

Alter Pharma subsidiary, Milla Pharmaceuticals, gets FDA approval for a generic version of Sodium Acetate Injection 2MEQ/mL

This marks Alter Pharma's second product on the US market

Alter Pharma is pleased to announce that its American subsidiary, Milla Pharmaceuticals, was granted abbreviated new drug application (ANDA) approval from the U.S. Food and Drug Administration (FDA) for its generic version of Sodium Acetate Injection 2MEQ/mL.

This news is particularly heartening, given the fact that Sodium Acetate Injection is currently on the <u>FDA list of drugs in shortage</u> in the United States. Having competition on the market through a generic version will help more people get affordable access to the medicines they need. It also means that Alter Pharma, a company dedicated to making affordable medicines available to all, is further working toward its mission in North America in addition to Europe, something that the company is very proud of.

Alter Pharma is also very pleased that its generic version of Sodium Acetate Injection was granted FDA **ANDA** approval in **first-cycle review**, an important achievement and a strong acknowledgement of the development and regulatory capacities of the team. By establishing the first commercial sale through its exclusive partner, Woodward Pharma Services LLC, Alter Pharma also garnered the FDA's coveted 180-day **CGT Exclusivity**, during which potential competitors are prohibited from entering the market with competing products. This further expands Alter Pharma's reach into North America, which began with the approval and launch of

a generic version of injectable acetaminophen (paracetamol for intravenous use) in December of 2020. This particular medication was <u>launched by Sandoz</u>.

"Getting FDA approval for our Sodium Acetate Injection is something we are very proud of, particularly because it is currently in shortage in the United States. We hope that our generic version will help increase access to this medicine for those in need, as this is an essential part of our company's mission."

Filip Van de Vliet, CEO of Alter Pharma

To learn more about the Alter Pharma Group, its subsidiaries around the world, and its mission to make affordable medicines available to all, visit its <u>website</u> or follow along on <u>social media</u>.

For additional information, please contact:



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