China FDA Publishes Draft Measures to Accelerate Medical Device Approvals

The China Food and Drug Administration (previously known as the State Food and Drug Administration) (the "CFDA") has published drafts of two tentative measures, *Fast Track Approval Process of Innovative Medical Devices* and *Circular on Simplification of Dossier Required for Medical Device License Renewal and Amendment*, for public comments through March 31, 2013. Both measures reflect the CFDA's intention to expedite the approval process for certain medical device products.

- Pursuant to the draft of the *Fast Track Approval Process of Innovative Medical Devices*, the CFDA will establish a new office with dedicated reviewers in charge of review and approval of innovative medical devices. The applicant for the fast track approval must be a medical device manufacturing company licensed in China and the subject product must satisfy the following criteria: (i) the core technology related to the product must be registered in China as an invention patent that the manufacturer owns or is licensed to use; (ii) the product's working or functioning mechanism is first seen in China, its performance or safety improves significantly compared with similar products, and its technology is worldwide pioneering and has evident value in the clinical application; and (iii) the manufacturer has completed the early stage R&D and the product's basic design, the R&D activities are authentic and under control, and the R&D data is complete and traceable. The provincial Food and Drug Administrations (the "Provincial FDAs") will decide whether the application is eligible for the fast track approval process. Once the application is admitted to the fast track, the CFDA and the Provincial FDAs will give priority to such application in the entire approval process, including regulatory testing and technical review. In addition, the CFDA and the Provincial FDAs are required to appoint a liaison official to respond to and guide the applicant in a timely manner.

- The draft *Circular on Simplification of Dossier Required for Medical Device License Renewal and Amendment* requires fewer documents in the dossier in the event of no material change in the product's efficacy or safety profile and to the extent that the products are not in vitro diagnostics. Specifically, when a license holder applies for license renewal or amendment in the manufacturing address or the product's indication, model, specification, product standards, functional structure or components, the application dossier only needs to include those technical documents relevant to such change, but not the unchanged product registration standards, the testing report for registration or the product manual. Furthermore, the review process by the CFDA and the Provincial FDAs would not involve technical reviews if the submission is to reflect a change in the manufacturing address. Once approved, the license holder is permitted to modify the product manual accordingly and does not need to apply for approval of such modification.

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