record Form for Pharmaceutical Processing upon the Entrustment of Overseas Pharmaceutical Manufacturers", such supplementary notes should be added: "This Form is designated only as a proof of record for the commissioned processing enterprises to accept supervision and inspection from the food and drug administration departments, it shall by no means be used as a permit for marketing provided to overseas agencies". The Record information should be informed to the local food and drug administration departments and units, and publicized in SFDA website.

Record filing applications that don't meet the requirements should be informed to the

## 国家食品药品监督管理局加强接受境外制药厂商委托加工药品监督管理

近年来，我国药品生产企业接受境外制药厂商委托进行药品加工行为得到一定规范，且发展较快，但由于国际上有些国家药品监管制度不同，药品管理状况十分复杂，个别企业盲目承揽药品加工，被境内外不法商人利用生产假冒伪劣产品，造成恶劣国际影响。为维护国家形象，必须加强接受境外制药厂商委托加工药品的监督管理，严格规范接受委托加工行为。为此，国家食品药品监督管理局于2011年7月22日发出通知，要求如下：

一、各省级食品药品监督管理部门应高度重视，切实加强辖区内药品生产企业接受境外制药厂商委托加工药品的备案管理，广泛深入宣传企业申报备案的重要性，具体指导和规范企业行为，促使企业认清盲目承揽境外药品加工的风险，自觉遵守备案和加工的相关规定。

二、严格审查接受境外制药厂商委托加工药品备案资料。委托方必须是境外制药厂商，且持有该药品境外上市许可，并须直接与我药品生产企业签订加工合同。对其药品上市许可证明文件真实性和合法性如有疑义，应要求委托方提供我驻该国使、领馆出具的认证文件。受托加工药品制剂的外标签或说明书必须标注受托加工企业的名称和地址，但不得有我国药品批准文号、进口药品注册证书号、委托加工备案号等内容。

药品生产企业不得接受境外制药厂商委托加工裸包装制剂，加工后成品应完成内包装，并带有标明药品名称和受托加工企业名称的标签。如属跨国公司等企业内部委托加工裸包装制剂的，应提供境外药品管理当局出具的相关证明文件。

三、各省级食品药品监督管理部门应严格按照规定做好备案工作，对符合要求的备案申请应及时办理，并在填写《接受境外制药厂商委托加工药品备案表》时加注：“本表仅供受托加工企业在接受食品药品监督管理部门监督检查时作为已备案证明之用，不得用作向境外机构提供的上市许可证明”字样。备案信息应告知本辖区的食品药品监督管理部门和单位，并在本局网站予以公开。

对不符合要求的备案申请，应在告知

manufacturer as denial with corresponding reasons, and be informed at the same time to relevant Food and Drug Administration departments.

Fourth, the provincial food and drug administration departments should strengthen the supervision and inspection on local pharmaceutical manufacturers' accepting commissioned drug processing for foreign pharmaceutical companies, and include this inspection in the supervision & inspection program as a routine practice. The production site inspections should focus on whether the enterprise has strictly abided by the processing sites, prescription, process, quality, labels, instructions and other requirements as recorded, whether the production is in line with the requirements of "Good Manufacturing Practice for Pharmaceutical Products", etc. For long-term processing with a single record, measures such as periodic enterprises reports and others should be taken to strengthen supervision and management.

Behaviors such as accepting commissioned processing without record filing, changing the processing location or technical requirements without authorization, and the failure to comply with "Good Manufacturing Practice for Pharmaceutical Products" etc., once found in the supervision and inspection, must be ordered for immediate correction, and punished in light of the "Measures for the Supervision over and Administration of Pharmaceutical Production Provisions for the Administration of Drug Production" and the relevant regulations.

Fifth, upon receipt of this Notice, the provincial food and drug administration departments shall organize a comprehensive supervision and inspection within the jurisdiction area over the commissioned pharmaceutical processing upon the entrustment of overseas pharmaceutical manufacturers, all manufacturers that are found not complying with the above requirements should be ordered for rectification within a set time limit, those who still fails to meet the requirements after the time limit must be ordered to stop processing. Related works and the supervision and inspection details should be reported to the State Food and Drug Administration by the end of November 2011 in accordance with the requirements of "2011 Work Plan for the Supervision over and Administration of Pharmaceutical Production".

Taking into account the national interests, the provincial food and drug administration departments shall fully understand the significance of the administration over drug processing upon the entrustment of overseas pharmaceutical manufacturers, earnestly implement the record management as well as the supervision and inspection responsibilities, to regulate the behaviors of local manufacturers. (July 21, 2011)

企业不予备案及其理由的同时，告知相关食品药品监督管理部门。

四、各省级食品药品监督管理部门应加强辖区内药品生产企业接受境外制药厂商委托加工药品的监督检查，列入监督检查计划，纳入日常监管。生产现场检查重点应包括企业是否严格遵循已备案加工地点、处方、工艺、质量及标签说明书等各项要求，是否按《药品生产质量管理规范》要求组织生产等。对一次备案常年加工的，应采取企业定期报告等措施加强监督管理。

监督检查中如发现不经备案即擅自受托加工、擅自改变已备案加工地点或技术要求、不遵守《药品生产质量管理规范》等行为，必须责令其立即改正，并按《药品生产监督管理办法》及有关规定进行处理。

五、各省级食品药品监督管理部门接本通知后，要对辖区内药品生产企业接受境外委托加工情况组织一次全面监督检查，凡发现不符合上述要求的应一律责令企业限期改正，逾期仍不符合要求的必须责令其停止加工。相关工作及监督检查情况请按《2011年药品生产监管工作计划》要求，在2011年11月底前报告国家食品药品监督管理局。

各省级食品药品监督管理部门应从国家利益出发，充分认识加强接受境外制药厂商委托加工药品监管的重要意义，认真落实备案管理和监督检查工作责任，切实规范企业行为。 (2011年7月26日)

## SFDA Carries out Special Inspection on the Biosafety Protection and Management of Bacteria (virus) Strains for Vaccine Production

To further enhance the management of bacteria (virus) strains for vaccine production and ensure vaccine quality and safety, the SFDA decided to launch a special inspection on the biosafety protection and management of bacteria (virus) strains for Vaccine production. The inspection shall be carried out in stages through the combination of enterprises' self-examination and the inspection by regulatory departments.

Vaccine manufacturers should complete the work of self-examination by the end of July 2011, and timely report the self-examination and improvement as well as the information

## 国家食品药品监督管理局开展疫苗生产用菌毒种生物安全防护及管理专项检查工作

为进一步加强疫苗生产用菌毒种的管理，确保疫苗质量及其安全，国家食品药品监督管理局决定开展疫苗生产用菌毒种生物安全防护及管理专项检查工作。 检查工作采取企业自查与监管部门监督检查相结合分阶段开展方式进行。

疫苗生产企业应在2011年7月底以前完成自查工作，并将自查及整改情况以及疫苗生产用菌毒种信息表及时上报所在地省级食品药品监督管理局；各相关省级食品药品监

table of bacteria (virus) strains for vaccine production to provincial Food and Drug Administration; the relevant provincial Food And Drug Administration shall, considering the vaccine manufacturers' biosafety protection and management of bacteria (virus) strains for Vaccine production as well as the self-examinations, select drug GMP inspectors who had participated in the World Health Organization's Vaccine Quality Risk Management Training Workshops and relevant personnel to carry out on-site inspections. The Inspections should include: the three-tier inventory management and detection of bacteria (virus) strains, requisition records and production process, the corresponding production order, storage methods and substantive management etc. The on-site inspection should be completed before the end of August 2011; SFDA shall take into account the on-site inspections conducted by the relevant provincial Food and Drug Administrations, as well as the GMP follow-up inspection program of vaccine manufacturers in 2011, and perform supervision and random inspection on the vaccine manufacturers' biosafety protection and management of bacteria (virus) strains for vaccine production. Center for Drug Certification of SFDA shall be responsible to organize the supervision and random inspection. (July 18, 2011)

督管理局应根据疫苗生产企业疫苗生产用菌毒种生物安全防护及管理自查情况，选派参加过世界卫生组织疫苗质量风险管理培训班的药品GMP检查员等相关人员开展现场检查工作。检查内容应包括：菌毒种的三级库管理、菌毒种的检测、领用记录与生产工艺、生产指令相对应、储存方式及实质性管理等。 现场检查工作应在2011年8月底以前完成；国家食品药品监督管理局将根据各相关省级食品药品监督管理局开展现场检查工作的情况，结合2011年度疫苗生产企业药品GMP跟踪检查工作计划，对疫苗生产企业疫苗生产用菌毒种生物安全防护与管理情况进行监督抽查。监督抽查工作由国家食品药品监督管理局药品认证管理中心负责组织。（2011年7月18日）

## SFDA Releases Alert on the Safety Information of Benzocaine-Induced Methemoglobinemia

Recently, the National Center for ADR Monitoring of SFDA issued the 39th Volume of "Adverse Drug Reaction Information Bulletin" to notify the latest serious adverse reactions of methemoglobinemia potentially attributable to Benzocaine, as discovered by foreign Drug Administration departments. Taking into account the concurrence of these risks in China's clinical practice, and that benzocaine products are mostly non-prescription drugs, to timely inform the health care professionals and patients of the risk of the application of these drugs, the SFDA remind the majority of medical personnel, pharmaceutical manufacturers and the public to keep a watchful eye on the safety information of Benzocaine-Induced Methemoglobinemia. (July 14, 2011)

## 国家食品药品监督管理局提醒关注苯佐卡因引起高铁血红蛋白血症的安全性信息

日前，国家药品不良反应监测中心发布了第39期《药品不良反应信息通报》并表示，近期国外药品管理部门发现苯佐卡因可能引起高铁血红蛋白血症的严重不良反应。考虑到此类风险在我国临床应用中也同样存在，且苯佐卡因产品多为非处方药，为使广大医务人员和患者及时了解该药品的使用风险，国家食品药品监督管理局提醒广大医务人员、药品生产企业和公众关注苯佐卡因引起高铁血红蛋白血症的安全性信息。 （2011年7月14日）

## Directory of the Normative Documents Announced as Abolished or Declared (Second Batch) as Invalid by SFDA

In order to comprehensively promote administration according to law, strengthen the rule of the laws and regulations, on the basis of the previous clearance of outdated regulations and normative documents, SFDA organized another clearance of relevant normative documents, and decided to repeal and declare as invalid a number of normative documents. On June 28, 2011, SFDA issued the Directory of the Normative Documents (Second Batch) Announced as Abolished or Declared as Invalid, as well as 25 normative documents that have been expressly abolished by operational management regulatory documents. Unless otherwise specified, the abolishment and annulment of the above normative documents shall all not tarnish the effectiveness of the past decisions made as based on these documents. (July 12, 2011)

## 国家食品药品监督管理局公布废止和宣布失效的规范性文件目录（第二批）

为全面推进依法行政，加强法治建设，国家食品药品监督管理局在前次清理规章和规范性文件的基础上，组织了对相关规范性文件的清理，并决定废止和宣布失效一批规范性文件。2011年 6月28日，公布了废止和宣布失效的规范性文件目录（第二批），并对业务管理工作文件中已明文废止的25件规范性文件予以公布。对上述规范性文件予以废止或者宣布无效，除另有明确规定外，均不涉及过去根据这些文件所做出的处理决定的效力。 （2011年7月12日）

## SFDA Issued the Notice on the Effective Electronic Supervising of Essential Drugs in 2011

As explicitly requested by the SFDA "Notice on the Issuance of Major Work Arrangements for Strengthening the Quality Supervision of Essential Drugs in 2011" (State Food and Drug Department of Policy & Regulations [2011] No. 121), by the end of February 2012, all essential drugs produced by manufacturers must be assigned with codes, all distributors of essential drugs must conduct data upload via electronic regulatory network, those distributors devoid of the capacity of registration & cancellation verification of essential drug varieties are unqualified for the delivery of essential drugs. To conscientiously implement the above documented requirements, and perform effective electronic essential drug supervising, on June 30, 2011, the SFDA issued a Supplementary Notice on relevant issues as follows:

The SFDA requires that the Food and Drug Administrations of all provinces (autonomous regions and municipalities) attach great importance to electronic supervising of essential drugs, strengthen supervision and management, all the manufacturers of essential drugs (including manufacturing enterprises of essential drugs who failed the bids), and distributors of essential drugs that have not introduced electronic supervising within the prescribed time limit are not allowed to undertake the production and distribution of essential drugs; to ensure the coherence and coordination of the electronic drug supervising policies, for the supplementary varieties of essential drugs in the provinces (autonomous regions and municipalities), if an enterprise won the bid of an essential drug variety in a province and implemented electronic supervising, this enterprise's supply of the drug variety to other provinces must also be assigned with codes regardless of whether or not this enterprise has successful won the bid in other provinces; drug wholesale enterprises should perform registration & cancellation verification of this product, to ensure the normal operation of the network and data integrity and reliability; and the training and technical guidance in this respect shall be further intensified. (July 7, 2011)

## 国家食品药品监督管理局印发关于做好2011年度基本药物电子监管工作的通知

为认真贯彻国家食品药品监督管理局《关于印发加强基本药物质量监管2011年度主要工作安排的通知》（国食药监法[2011]121号）等文件中已明确的要求，2012年2月底前，所有生产企业生产的基本药物品种必须赋码，所有基本药物配送企业必须通过电子监管网实现数据上传，不能开展基本药物品种核注核销的企业不得承担基本药物配送工作等要求，切实做好基本药物电子监管工作，2011年6月30日，国家食品药品监督管理局就有关事宜补充通知如下：

国家食品药品监督管理局要求各省（区、市）局要高度重视基本药物电子监管工作，切实加强监督管理，凡基本药物生产企业（含未中标的基本药物生产企业）、基本药物配送企业未在上述规定期限内实施电子监管的，一律不得承担基本药物生产与配送工作；为保证药品电子监管政策的统一与协调，各省（区、市）增补的基本药物品种，如果某企业该品种在一个省份中标并实施电子监管，不管其在其他省份中标与否，该企业向其他省份供应的该品种也一律进行赋码，药品经营批发企业均应对该产品进行核注核销，以保证网络的正常运行和数据的完整、可靠；进一步加大培训和技术指导工作力度。（2011年7月7日）

## SFDA Issued the Notice on Electronic Document Standards in CTD Format for Pharmaceutical Information of Chemicals (Interim) and the Format and Filing Codes of Drug Registration & Application Dossiers

To facilitate the submission of electronic Common Technical Documents (abbreviated as CTD), the SFDA organized the development of "Electronic Document Standards in CTD Format for Pharmaceutical Information of Chemicals (Interim)" and the "Format and Filing Codes of Drug Registration & Application Dossiers", which have been issued and entered into force as of June 27, 2011 (http://www.sda.gov.cn/syjbz1198). (July 7, 2011)

## 国家食品药品监督管理局印发化学药药学资料CTD格式电子文档标准（试行）和药品注册申报资料的体例与整理规范的通知

为推进通用技术文件（Common Technical Document，简称CTD）格式电子文档的提交，国家食品药品监督管理局组织制定了《化学药药学资料CTD格式电子文档标准（试行）》和《药品注册申报资料的体例与整理规范》，并于2011年6月27日印发执行（http://www.sda.gov.cn/syjbz1198）。（2011年7月7日）

## SFDA Requires the Effective Implementation of "Provisions for Adverse Drug Reaction Reporting and Monitoring"

The newly revised Provisions for Adverse Drug Reaction Reporting and Monitoring (hereinafter referred to as the "Provisions") has come into effect as of July 1, 2011. On June 29, the SFDA and the Ministry of Health jointly issued a Notice requiring all levels of food and drug regulatory authorities and health authorities to further improve the monitoring system of adverse drug reactions (ADRs); continue to establish a joint working mechanism for the monitoring and handling of ADRs, to increase supervision and inspection, supervise and urge drug manufacturers, distributors and medical institutions to strengthen the ADR monitoring, so as to improve the management level on ADR reporting and monitoring.

The Notice indicates that all levels of food and drug regulatory authorities and health administrative departments should strengthen supervision and inspection, urge drug manufacturers, distributors and medical institutions to strengthen ADR monitoring; proactively monitor, report, analyze and evaluate adverse drug reactions. In particular, drug manufacturers should take the initiative to carry out emphatic monitoring of drugs, actively take risk management measures to control drug risks. It is reported that SFDA shall organize the development of relevant technical guidelines focusing on ADR monitoring, to guide key ADR monitoring works. (July 4, 2011)

## 国家食品药品监督管理局要求做好贯彻落实《药品不良反应报告和监测管理办法》工作

新修订的《药品不良反应报告和监测管理办法》（以下简称《办法》）自2011年7月1日起施行。6月29日国家食品药品监管局和卫生部联合发出通知，要求各级食品药品监管部门和卫生行政部门进一步完善药品不良反应监测体系，不断建立健全药品不良反应监测处置联合工作机制，加大监督检查力度，督促药品生产、经营企业和医疗机构加强药品不良反应监测工作，提高药品不良反应报告和监测的管理水平。

通知指出，各级食品药品监管部门和卫生行政部门要加大监督检查力度，督促药品生产、经营企业和医疗机构加强药品不良反应监测工作，主动监测、报告、分析和评价药品不良反应，特别是药品生产企业应主动开展药品重点监测，积极采取风险管理措施控制药品风险。今后，国家食品药品监督管理局将组织制定药品不良反应重点监测相关技术指导原则，指导重点监测工作的开展。 (2011年7月4日)

Q&A 问与答

## Answers from the Center for Drug Evaluation of SFDA for submitting dossiers in CTD format

## 国家食品药品监督管理局药品审评中心关于提交CTD格式资料有关问题的解答

(To continue)

**XII. In a manufacturing process, a sustained-release capsule is filled with sustained-release pellets, in which the drug layer of the sustained-release pellets covers the blank pellet core and then is seal-coated. Weight increases from the drug layer coating are within a range and the drug loading yield can not reach 100%. Under these circumstances, how should the sustained-release capsule formula be written in CTD format?**

A: It is suggested that section 3.2.P.1 Formulation of the application dossier in CTD format should be written with the following model for reference:

Tabulate the unit composition of pellet core, drug layer and seal coating respectively, and indicate the function of each ingredient, and its execution standard in the formulation. The solvents used in formulation but need to be removed from the final product should also be listed, and it should be noted below the form that the solvent will be removed during production process.

For the formulation of the drug coating layer, it is suggested to tabulate drug substance, sustained-release excipients and other excipients, and to list their corresponding unit amounts based on 100% theoretical amount. Since the

（接上期）

十二、某缓释胶囊填充的缓释微丸采用将药物层包裹在空白丸芯外，再进行密封包衣的生产工艺，药物层包衣增重有一定范围，上药时收率也无法达到100%，此时缓释胶囊处方如何按CTD格式书写？

**回答：**建议CTD格式申报资料3.2.P.1处方部分参照以下方式书写：

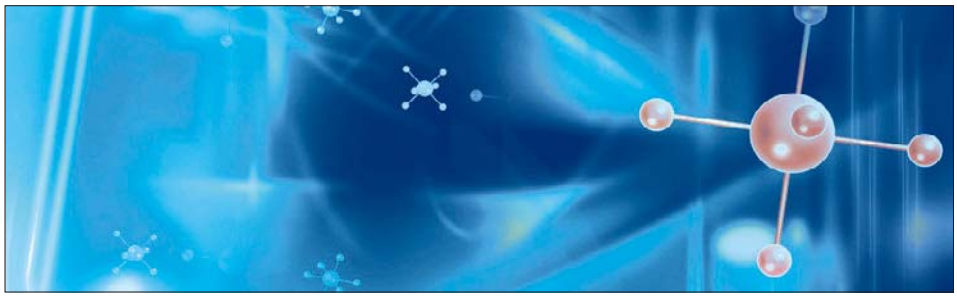
按照丸芯部分、药物包衣层、密封包衣层分别以表格方式列出单位剂量产品的处方组成，列明各成份在处方中的作用，执行的标准。对于处方中用到但最终需去除的溶剂也应列出，并在表格下方标注说明该溶剂在制备过程中去除。

对于药物层包衣处方，建议以表格方式分别列出药物、缓释辅料和其他辅料，按标示量的100%（理论量）列出单位剂量产品的药物量，及相应的缓释辅料和其他

weight gain after drug coating is within a certain range during production, its specificity can be provided in the manufacturing process section of the application dossier in CTD format, as well as the drug loading yield from scale-up production and process validation.

If the coating products in the market such as Opadry are used in the seal coating, the model (e.g. Opadry II White 86F18422), amount in unit dose product (e.g.: 5.0 mg) and 6 20110809 | RDPAC CMC FG

function (e.g.: coating materials) of the Opadry should be tabulated, and the composition of this Opadry model should be noted below the form. (e.g. Opadry II White 86F18422 contains PVA, polyglycol, titanium dioxide, talcum powder, etc.)



**XIII. For the batch formula of production scale in the application dossiers in CTD format, should the production scale be fixed, or can it be written as within a certain range?**

A: The batch formula composition of production-scale products and the execution standard of each ingredient are required to be tabulated in section 3.2.P.3.2 "The proposed large production scale" in section 3.2.P.3.3 refers to the largest scale in commercial production, and it is required to provide the batch formula in section 3.2.P.3.2; for other representative commercial production scales (smaller scale than the largest commercial production scale), batch formula can be also tabulated in section 3.2.P.3.2. For example, if an IR tablet's registered batch production scale is 100,000 tablets, the largest scale of proposed commercial production is 500,000 tablets, and other representative commercial production scale is 200,000 tablets, then the batch formulas of 500,000 tablets and 200,000 tablets can also be tabulated.

**XIV. Can the clinical batch be the pilot scale-up batch? Can the registration batch be the pilot scale-up batch (using production equipment with the same operating principle)? Can the process validation batch be used as the stability batch?**

A: The pilot scale-up batch refers to the scale-up batch, in which the commercial representative process and flow, and equipments with the same operating principle are used, and the batch size is at least one tenth of the commercial production scale. The pilot scale-up batch can be used for stability and clinical study.

The process validation batch refers to the batch for process study carried out in production line in order to investigate the reproducibility and feasibility of large scale production. The process validation batch can be used for stability study.

The production batch size of the samples for clinical study (bioequivalence study) shall not be less than one tenth of the largest scale in commercial production. Since the production information and quality information of the batch are key to support the evaluation of the quality

辅料的用量。由于生产中药物包衣增重有一定范围，可在CTD格式申报资料生产工艺部分进行说明，同时说明经过放大生产和工艺验证后的上药收率。

对于密封包衣层采用欧巴代等市售包衣产品进行包衣的，表格中应列出使用的欧巴代型号（如白色欧巴代II 86F18422），单位剂量产品的欧巴代用量（例如：5.0mg）及其功能（例如：包衣材料），并于表格下方注明该型号欧巴代的组成（例如：白色欧巴代II 86F18422含聚乙烯醇、聚乙二醇、二氧化钛和滑石粉等）。

十三、对于CTD格式申报资料中的生产规模批处方，生产规模是固定的，还是可以书写为一定批量范围？

**回答：**CTD格式申报资料3.2.P.3.2 批处方是以表格的方式列出生产规模产品的批处方组成，列明各成份执行的标准。3.2.P.3.3中"拟定的大生产规模"是指商业化生产的最大规模，需要在3.2.P.3.2中提供其批处方；对于其他代表性的商业化生产规模（低于商业化生产的最大规模），也可以在3.2.P.3.2中以表格的方式列出批处方。例如对于普通片剂，注册批生产规模为10万片，拟定商业化生产的最大规模为50万片，其他代表性的商业化生产规模还包括20万片，则可以分别以表格的方式列出50万片、20万片的批处方。

十四、临床研究批可以是中试放大批吗？注册批可以是中试放大批吗（采用操作原理一致的生产设备）？工艺验证批可以作为稳定性试验批吗？

**回答：**中试放大批是指在中试车间模拟工业化生产所用的工艺及流程，采用操作原理一致的生产设备，且批量至少为工业化生产规模的十分之一的条件下所进行的放大研究批次，中试放大批可以用作稳定性研究和临床研究。

工艺验证批是指为考察工艺的大生产重现性与可行性，在生产线上所进行的工艺研究批次，工艺验证批可以作为稳定性试验批。

临床研究（生物等效性研究）批样品的生产批量应不低于工业化生产最大规模的十分之一。由于该批次的生产信息和质量信息是评价药品质量可控性的重要支持性数据，在申报资料中应注意提供该批次的批生产纪录、检验报告等。

十五、对于过量投料，如果原料药不是很稳定，为保证产品质量，在不影响安

controllability of the drug, the batch production record and test report, etc. should be provided in the dossier.

**XV. For the overage, if drug substance is not so stable, in order to ensure product quality, is overage allowed on the premise that safety is not affected?**

A: Extreme caution must be taken for overage in production. Generally, the overage in production should be avoided through optimization of formulation formula, manufacturing equipment, and process parameters, etc. If overage is essential, it is required to provide detailed supporting information to describe the necessity and rationale of overage. Application of overage generally requires multiple batch validations.

Generally, overage is not recommended to compensate the degradation of drug substances during production and storage of drug products. If overage is essential, it is required to provide degradation pathway and degradation products of drug substances, and the safety information of the degradation products to demonstrate the product safety. It is also required to describe whether the amount of overage matches with the amount degraded during production and storage of drug product. (June 13, 2011)

全性的前提下，是否允许过量投料?

**回答**：对于生产中的过量投料需非常慎重，一般应首先通过优化制剂处方和生产设备、生产工艺参数等方法，避免生产中的过量投料；对于生产中确需过量投料的，需要提供详细的支持性资料，说明过量投料的必要性和合理性，过量投料一般需经过重复批次验证。

一般而言，不鼓励为补偿制剂生产及贮存过程中原料药的降解而进行过量投料。如确需过量投料，需要提供制剂生产及贮存过程中原料药的降解途径和降解产物研究资料以及降解产物的安全性资料，以论证产品的安全性，同时说明原料药多投的量与制剂生产及贮存过程中降解的量是否匹配。 (2011年6月13日)

## Center for Drug Evaluation of SFDA Started the Preliminary Review of CTD Application Dossiers

To progressively realize the internationalization of the technical standards of application dossiers, Center for Drug Evaluation of SFDA (CDE) has officially launched the preliminary review of CTD application dossiers since July, 2011.

The preliminary review will be based on the technical requirements of the CTD format attached to SFDA Department of Drug Registration [2010] No. 387 Document, and focus on assessing whether the application dossiers conform to the concepts of combining process control and endpoint control, combining research and validation, and the comprehensive and systematic drug quality control as embodied in the technical requirements of the CTD format.

The preliminary review will be conducted through collective decision-making in conferences. The preliminary review conferences shall be held monthly, personnel from relevant evaluation and management departments of CDE shall participate the review, and extract 10 applied drug species in sequential order from the "Review Sequence of CTD-Formatted Application Dossiers to Be Confirmed", the pre-qualified species shall be included into the monthly review plan, and their review reports shall be delivered to the appropriate applicants according to the requirements of the "Review Principles & Procedures". Dossiers that conform to CTD format only in the form (the contents do not meet the CTD technical requirements) shall be included and reviewed in the "Normal Review Sequence". (July 8, 2011)

## 国家食品药品监督管理局药品审评中心启动CTD申报资料预审工作

为逐步实现申报资料的技术标准国际化，国家食品药品监督管理局药品审评中心自7月份起，正式启动CTD申报资料的预审工作。

预审工作将依据国食药监注[2010]387号文所附的CTD格式技术要求，重点评估申报品种是否符合CTD格式技术要求体现的过程控制和终点控制相结合、研究和验证相结合、全面系统的药品质量控制理念。

预审工作将采取会议方式，实行集体决策。预审会议每月一次，由国家食品药品监督管理局药品审评中心相关审评及管理部门人员参加，从“待确认纳入CTD格式申报资料审评序列”中按序抽取十个品种，预审符合要求的品种，纳入当月审评计划，并将按照《审评原则和程序》的要求将审评报告向相应的申请人公开。对于仅在形式上按CTD格式整理资料，研究内容不符合CTD技术要求的，将进入“正常审评序列”，按一般程序排序审评。

(2011年7月8日)

# The Output Value of China's Pharmaceutical Manufacturing and the Situation Analysis of Pharmaceutical Import and Export in the First Half of 2011

# 2011年我国上半年医药制造业产值及医药进出口情况

From January to June 2011, China has achieved a total pharmaceutical industrial output value of 684.879 billion yuan, up by 28.23% over the same period in 2010, and up by 2.24 percentage points in terms of the growth rate.

From January to June, the manufacturing output of chemical medicine is 343.145 billion yuan, up by 24.27% over the same period in 2010 and 2.81 percentage points in terms of the growth rate, the rise in growth rate is significant; the manufacturing output of Patent Traditional Chinese Medicine is 157.244 billion yuan, a growth of 31.96% over the same period in 2010 and 4.22 percentage points in terms of the growth rate, the fastest growth rate in the whole industry; the manufacturing output of biological and biochemical products is 74.079 billion yuan, up by 25.4% over the same period, while the increase rate decreased 11.54 percentage points over the same period in 2010, the sharpest decrease in growth rate.

The export of China's pharmaceutical foreign trade in the first half year is 21.382 billion U.S. dollars, up by 36.62% in equal terms; the import is $ 13.164 billion, an increase of 45.67 percent over the same period, still maintained a rapid growth momentum.

As of June, the growth rate of China's pharmaceutical export to developed countries of the European Union, the United States, Japan is 32.11%, 29.49%, and 27.9% respectively, the total export value to the three markets accounted for 49.96% of China's total pharmaceutical exports, decreased with 2.44 percentage points over the same period last year. Meanwhile, the structure of export

2011年1～6月，我国共实现医药工业总产值6848.79亿元，同比增长28.23%，增幅较2010年同期上涨2.24个百分点。

1～6月，化学药品制造业总产值为3431.45亿元，同比增长24.27%，增幅较2010年同期回升2.81个百分点，增速涨势明显；中成药制造业总产值为1572.44亿元，同比增长31.96%，增幅较2010年同期上升4.22个百分点，总体看来其增速在整个行业中最快；生物生化制品制造业总产值为740.79亿元，同比增长25.4%，增幅较2010年同期下降11.54个百分点，增速跌幅最大。

我国上半年医药外贸出口额213.82亿美元，同比增长36.62%；进口额131.64亿美元，同比增长45.67%，仍保持着快速增长势头。

截至6月，我国对发达国家欧盟、美国、日本医药出口增速分别为32.11%、29.49%、27.9%，三个市场合计占我国医药出口比重49.96%，比去年同期下降2.44个百分点。同时，对发达市场出口产品结

2011年上半年医药保健品进出口情况
China's Import and Export of Medicines & Health Products in the first half of 2011

| 商品名称 Commodity Name | 进出口 Import and export | | | 进口 Import | | | 出口 Export | | |
|---|---|---|---|---|---|---|---|---|---|
| | 进出口额 Import and export Amount | 同比 Growth rate in equal terms (%) | 比重 Proportion (%) | 进口额 Import Amount | 同比 Growth rate in equal terms (%) | 比重 Proportion (%) | 出口额 Export Amount | 同比 Growth rate in equal terms (%) | 比重 Proportion (%) |
| 总计 Total | 345.46 | 39.93 | 100 | 131.64 | 45.67 | 100 | 213.82 | 36.62 | 100 |
| 中药类 Traditional Chinese Medicine | 14.38 | 41.43 | 4.16 | 3.26 | 36.5 | 2.48 | 11.11 | 42.95 | 5.2 |
| 保健品 Health Products | 1.68 | 120.53 | 0.49 | 0.7 | 122.15 | 0.53 | 0.98 | 119.4 | 0.46 |
| 提取物 Extracts | 6.11 | 44.46 | 1.77 | 0.86 | 27.53 | 0.65 | 5.25 | 47.68 | 2.46 |
| 中成药 Patent TCM | 2.14 | 5.66 | 0.62 | 1.01 | -8.98 | 0.77 | 1.13 | 23.36 | 0.53 |
| 中药材及饮片 TCM crude drugs and slices | 4.44 | 41.25 | 1.29 | 0.7 | 137.32 | 0.53 | 3.74 | 31.33 | 1.75 |
| 西药类 Western Medicine | 210.57 | 31.19 | 60.95 | 79.2 | 38.67 | 60.17 | 131.36 | 27.05 | 61.44 |
| 西药原料 APIs of Western Medicine | 143.59 | 25.53 | 41.57 | 33.16 | 16.22 | 25.19 | 110.43 | 28.63 | 51.65 |
| 西成药 Western patent medicine | 46.8 | 59.5 | 13.55 | 37.34 | 68.92 | 28.37 | 9.45 | 30.71 | 4.42 |
| 生化药 Biochemical | 20.18 | 20.22 | 5.84 | 8.7 | 34.37 | 6.61 | 11.49 | 11.34 | 5.37 |

products to developed markets changed significantly, the medical device products continue to maintain a rapid growth, the increase rate amounts to 54.34%, while the export of API product is significantly slowing down, the growth rate is 18.93%, which is below the average market growth of 28.63%. The exports to emerging markets maintained its rapid development, the growth rate of China's pharmaceutical export to the ASEAN countries, India, Brazil and Russia is 44.73%, 31.31%, 57.38%, and 53.43% respectively, the total exports to the four emerging markets is $4.508 billion in grand sum, up by 1 percentage point approximately in terms of the proportion in total exports over the same period of the previous year. (August 12, 2011)

构发生明显变化，医疗器械类产品继续保持高速增长，增幅达到54.34%，而原料药产品明显放缓，增速为18.93%，低于平均28.63%的平均市场增幅。新兴市场继续高速发展，我对东盟、印度、巴西、俄罗斯医药出口增速分别为44.73%、31.31%、57.38%、53.43%,对上述四个新兴市场出口共计45.08亿美元，占出口总额的比重比上年同期提高约1个百分点。

（2011年8月12日）

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

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