China Solicits Comments on New Drug Technical Review Guidelines

The Center of Drug Evaluation ("CDE") of the China Food and Drug Administration ("CFDA") recently announced the *Draft Guidelines for Clinical Evaluation of NDA/BLA Applications* ("Draft Technical Review Guidelines") for public comments. The Draft Technical Review Guidelines are expected to lay the foundation of Good Review Practices and will standardize CDE's approach for new drug technical reviews.

With reference to the ICH guidelines and technical guidelines adopted by regulatory authorities in developed countries, the Draft Technical Review Guidelines are structured in accordance with the typical flow of new drug development and will serve as a basic framework for technical review opinions. More importantly, the Draft Technical Review Guidelines set a higher evaluation standard for source data in order to accurately and scientifically interpret data derived from different sites or different phases of clinical development programs.

NDA/BLA reviews should focus on quality, efficiency, standardization, clarity, consistency and transparency. The Draft Technical Review Guidelines are developed in line with these principles and cover the following main areas:

- Background of the application
- Compliance with medical ethics, Good Clinical Practices and other statutory requirements
- Source data
- Data related to CMC, clinical microbiology, and clinical pharmacy
- Evaluation of efficacy
- Evaluation of safety
- Post-market data
- Risk/benefit analysis
- Product label
- Conclusion of technical review and recommendation

The NDA/BLA applicants are encouraged to organize their regulatory submissions in alignment with the same structure as the Draft Technical Review Guidelines to allow better communication with the CDE reviewers and shorter timelines for marketing authorizations.

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