SFDA Requirement for Generic Pharmaceutical Re-Evaluation

China has become the world’s largest market for generic pharmaceuticals. Generics account for more than 90% of China’s total pharmaceutical market.


The Generics Quality Plan seeks to canvass opinion as to how, and under what timetable, SFDA should implement one of the key policies outlined in the Drug Safety Plan, namely that:

any China–manufactured generic pharmaceutical product, registered in China before October 2007 (“Pre-07 Generic”), must be re-tested and re-evaluated (“Re-Evaluation”) for its registration to remain valid.
Further information

If you would like further information on any issue raised in this update please contact:
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The Generics Quality Plan calls for Re-Evaluation of all oral Pre-07 Generics by 2015, and all injectable Pre-07 Generics by 2020.

The Generics Quality Plan is open for public comment and submissions for two weeks – until 6 December 2012. The Generics Quality Plan will be finalized and adopted January 2013.