The China Food and Drug Administration’s 2017 Reform Efforts Highlighted Seven Priorities

On February 27, in a press conference held by China’s State Council, Mr. Bi Jingquan, the head of the China Food and Drug Administration (CFDA), stated that the agency will pursue its reform of the drug and medical device approval system in 2017 with seven priorities:

1. **Drug Innovation.** The CFDA will continue to develop policies to (a) encourage drug innovation, (b) improve patent linkage and data exclusivity systems, (c) achieve international bilateral or multilateral recognition of clinical trial data and (d) lower R&D costs for companies.

2. **Quality and Efficacy Equivalence Assessments for Generics.** The CFDA will approve more clinical study sites for equivalency assessments and explore new methodologies for equivalence assessments of generic intravenous products.

3. **Drug and Device Approval System.** The CFDA will increase resources for technical review and inspections to establish an approval system for drugs and medical devices that is not only focused on technical review, but also supported by on-site inspection and product testing.

4. **On-site Inspections.** The CFDA will strengthen its data integrity assessment of regulatory dossiers, continue its on-site inspections on clinical trials and manufacturing processes for both drugs and medical devices, and clarify the legal responsibilities of its inspectors.

5. **Drug Master Files.** The CFDA will establish a database for each approved drug, including its formulation, active pharmaceutical ingredients, excipients and packaging materials, quality standards, label information, post-market safety information and changes in manufacturing process, etc.

6. **Electronic Common Technical Document (eCTD) System.** The CFDA will establish an eCTD system for drugs and will start accepting and reviewing all drug applications through the eCTD system by the end of this year.

7. **Manufacturing Process Verifications.** The CFDA is developing further guidelines on verification of manufacturing processes for approved drugs to ensure all the drugs marketed in China are manufactured with CFDA-approved manufacturing processes.
The CFDA started in 2015 an unprecedented reform of its approval systems for drugs and medical devices, coupled with increased good clinical practice and good manufacturing practice enforcement in and outside China. It is encouraging to see the CFDA steering its reform toward areas such as patent linkage, data exclusivity and drug master files.

If you have any questions regarding this update, please contact the Sidley lawyer with whom you usually work, or

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