FedBizOpps

**Sources Sought Notice**

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**CLASSIFICATION CODE**

**SUBJECT**

**CONTRACTING OFFICE'S**

**ZIP-CODE**

**SOLICITATION NUMBER**

**RESPONSE DATE (MM-DD-YYYY)**

**ARCHIVE**

**DAYS AFTER THE RESPONSE DATE**

**RECOVERY ACT FUNDS**

**SET-ASIDE**

**NAICS CODE**

**CONTRACTING OFFICE**

**ADDRESS**

**POINT OF CONTACT**

(POC Information Automatically Filled from

User Profile Unless Entered)

**DESCRIPTION**

**See Attachment**

**AGENCY'S URL**

**URL DESCRIPTION**

**AGENCY CONTACT'S EMAIL**

**ADDRESS**

**EMAIL DESCRIPTION**

**ADDRESS**

**POSTAL CODE**

**COUNTRY**

**ADDITIONAL INFORMATION**

**GENERAL INFORMATION**

**PLACE OF PERFORMANCE**

**\* = Required Field**

FedBizOpps Sources Sought Notice

Rev. March 2010

68

VA258-17-N-0483

 AVICEL PH302

Pharmaceutical Chemical

Name Brand Only

85014

VA258-17-N-0483

05-26-2017

1

N

325412

Department of Veterans Affairs

VISN/18PHX

777 E. Missouri, Suite 300

Phoenix AZ 85014

VA Cooperative Studies

2401 Centre Avenue SE

Albuquerque NM 87106

87106

USA

theresa.hamilton@va.gov

**Sources Sought Notes**

This is a SOURCES SOUGHT ANNOUNCEMENT ONLY. It is neither a solicitation announcement nor a request for proposals or quotes and does not obligate the Government to award a contract. Requests for a solicitation will not receive a response. Responses to this sources sought must be in writing. The purpose of this sources sought announcement is for market research to make appropriate acquisition decisions and to gain knowledge of potential qualified Service Disabled Veteran Owned Small Businesses and Veteran Owned Small Businesses interested and capable of providing the services described below. Documentation of technical expertise must be presented in sufficient detail for the Government to determine that your company possesses the necessary functional area expertise and experience to compete for this acquisition. Responses to this notice shall include the following: (a) company name (b) address (c) point of contact (d) phone, fax, and email (e) DUNS number (f) Cage Code (g) Tax ID Number (h) Type of small business, e.g. Services Disabled Veteran Owned small Business, Veteran-owned small business and (i) must provide a capability statement that addresses the organizations qualifications and ability to perform as a contractor for the work described below.

Important information: The Government is not obligated to nor will it pay for or reimburse any costs associated with responding to this sources sought synopsis request. This notice shall not be construed as a commitment by the Government to issue a solicitation or ultimately award a contract, nor does it restrict the Government to a particular acquisition approach. The Government will in no way be bound to this information if any solicitation is issued. The VA is mandated by Public Law 109-461 to consider a total set-aside for Service Disabled Veteran Owned Small Business set aside. However, if response by Service Disabled Veteran Owned Small Business firms proves inadequate, an alternate set-aside or full and open competition may be determined. No sub-contracting opportunity is anticipated. The North American Classification System (NAICS) code for this acquisition is 325998 (500 employees).

Notice to potential offerors: All offerors who provide goods or services to the United States Federal Government must be registered in the System for Award Management (SAM) at www.sam.gov and complete Online Representations and Certifications Application (ORCA). Additionally, all Service Disabled Veteran Owned Businesses or Veteran Owned Businesses who respond to a solicitation on this project must be registered with the Department of Veterans Affairs Center for Veterans Enterprise VetBiz Registry located at http://vip.vetbiz.gov. All interested Offerors should submit information by e-mail to. All information submissions shall be received no later than 5:00 pm Eastern Time on May 26, 2017. After review of the responses to this announcement, the Government intends to proceed with the acquisition and a subsequent solicitation may be published.

Date of Response: May 26, 2017

Time of Response: no later than 5:00 pm Eastern Time

Responses shall be sent by electronic mail to POC: at Theresa.hamilton@va.gov

# STATEMENT OF WORK (SOW)

# Avicel PH-302, NF

1. **SCHEDULE OF SERVICES AND/OR SUPPLIES.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Line Item #** | **Item/Stock#** | **Description** | **Est. Qty.** | **Unit** |
| 1 | PH302-NFDR050I | Avicel PH 302, NF, 50 kg per drum  | 5 | DR |
| 2 |  | Estimated S&H | 1 | EA |

1. **BACKGROUND.**

The VA Cooperative Studies Program Clinical Research Pharmacy Coordinating Center (CSPCRPCC) needs to purchase Avicel PH-302, NF, a proprietary high grade, high density, pharmaceutical grade microcrystalline cellulose, for the manufacture of tablets and capsules used for *RESEARCH PURPOSES* in veteran patient clinical trials:

* CSP590 - Double Blind Placebo Controlled Study of Lithium For Preventing Repeated Suicidal Self-Directed Violence in Patients with Depression or Bipolar Disorder, and
* CSP594 - Comparative Effectiveness in Gout: Allopurinol versus Febuxostat.
1. **SCOPE.**

Avicel PH-302 is proprietary microcrystalline cellulose, NF that is only manufactured by FMC Inc. This is a Brand Name Only request. Must be manufactured by FMC to maintain the consistency needed for the in progress research studies. It is the primary ingredient used to manufacture placebo tablets for CSP590 and CSP594. It is the primary excipient used in CSP594 allopurinol capsules. Both clinical trials are ONGOING.

We must use the same ingredients in the Products used in the Research Clinical Trials CSP594 and CSP590 each time we manufacture them. We previously manufactured Products which are currently being used in these clinical trials.

1. **TASK**
	1. **Task 1 – Provide 250 kilograms of Avicel PH-302, NF and a Certificate of Analysis for the product. The Avicel PH-302 must meet the following:**

|  |  |  |
| --- | --- | --- |
| Nominal Particle Size | Moisture | Loose Bulk Density |
| 100 µm | 3.0 to 5.0% | 0.35 – 0.46 g/cc |

**It must exhibit the following characteristics:**

* High density
* Maximize/high flow for capsule powder filling and direct compression
* Low lubrication required
* Excellent compression and compactability
* Strong binder
* Rapidly disintegrating for immediate release
* Anti-adherent
* Low tablet friability
* High dilution potential (allows for higher drug levels)
1. **SECURITY REQUIREMENTS**

**The C&A requirements do not apply. A Security Accreditation Package is not required.**

1. **OTHER PERTINENT INFORMATION OR SPECIAL CONSIDERATIONS.**
2. Identification of Possible Follow-on Work.

We expect to make additional purchases over the life of each study. Because the tablet and capsule requirements for a Research Clinical Trial change constantly, we cannot predict when we will need to buy additional Avicel PH-302. While we could use an IDIQ, it is difficult to predict the variations in the amount of material we will need each year.

The material has an expiration date. We prefer to not order excessively large quantities of the material at one time because it could expire before it can be used, wasting VA and taxpayer dollars.

1. Identification of Potential Conflicts of Interest (COI).

The CSPCRPCC is not aware of any conflicts of interest between its employees and the vendor.

1. **RISK CONTROL.**

Material will be inventoried and inspected upon delivery

1. **PERIOD OF PERFORMACE.**
2. Items shall be delivered 30 days ARO.
3. **DELIVERY:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Deliverable Title** | **Format** | **Number** | **Calendar Days After CO Start** |
| Receipt of 250 kilograms of Avicel PH-302, NF and Certificate of Analysis. | Packaged product | Five 50 kilogram drums of Avicel PH-302, microcrystalline cellulose, NF | Determined by availability. Typically 3 weeks from order placement |

1. Items will be delivered to VA Cooperative Studies Program Clinical Research Pharmacy Coordinating Center (CSPCRPCC) at the following address:

CSPCRPCC

2401 Centre Avenue, SE

Albuquerque, NM 87106-4180

1. Delivery will be made NLT (no later than) 30 days after award of contract but earlier is preferred.
2. VA shall not pay for freight charges exceeding $250.00, Per VAAR 847.303-1 F.O.B. origin.
3. A copy of a packing slip will be furnished at the time the order is delivered.
4. **ACRONYMS.**
5. **Avicel PH-302, NF –** high density microcrystalline cellulose, NF used in the manufacture of tablets and capsules.
6. ARO- After Receipt of Order
7. **CO** – Contracting Officer. The Federal employee who is warranted by the Government to enter into contracts on behalf of the Government and is the only person authorized to make changes to those contracts.
8. **COR** – Contracting Officer’s Representative. Individual designated by the CO to place orders, furnish technical guidance, advice, certify invoices, and provide general supervision of the work performed under the executed contract.
9. **CSPCRPCC** – Cooperative Studies Program Clinical Research Pharmacy Coordinating Center.
10. **FDA** – Food and Drug Administration
11. **NF** – National Formulary – a book of standards/specifications for pharmaceuticals and raw materials used in pharmaceuticals that are not included in the USP.
12. **Excipient –** a pharmacologically inert substance, used as an ingredient of a tablet or capsule.
13. **NMVAHCS** – New Mexico Veterans Affairs Healthcare System
14. **VAMC** – Department of Veterans Affairs Medical Center
15. **CSP590** - Double Blind Placebo Controlled Study of Lithium For Preventing Repeated Suicidal Self-Directed Violence in Patients with Depression or Bipolar Disorder, and
16. **CSP594** - Comparative Effectiveness in Gout: Allopurinol versus Febuxostat