

DEPARTMENT OF VETERANS AFFAIRS**Justification and Approval****For****Other Than Full and Open Competition**


- 1. Contracting Organization:** Department of Veterans Affairs, VISN 8, VACHS Medical Center
- 2. Description of Action:** Radioactive FDG-18 Radiopharmaceuticals doses to perform Nuclear Medicine PET Studies on a daily basis in our Service.
- 3. Description of Supplies or Services:** PET (positron emission tomography) imaging is a powerful diagnostic tool that, in many cases, renders answers that no other imaging test can provide. Metabolic changes caused by certain diseases are detected by the PET scanner after an IV injection of a trace amount of FDG-18, a radioactive, sugar like substance to perform such studies. This specific radiopharmaceutical cannot be stored since the dose does not have an extensive life duration (a half life of 90 Minutes) and they have to be delivered at the time which the medication is required, to be use as soon as it arrives or otherwise, it cannot be used. Nevertheless, radiopharmaceuticals are needed immediately for patient studies.
- 4. Statutory Authority:**
(x) (1) In Puerto Rico only one responsible source satisfy the supplies or services required of delivery time, amount dose and frequency by Nuclear Medicine Service.
Validity of Use of Statutory Authority: Lantheus Radiopharmaceutical is the only source that complies with service requirements and supplies of radioactive FDG-18 doses in the Caribbean within service necessities as the time frame that it is required to perform patient's studies. This specific radiopharmaceutical cannot be stored or use after the calibration time.
- 5. Actions to Promote Competition:** N/A
- 6. Determination of Fair and Reasonable Price:** The anticipated price to the Government is \$22,740.00. Prices seem fair market value due to the fact that price offered was compared to Lantheus Pharmaceuticals price list and is accurate. Moreover, the price of \$379.00 per unit has been paid before on previous procurements.
- 7. Market Survey (FAR 10):** N/A

8. Other Considerations: It is cost-effective to use Lantheus Radiopharmaceutical due to the fact that the transportation and delivery of radioactive material is very expensive and Lantheus has items in Puerto Rico and there are no delivery charges. Company has a well earned reputation delivering items on a timely manner which is crucial for this type of medication which has a life duration of 90 minutes.

9. Listing of Sources that expressed, in writing, an interest in the acquisition: N/A

10. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required: N/A

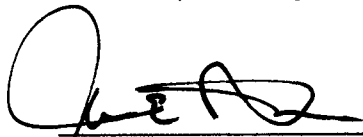
11. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.


Name Roberto P. Bordewyk, MD
Title Acting Chief of Nuclear Medicine
Facility VACHS

9/16/2011
Date

12. Approvals in accordance with FAR 6.304

- a. **Contracting Officer's Certification:** (required) I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


Name
Contracting Officer
Facility

10/3/11
Date

- b. **Product Line Supervisor (PLS):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.


Name Daniel Perez
Contracting Supervisor
Facility

10/3/11
Date

- c. **DNCM/NCM:** (SAT to \$500,000) I certify the justification meets requirements for other than full and open competition.

Mitchell Thomas
Network Contract Manager
VISN 8

Date