Decision on Adjusting the Relevant Matters Concerning the Registration and Administration of Imported Drugs

(Draft)

According to requirement of the Opinions of the State Council on Reforming the System for Review and Examination and Approval of Drugs and Medical Devices (No. 44 document of China State Council 2015), to encourage overseas listing of new drugs after approval at home and abroad to carry out clinical trials simultaneously, shorten the time to market at home and abroad to meet the public demand for new drugs, under the notice of China Food and Drug Administration executive meeting, the following adjustments of import drug registration matters were implemented:

1. Multi-regional clinical trials (MRCT) of imported drugs (excluding vaccines) can be conducted in China even though the drugs have not been registered overseas or have not entered into either Phase II or Phase III clinical trials.
2. The 'drug marketing registration' application can be submitted immediately upon completion of the MRCT in China. Also, the Measures for the Administration of Drug Registration and requirement of relevant documents are required to be applied.
3. New chemical drugs that are imported as well as new therapeutic biologics are no longer required to be registered abroad.
4. A 'qualified import drug registration' application supported by clinical data obtained through MRCTs can be approved without local clinical trials.

This decision will be put into force since _____.

If Drug Import Registration Requirements are inconsistent with this decision, they shall be implemented in accordance with this decision.

Food and Drug Administration

Date (dd/mm/yy)