Chinese FDA Unveils Plan for Regulatory Reform

The Chinese State Food and Drug Administration ("SFDA") announced a plan for regulatory reform ("Reform Plan") and is soliciting public comments through January 15, 2013. The Reform Plan sets forth the following key strategic priorities:

1. **To accelerate technical reviews and regulatory approvals for innovative drugs**

- SFDA will reward drug R&D which delivers better therapeutic effects on critical diseases and leads to indigenous intellectual property by accelerated technical reviews and regulatory approvals for the resulting innovative drugs.
- Innovative drugs whose R&D is sponsored by Chinese government will be given high priority in technical reviews.
- Pre-clinical studies of innovative drugs should be risk-based and their technical evaluation should aim for better control of quality risks. SFDA may outsource the task of technical review for pre-clinical studies to designated third parties.
- SFDA will explore the feasibility of performing technical reviews for innovative drugs along with the ethics review and consider allowing transfer of clinical trial authorizations.

2. **To accelerate technical reviews and regulatory approvals for high priority generics**

- SFDA will establish an evaluation mechanism for marketed generic drugs. Generic drugs which fail to demonstrate sufficient clinical values will be discouraged from further development and manufacturing. The agency plans to involve relevant authorities, industry experts, and nongovernment organizations in the development of the evaluation mechanism.
- Generics which have a shortage in supply, insufficient competition, limited patient access and affordability, an indication for pediatric, rare or special diseases and have been evaluated as urgently required for clinical use will be given high priority in technical reviews and regulatory approvals.
- The review process for high priority generics will be streamlined. The high priority generics will be separated from other generics for technical reviews, on-site inspections of manufacturing facilities and product testing. A prior recordal registration for BA/BE studies may be introduced in place of a clinical study authorization from SFDA. Failure to complete the registration record will prohibit the high priority generics from market authorization.
- The quality consistency evaluation for generics will be a major policy initiative in the next couple of years and will lead to the formation of a Chinese Orange Book.

3. **To improve quality control for clinical studies**

- SFDA will impose more stringent requirements on the organizational structure, personnel and operational procedure of ethics committees to ensure effective and independent ethics reviews.
- SFDA will establish an information disclosure mechanism to enhance transparency of clinical studies and raise public awareness of the notion of, and need for, clinical studies.
- SFDA will enhance oversight on the implementation of clinical studies and require sponsors, study sites and ethics committees to strictly comply with statutory requirements. Noncompliance will lead

to suspension of the relevant studies. Falsification of study data will disqualify the study sites and prohibit the study drug from market authorization.

4. **To encourage development and manufacturing of pediatric drugs**

- SFDA will work with other relevant government agencies to define incentives for pediatric drugs in relation to tendering, pricing and reimbursement. Generic drugs with specification and dosage form suitable for pediatric diseases will be given high priority in technical reviews and regulatory approval. Pediatric drugs may be subject to special monitoring periods and enjoy certain exclusivity.

To implement the above strategic priorities successfully, SFDA plans to revise the Drug Registration Rules and align the Rules with the international norm. To improve operational efficiency and better manage workload at SFDA, the agency has piloted the delegation of review and approval authorities in relation to contract manufacturing and technology transfer to Guangdong FDA in 2012 and may expand the delegation of authority or further roll out the pilot. Chinese drug manufacturers are encouraged to develop and manufacture drugs to conform to international standards and their data derived from overseas clinical studies will be admitted for domestic technical reviews and regulatory approvals. SFDA will also enhance transparency of the regulatory approval process by establishing an online communication platform for applicants with Center of Drug Evaluation ("CDE") and introducing formal meeting minutes to document consensus between applicants and CDE reviewers.

If you would like to discuss the foregoing or any other related matter, please contact Katherine Wang or your usual Ropes & Gray advisor.