

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval**

**For**

**Other Than Full and Open Competition**

**Acquisition Plan Action ID:** VA268-16-AP-0038

**1. Contracting Activity:**

Veterans Health Administration (VHA)  
Program Contracting Office (PCO) – East  
323 North Shore Drive, Suite 500  
Pittsburgh, PA 15212

**Requiring Activity:**

VA Portland Medical Center  
3710 SW US Veterans Hospital Rd  
Portland, OR 97239

2237 Number: 648-16-2-169-0961

**2. Nature and/or Description of the Action Being Processed:**

This is a new contract request for Other than Full and Open Competition for a Firm Fixed Price contract with Organix, Inc. in accordance with FAR 6.302-1. This requirement is for a base year and three (3) option periods of one year each. This contract request is a follow on to previous contract VA648-D-11521.

**3. Description of Supplies/Services Required to Meet the Agency's Needs:**

This contract involves the synthesis and delivery of new drugs. At least 25 drugs will be synthesized and their molecular structures verified by the Contractor. The Principal Investigator at the VA Portland Medical Center will test the drugs for their ability to effect the Trace Amine Associated Receptor 1 (TAAR1). These drugs will be used both in vivo and in vitro, specifically for their ability to alter methamphetamine-induced effects.

(Redacted)

The schedule for development is as follows:

- **Base Period:** Prepare five standards in sufficient quantity for in vivo and in vitro studies. Begin synthesis of (redacted) compounds.

- **Option Period 1:** Continue synthesis of compounds related to (redacted). Develop methods of enantio- and diastereo-resolutions, if needed. Begin synthesis of compounds related to (redacted).
- **Option Period 2:** Continue synthesis of compounds related to (redacted). Develop effective synthetic methods for scale up of promising compounds for in vivo studies. Begin synthesis of compounds of (redacted).
- **Option Period 3:** Continue synthesis of compounds of (redacted). Continue scale-up of promising compounds.

**Estimated Period of Performance:**

Base Year:	06/01/2016 – 05/31/2017
Option Year I:	06/01/2017 – 05/31/2018
Option Year II:	06/01/2018 – 05/31/2019
Option Year III:	06/01/2019 – 05/31/2020

**4. Statutory Authority Permitting Other than Full and Open Competition:**

41 USC §3304(a)(1), as implemented by FAR 6.302-1.

**(X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;**

- ( ) (2) Unusual and Compelling Urgency per FAR 6.302-2;
- ( ) (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- ( ) (4) International Agreement per FAR 6.302-4;
- ( ) (5) Authorized or Required by Statute FAR 6.302-5;
- ( ) (6) National Security per FAR 6.302-6;
- ( ) (7) Public Interest per FAR 6.302-7.

**5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

This contract will be a follow-on to previously awarded contract VA648-D-11521, a sole source award to Organix Inc. The drug synthesis services requested involve proprietary data that only Organix Inc. can process, and a licensing agreement has already been established.

**6. A description of efforts to ensure that offers were solicited from as many potential sources as is practicable:**

In conducting market research, the CO posted an intent to sole source to FBO. One response was received from a different vendor. The capability statement was reviewed by the end user, and determined to be insufficient, and the vendor is also unable to satisfy the requirement due to the proprietary nature of the research, and the licensing agreement that has been established with Organix, Inc.

**7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**

(Redacted)

**8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

Based on the other vendor's response to the FBO sources sought notices, the capability statement was reviewed by the end user, and determined to be insufficient. That vendor is also unable to satisfy the requirement due to the proprietary nature of the research, and the licensing agreement that has already been established with Organix, Inc.

Organix Inc., is active in SAM with no exclusions. FPDS was searched for these services, and the previous Portland VAMC sole source contract VA648-D-11521 with Organix, Inc. was found. The FPDS printout showing contract and price history is included in the contract file.

**9. Any Other Facts Supporting the Use of Other than Full and Open Competition:**

There are no additional facts supporting the use of Other than Full and Open Competition.

**10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

Organix, Inc. and (redacted) expressed interest in this acquisition.

**11. 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:**

Given the proprietary nature of this requirement and the collaborative research being conducted, services must continue to be met through a sole source contract to Organix, Inc. in accordance with FAR 6.302-1.

**12. 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.

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**13. 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.

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- b. **Director of Contracting /Designee (Required over \$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

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