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FOR IMMEDIATE RELEASE

LSNE Generates a Site Master File (EU) and Drug Master File (FDA) for the
25 Commerce Drive Manufacturing Facility, Bedford, NH

In order to serve our clients more completely, Lyophilization Services of New England is expanding its capabilities by providing regulatory support of Marketing Authorization Applications and New Drug Applications for drug submissions in the European Union and in the United States in the following manner.

Site Master File sent to MHRA in the United Kingdom

LSNE has created and sent to the European Union (EU) Medicines and Healthcare products Regulatory Agency (MHRA) a Site Master File (SMF) for the 25 Commerce Drive facility. Before a regulatory Competent Authority (CA) conducts an inspection of the facilities and controls, they will request the drug manufacturer's current Site Master File. This SMF is an overview of the company assembled by the drug manufacturer that describes current Good Manufacturing Practices and controls for the manufacturing facility. The Competent Authority reviews the SMF, references and appendices for completeness. LSNE has submitted the Site Master File to the MHRA, has successfully completed an MHRA GMP Inspection and has been granted a Certificate of GMP Compliance of a Manufacturer of Lyophilisates (freeze dried drug products) and of SVP and LVP (small volume and large volume parenteral) liquid products for human use in EU member states.

Drug Master File submitted to U.S. FDA

LSNE has been working with the FDA Drug Master File (DMF) Staff in order to format and submit a Type V DMF in support of Client drug application submissions (INDs, NDAs, ANDAs, PASs, etc.) for the 25 Commerce Drive facility. A Type V DMF is used to document FDA Accepted Reference Information. As described by the FDA, a Drug Master File (DMF) is a submission to the Food and Drug Administration (FDA) that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. The submission of a DMF is not required by law or FDA regulation. A DMF is submitted solely at the discretion of the holder (in this instance LSNE). The information contained in the DMF may be used to support an Investigational New Drug Application (IND), a New Drug Application (NDA), an Abbreviated

New Drug Application (ANDA), another DMF, an Export Application, or amendments and supplements (alternate site PAS) to any of these.

LSNE, the DMF holder submits in duplicate to the DMF on file, a letter of authorization (LOA) permitting the FDA to reference the DMF in relation to a Client application. A copy of the LOA is then sent to affected drug applicant / sponsor who is then authorized to incorporate, by reference, the information contained in the DMF. The applicant is also required to include a copy of the LOA in their application.

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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