Press release, 15 December 2011

Meda announces PDUFA timeline for Dymista

FDA, the U.S. Food and Drug Administration, has informed Meda that the PDUFA (Prescription Drug User Fee Act) date for Dymista will be early May 2012.

FDA needs an additional three months to review earlier submitted data, related to CMC (Chemistry, Manufacturing and Controls). The extension of the timeline is in line with FDA's standard review regulations.

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