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Generic Approvals - Methotrexate Injection PF

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Methotrexate Injection PF - APP Pharmaceuticals

On February 22, APP Pharmaceuticals, Inc. of Schaumburg, Illinois announced that it received approval from the FDA to market preservative-free (PF) Methotrexate Injection.

Due to the nationwide shortage of preservative-free Methotrexate, APP worked collaboratively with the FDA to expedite approval of this critically needed oncology drug. Once APP received notification of the approval, the company immediately began the process of quickly scheduling its production so that APP can ship to customers within the next 4 to 6 weeks (from this announcement date).

APP also currently manufactures Methotrexate Injection with preservative. In 2011 in the U.S., there were approximately 1.8 million units sold of both formulations.

John Ducker, President & CEO of APP Pharmaceuticals, said: "APP is acutely aware of the pressure that oncologists are under when a critically needed cancer treatment is unavailable. By working collaboratively with the FDA, we have helped address several industry-wide shortages of critical generic sterile injectable chemotherapeutic agents. During the past year, a number of oncology drug suppliers have reduced output due to manufacturing issues causing significant disruption to availability. I am delighted that in many cases APP Pharmaceuticals has helped to minimize shortages by significantly increasing our production. This ability to respond rapidly is one of the key strengths of our U.S.-based manufacturing platform."