



11960 Southwest 144th Street
Miami, Florida 33186
305-253-1916 ▼ Toll-Free: 888-253-5099
www.noven.com

PRESS RELEASE

NOVEN ANNOUNCES SUCCESSFUL RESOLUTION OF FDA WARNING LETTER

Miami, FL and Jersey City, NJ, April 25, 2018 -- Noven Pharmaceuticals, Inc. announced today that it has received a close-out letter from the U.S. Food and Drug Administration (FDA) lifting a 2016 Warning Letter related to its Miami, Florida manufacturing facility. The FDA notice follows a reinspection earlier this year by the FDA of Noven's Miami facility.

The lifting of the Warning Letter is the result of a comprehensive remediation program that not only addressed the issues raised by FDA in the 2016 Warning Letter, but included the assessment and remediation of all aspects of Noven's quality systems to ensure alignment with current Good Manufacturing Practices.

"For more than two years now, we have been focused on creating a robust and sustainable quality program based on a culture of quality, accountability across the entire organization and the continuous improvement of our people, processes and products," said Jeff Mihm, Noven Chief Executive Officer. "I would like to thank the many Noven colleagues who have worked diligently to achieve this important milestone."

"Noven's enhanced quality program provides a strong foundation for our plans to bring new transdermal products to patients in the United States and abroad," Mr. Mihm added. A leading developer of transdermal prescription products, Noven currently manufactures and sells three transdermal products in the United States, and together with its Japanese parent company, Hisamitsu Pharmaceutical Co., Inc., has several new transdermal products in mid-to late-stage development.

About Noven

Noven Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of prescription pharmaceutical products. Noven's mission is to develop and offer pharmaceutical products that meaningfully benefit patients around the world, with a commitment to advancing patient care through transdermal drug delivery. Noven is a stand-alone operating subsidiary of Japan-based Hisamitsu Pharmaceutical Co., Inc., serving as Hisamitsu's U.S. platform in prescription pharmaceuticals, and helping Hisamitsu bring the benefits of patch therapy to the world. For more information about Noven, visit www.noven.com. For information about Hisamitsu, visit <http://global.hisamitsu/>.

Contact:

Stephanie Lamenta
Noven Pharmaceuticals, Inc.
305-253-1916