Chinese FDA Soliciting Public Comments on Rules for Re-Packaging of IVDs

The State Food and Drug Administration ("SFDA") in China published a draft of the Tentative Measures for the Administration of the Registration of Re-Packaging In-Vitro Devices (IVDs) ("Draft Measures") on November 2 for public comments through November 20. The Draft Measures define re-packaging of IVDs as the activities undertaken by a domestic medical device manufacturer to arrange exterior packaging of bulk IVDs produced in accordance with the regulatory specifications approved by SFDA into the smallest sales units; placing Directions-for-Use ("DFUs") or labels on the IVDs are not considered re-packaging under the Draft Measures. In addition, certain high-risk IVDs whose Quality Management Systems ("QMS") or GMP system is to be certified by SFDA are not eligible for re-packaging pursuant to the Draft Measures.

A domestic medical device manufacturer may apply for a re-packaging license for IVDs duly registered in China with the competent provincial FDAs or SFDA. The applicant must be a medical device manufacturer with a valid medical device manufacturing license covering the IVDs to be intended for re-packaging as well as a valid QMS/GMP certification. The applicant must also obtain an authorization from the manufacturer of bulk IVDs and enter into a quality assurance agreement with the same manufacturer specifying the quality metrics, testing and delivery acceptance requirements. The manufacturer of bulk IVDs shall conduct an on-site due diligence of the manufacturing facilities of the applicant and apply for a product registration or license amendment with the competent provincial FDAs or SFDA for the bulk specification of the IVDs in question.

The applicant for a re-packaging license must conduct necessary tests to evaluate the performance of the re-packaged IVDs, arrange such IVDs for a registration testing and complete the relevant QMS/GMP certification before submitting the application. The re-packaged IVDs shall comply with the registration standards of the bulk IVDs in principle, but the manufacturer of the re-packaged IVDs may revise the registration standards of the re-packaged IVDs to the extent necessary upon completion of the performance evaluation.

The product license of the re-packaged IVDs will include the name and address of the bulk IVD manufacturer, license number and effective date of the bulk IVD and its shelf life. Should there be any change in the product license of the bulk IVDs, the manufacturer of the bulk IVDs must inform the manufacturer of the re-packaged IVDs upon completion of license amendment or renewal to allow amendment or renewal of the re-packaging license. The manufacturer for re-packaged IVDs must cease re-packaging and submit the re-packaging license for revocation once the product license of the bulk IVDs is revoked, withdrawn, cancelled or expired.

The manufacturer for re-packaged IVDs will be held responsible for the quality of the re-packaged IVDs and is required to report adverse events of the re-packaged IVDs as well as arrange recalls of the re-packaged IVDs if needed. It is worth noting, however, that according to the Draft Measures, the product license of bulk IVDs may be revoked by the competent provincial FDAs or SFDA in light of quality problems of the re-packaged IVDs.

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