China Food and Drug Administration Simplifies Approval Procedures for Drugs and Medical Devices

The China Food and Drug Administration (CFDA) published two announcements on April 5 and 6, 2017, delegating some of its approval authority for drugs and medical devices to CFDA’s Center for Drug Evaluation (CDE) and Center for Medical Device Evaluation (CMDE).

Beginning May 1, 2017, the CDE and CMDE will approve the following on behalf of the CFDA:

1. Clinical trial applications for both imported and locally manufactured drugs;
2. Supplementary applications for approved drugs;
3. Re-registration of imported drugs;
4. Clinical trial applications for certain high risk Class III medical devices;
5. Changes of registration for locally manufactured Class III medical devices and imported medical devices; and
6. Renewal of registration of domestic Class III medical devices and imported medical devices.

The approval decisions on these matters must be made within 20 to 30 days after completion of the technical review of the relevant applications. These decisions made by the CDE or CMDE may be challenged through administrative review proceedings with the CFDA or administrative litigation in the local court.

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

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