Working to improve your health

1 May 2023

US FDA sets PDUFA date for Maxigesic IV®

AFT Pharmaceuticals today announces the US Food and Drug Administration has set 17 October 2023 as the date by which it expects to respond to AFT's application to register Maxigesic IV in the US.

The FDA provided the Prescription Drug User Fee Act (PDUFA) date in a letter confirming it had received a complete response in relation to its questions on extractables and leachables from Maxigesic IV's primary packaging (the glass vial in which the medicine is stored and the vial's stopper). The FDA requested the additional data in July 2022.

Maxigesic IV, is a novel, unique combination of 1000mg paracetamol and 300mg ibuprofen solution for infusion, for the treatment of post-operative pain. It has been developed in collaboration with Hyloris and is currently licensed in more than 100 countries around the globe. It has also been registered in 43 countries and launched in 19 countries including Australia, France, Germany, and Korea. The medicine is protected by several granted patents and pending patent applications.

For and on behalf of AFT Pharmaceuticals Limited by Malcolm Tubby, Chief Financial Officer.

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About AFT Pharmaceuticals

AFT is a growing multinational pharmaceutical company that develops, markets, and distributes a broad portfolio of pharmaceutical products across a wide range of therapeutic categories which are distributed across all major pharmaceutical distribution channels: over the counter (OTC), prescription and hospital. Our product portfolio comprises both proprietary and in-licensed products, and includes patented, branded, and generic drugs. Our business model is to develop and in-license products for sale by our own dedicated sales teams in our home markets of Australia and New Zealand and in certain Southeast Asian markets, and to out-license our products to local licensees and distributors to the rest of the world. For more information: www.aftpharm.com