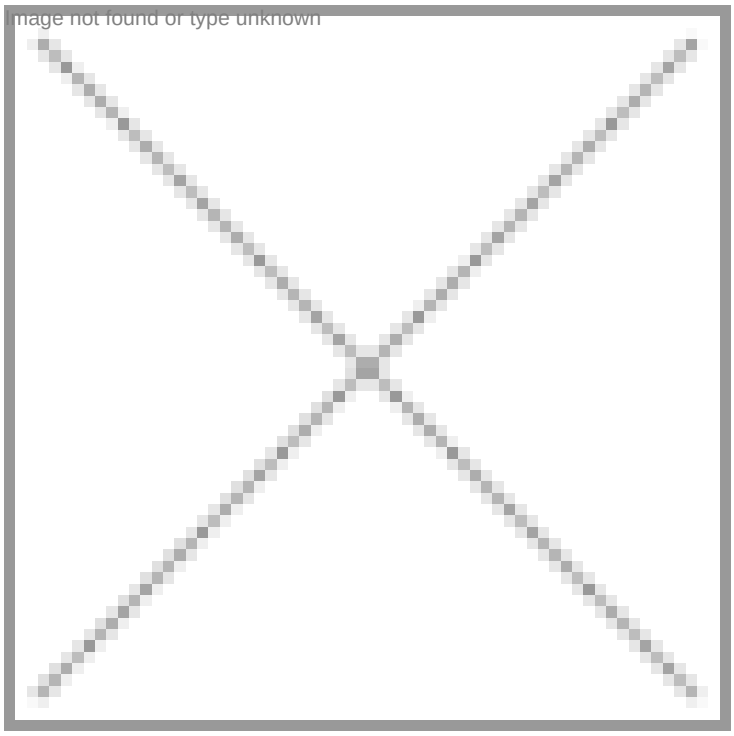
BioSpectrum the business of Bio & Health Sciences ASIA EDITION

QRxPharma to resubmit NDA to FDA for pain relieving drug

24 April 2014 | News | By BioSpectrum Bureau



Singapore: Australia's QRxPharma has received Complete Response Letter (CRL) from USFDA for its MOXDUO New Drug Application (NDA) for treatment of moderate to severe acute pain.

With the issue of the CRL, in order to maintain FDA review, the Company is required to resubmit its NDA. QRxPharma plans to complete its refiling in Q4 2013, inclusive of the additional information and analysis as requested by the FDA. QRxPharma anticipates a new PDUFA (Prescription Drug User Fee Act) date in Q2 2014, preceded by an Advisory Committee meeting.

"The importance of these documents and their impact on the approval process in terms of accuracy of data, clarity of clinical benefit and comprehensiveness of response, cannot be overstated," said Dr. John Holaday, Managing Director and Chief Executive Officer, QRxPharma. "In our market update of 26 June, we announced timing misalignments in our oxygen desaturation data as the reason for the Advisory Committee meeting delay. At that time, the duration of the delay was not clear. We now have clarity from the FDA as to next steps, and a six month clock will begin upon refiling the NDA."