

FOR IMMEDIATE RELEASE

Amneal Launches First Vagifem® Generic

Bridgewater, NJ (USA), October 18, 2016 – Amneal Pharmaceuticals LLC (“Amneal”) announced that its newest women’s health product, Yuvaferm® (estradiol vaginal inserts, USP) 10 mcg, began shipping on October 17th to distributors, wholesalers and directly to the trade.

This first-to-market generic equivalent for Vagifem® delivers the same low dose of vaginal estrogen as the brand in a preloaded, single-use, disposable applicator. The Amneal product is packaged in 8- and 18-count sizes to provide appropriate quantities for both new and maintenance prescriptions.

Prior to approving the Amneal ANDA for Yuvaferm®, FDA required a clinical endpoint study, which the company successfully completed. Amneal R&D efforts are dedicated to making these types of complex medicines more affordable and accessible to patients by bringing the generic equivalent to market.

“Patients and healthcare providers have been eager to see a generic for this unique dosage-form in order to benefit from the cost savings such multi-source products can deliver,” said Chirag Patel, Amneal co-CEO and chairman. “As a company, we are not only pleased to be able to offer a potentially more affordable option in this therapeutic category, but to add to our rapidly-growing portfolio of oral contraceptives and hormone replacement therapies in such a significant way.”

Annual U.S. sales of Vagifem® were \$423 million, according to July 2016 IMS market data.

[Click here for full prescribing information for Yuvaferm®.](#)

About Amneal

Amneal Pharmaceuticals LLC, a privately-held company headquartered in Bridgewater, New Jersey, is one of the largest and fastest growing generics pharmaceutical manufacturers in the United States. Founded in 2002, Amneal now has more than 4,000 employees in its operations in North America, Asia, Australia and Europe, working together to bring high quality affordable medicines to patients worldwide. Amneal has significantly expanded its portfolio of generic products to include complex dosage forms in a broad range of therapeutic areas. For more information, visit www.amneal.com.

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