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FOR IMMEDIATE RELEASE

LYOPHILIZATION SERVICES OF NEW ENGLAND RECEIVES  
APPROVAL TO MANUFACTURE COMMERCIAL ASEPTIC PRODUCT

**Bedford, NH** – Lyophilization Services of New England, Inc. (LSNE) announced today that following an FDA Pre-Approval Inspection (PAI) in November 2014, their Harvey Road manufacturing site has received approval to manufacture commercial drug product for US distribution. The PAI resulted in no Form 483 being issued, as there were no observations noted by the FDA. This facility is located in Bedford, NH and is dedicated to the aseptic filling and lyophilization of a product that is currently on the market.

Shawn Cain, Chief Operating Officer of LSNE stated, “We are very pleased with the positive results of the latest FDA inspection, which is another important milestone and further adds to our successful regulatory history. This approval is the culmination of years’ worth of preparation and diligence and this success helps position us for our future growth. Specifically, we are looking to expand our analytical capabilities to better support all of our client’s needs.”

LSNE has added additional capabilities across their three sites in 2014 and they plan to continue expanding in 2015. The 2015 master plan includes expansion of QC analytical testing capabilities, ICH stability chambers, additional complex/potent compound handling capabilities, as well as increased manufacturing capacity. LSNE continues its path towards becoming the premier turn-key CMO for its clinical and commercial clients and its commitment to reduce the time and cost of bringing clients projects from bench to market.

**About LSNE Contract Manufacturing**

LSNE Contract Manufacturing is a privately held company with three GMP facilities located in New England. LSNE has been providing contract lyophilization services to the pharmaceutical, biotechnology and medical device industries since 1997, specializing in a wide range of services including cycle development, cGMP fill/finish, and lyophilization. Through the thoughtful integration of three processing facilities, qualified staffing, and an extensive manufacturing history, LSNE is strategically positioned to provide uninterrupted manufacturing for clinical through commercial supply for medical device and pharmaceuticals to a multi-national market.

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