

FDA accepts resubmission of Moxduo NDA by QRxPharma

15 March 2013 | News | By BioSpectrum Bureau



Singapore: The US Food and Drug Administration (FDA) has set August 26, 2013, as the date for action on QRxPharma's resubmitted Moxduo new drug application (NDA) under Prescription Drug User Fee Act.

"We are pleased that the FDA has formally accepted our resubmitted Moxduo NDA," said Dr John Holaday, managing director and chief executive officer, QRxPharma. "We expect the advisory committee meeting to be scheduled between late June and late July and will update shareholders once formal notification has been received," added Dr Holaday. QRxPharma is an Australian company.

The NDA is the basis for recommencing the regulatory approval process for Moxduo for the treatment of moderate to severe acute pain, a \$2.5 billion segment of the \$8 billion spent annually on prescription opioids in the US. Moxduo, an immediate release dual opioid pain therapy, is a patented 3:2 fixed ratio combination of morphine and oxycodone.