

### Healthcare Sector Imaging & Therapy Systems Division

#### **PETNET Solutions Receives FDA Approval for Fludeoxyglucose F 18 Injection, USP**

Siemens demonstrates industry leadership well in advance of regulatory requirements.

**Knoxville, Tenn., March 9, 2011 – PETNET Solutions, Inc. a wholly-owned subsidiary of Siemens Medical Solutions USA, Inc. announced today the approval of an Abbreviated New Drug Application (ANDA) for Fludeoxyglucose F 18 Injection, USP ( $[^{18}\text{F}]\text{FDG}$ ). PETNET Solutions' submission of an ANDA, well in advance of regulatory requirements for the positron emission tomography (PET) radiopharmaceutical industry, reinforces its industry leadership in manufacturing and distribution of  $[^{18}\text{F}]\text{FDG}$ . Siemens PETNET Solutions is the first commercial manufacturer and distributor to achieve approval of an ANDA for  $[^{18}\text{F}]\text{FDG}$ .**

“PETNET Solutions continues to set the standard in manufacturing and delivery of molecular imaging biomarkers,” said Ian Turner, CEO, Siemens PETNET Solutions. “U.S. Food and Drug Administration (FDA) approval ensures our customers that they are receiving product that meets all regulatory and pharmacopeial requirements for safety, quality and purity for  $[^{18}\text{F}]\text{FDG}$ . This achievement is unique in the commercial PET radiopharmaceutical marketplace for  $[^{18}\text{F}]\text{FDG}$ . We are committed to the highest level of quality manufacturing throughout our global network of production facilities. With the FDA approval of our ANDA for  $[^{18}\text{F}]\text{FDG}$ , we continue to demonstrate an enduring commitment to leadership in the U.S. market for PET radiopharmaceuticals.”

This milestone comes in parallel with PETNET Solutions' significant investments to increase its radiopharmaceutical manufacturing and distribution capabilities worldwide, and lays the foundation for quality manufacturing of new molecular imaging biomarkers as they are commercialized. PETNET Solutions operates the largest network of PET radiopharmaceutical production facilities with 54 production and distribution centers worldwide.

$[^{18}\text{F}]\text{FDG}$  is used in oncology for the assessment of abnormal glucose metabolism to assist in the evaluation of known or suspected abnormalities; in cardiology, when used together with myocardial perfusion imaging to assist in identification of left ventricular myocardium with residual glucose

metabolism and reversible loss of systolic function in patients with coronary artery disease and left ventricular dysfunction; and in neurology, for the identification of regions of abnormal glucose metabolism associated with epileptic seizure foci.

Because radiation-emitting products including [<sup>18</sup>F]FDG may increase the risk for cancer, especially in pediatric patients, the smallest dose necessary for imaging should be used. In the oncology and neurology settings, suboptimal imaging may occur in patients with inadequately regulated blood glucose levels; medical therapy and lab testing may be used to assure at least two days of normal levels prior to [<sup>18</sup>F]FDG administration. Hypersensitivity reactions with pruritus (itching), edema and rash have been reported, therefore emergency resuscitation equipment and personnel should be available.

The full prescribing information for [<sup>18</sup>F]FDG at [http://www.petnetsolutions.com//files/FDG\\_Prescribing\\_Information.pdf](http://www.petnetsolutions.com//files/FDG_Prescribing_Information.pdf)

The **Siemens Healthcare Sector** is one of the world's largest suppliers to the healthcare industry and a trendsetter in medical imaging, laboratory diagnostics, medical information technology and hearing aids. Siemens offers its customers products and solutions for the entire range of patient care from a single source – from prevention and early detection to diagnosis, and on to treatment and aftercare. By optimizing clinical workflows for the most common diseases, Siemens also makes healthcare faster, better and more cost-effective. Siemens Healthcare employs some 48,000 employees worldwide and operates around the world. In fiscal year 2010 (to September 30), the Sector posted revenue of 12.4 billion euros and profit of around 750 million euros. For further information please visit: [www.siemens.com/healthcare](http://www.siemens.com/healthcare).

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