SOURCES SOUGHT NOTICE

Notice Number: HHS-NIH-NCI-SBSS-TSB-37003-94

Title: "Registration, Storage and Distribution of Chemicals and Drugs for Pre-Clinical Discovery Evaluation and Development."

This is a Sources Sought notice. This is **NOT** a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding: (1) the availability and capability of all qualified small business sources; (2) whether they are small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged business; and (3) their size classification relative to the North American Industry Classification System (NAICS) code for the proposed acquisition. Your responses to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible. An organization that is not considered a small business under the proposed NAICS code should not submit a response to this notice.

This National Cancer Institute (NCI), National Institutes of Health (NIH) project is for the renewal of contract HHSN261200800005C with Fisher BioServices, Inc (Fisher) that was awarded on a competitive basis for a five year period. Freedom of Information Act (FOIA) requests regarding the current contract with Fisher Incorporated should be directed to Suzy Milliard at milliars@mail.nih.gov. This Small Business Sources Sought Notice (SBSS) is for information and planning purposes only and shall not be construed as a solicitation or as an obligation on the part of the National Cancer Institute (NCI).

A determination by the Government not to compete this requirement as a set-aside based upon responses to this Notice is solely within the discretion of the Government.

Interested parties are expected to review this Notice and the draft ***Statement of Work*** to familiarize themselves with the requirements of this project; failure to do so will be at your firm's own risk.

Background

The Drug Synthesis and Chemistry Branch (DSCB) of the Developmental Therapeutics Program (DTP) of the Division of Cancer Treatment and Diagnosis (DCTD) of the National Cancer Institute (NCI) is seeking support services to operate and maintain the National Cancer Institute's Chemotherapeutic Agents Repository (NCI-CAR). The principal goal of this contract is to support the DTP anticancer pre-clinical drug evaluation program which seeks to identify new small molecule therapeutic agents. The primary tasks of the contract are the receipt, registration, storage, analysis, arraying and distribution of small molecules and purified natural products that will be evaluated in DTP anti-cancer screens, and also distributed to extramural researchers. In addition, a small number of

compounds from other NIH (e.g. NIAID, CBC) programs may be handled through this contract.

This contract is also responsible for providing an informational interface with NCI and external investigators that are submitting or requesting research compounds; for updating of the chemical database which includes chemical, inventory, receiving and shipping information; systematic file and record keeping of both current and archival information related to Repository activities; and reacquisition of samples for continued chemical and biological studies.

The program is highly flexible and the Contractor shall have the flexibility to respond to changing Program priorities.

Purpose and Objectives:

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work below.

Project Requirements:

Specific Tasks

1. Acquisition/Documentation

   a. Execute registration policies and procedures developed by DTP for the submission of structures, associated chemical data and compound samples using the DTP website: http://dtp.nci.nih.gov/. These procedures may be revised and updated over time. This includes the assignment of NSC registration numbers to chemical structures and other entities (e.g. biologics, creams, investigational, ethical and OTC drug products) using policies and procedures developed by DSCB.

   b. Maintain and execute procedures for the non web-based manual submission and registration of structures, associated chemical data and the compounds.

   c. Act as primary point-of-contact between DSCB and compound submitters.

   d. Assist investigators on structure and sample submission, and website registration procedures.

   e. Input chemical structures and chemical data into the NCI chemical database. The majority of structures are submitted by investigators requesting anti-cancer testing.

   f. Check the chemical accuracy of structures and chemical data entered into the database.

   g. Maintain permanent files of all supplier correspondence related to submission of structures, chemical data and physical compound samples. This includes a file of legal confidentiality agreements between NCI and investigators.

h. Reacquire compounds from submitters as requested by the COR. Generally, this material will be used for additional in vitro/in vivo evaluation.

i. Acquire, through purchase order process, additional quantities of commercial compounds as requested by the COR.

j. Distribute copies of requested documentation to NCI staff and external investigators as directed by the COR. These may be as hard copies or in electronic form.

k. Maintain relevant, accurate, and current records such as identity, inventory and shipping history, for all registered compounds.

2. Receipt and Storage

a. Store chemicals, purified natural products and bulk compounds. This includes approximately 500,000-600,000 individual samples in current long-term storage. The majority of compounds are in amounts ranging from 5 mg to 20 g, with a few samples of bulk drug up to 50 kg.

b. Receive weekday chemical sample shipments and related documentation and, safely store until registered and moved to permanent storage or shipped to researchers.

c. Store chemicals, drugs and plated sets under their recommended storage conditions. This includes capabilities for temperature storage at controlled ambient, 0-5 deg C., -15 to -20 deg C., and -70- to -80 deg C; under nitrogen or argon atmosphere; protected from light; under controlled humidity conditions.

d. Provide sufficient monitoring of storage conditions to guarantee continuous proper storage including, for a limited number of bulk API samples, adequate monitoring and documentation to meet cGMP guidelines.

e. Notify COR immediately when physical changes in chemical samples are noticed.

f. Provide safe storage and security measures to conform to all pertinent drug/chemical regulations. This includes an adequate waterless fire suppression system to protect staff, the chemical inventory and storage infrastructure.

g. Prepare Material Safety Data Sheets for specific compounds as directed by COR.

h. Maintain the current computerized inventory of compounds of interest and bulk drugs in the repository. In addition, infrequently requested drugs shall be inventoried for accuracy at the time an order request is filled.

i. Provide for the safe and proper disposal of items to be eliminated from the inventory stock as the result of decomposition or for other reason at the request of the COR. No samples should be disposed without authorization of the COR.

j. Receive returned chemicals and drugs and return to inventory or dispose.

k. All work shall be performed utilizing good laboratory techniques in accordance with accepted industry standards.

3. Shipping and Distribution

a. Weigh, package and ship chemicals and drugs as approved by the COR to NCI screening laboratories and external research investigators. These may be located domestically or internationally (e.g. Europe, Asia, and Australia).

b. Provide special handling and packaging for heat and/or light sensitive and labile chemicals and drugs. The shipments shall conform to all laws and regulations, both domestic and international, governing the shipping of hazardous substances and other regulated substances.

c. Furnish shipping cartons, cushioning materials, labels, containers, insulating material, dry ice and any other supplies to insure the safe, intact arrival of the contents of each package shipped.

d. Update inventory transactions, document the shipment of compounds, and associated data to the NCI chemical database.

e. Provide for regular (3-4/week) overnight shipments of samples to the NCI testing and screening laboratories in Frederick, MD. Include provisions for 1-day turnaround for a limited number of expedited shipments.

4. Plating Operations

a. Array selected compounds in 96-well plates. Plates will generally be generated using DMSO solvent. Employ appropriate methods to preclude absorption of water both while generating and storing plates (e.g. inert atmosphere conditions). Maintain government provided plating apparatus in good working condition.

b. Create mother plates and replicate copies (up to 50) of plated compound sets for distribution to investigators as needed. These sets include a Diversity Set of ~1600 samples representative of the total structural database, a Mechanistic Diversity Set of ~880 compounds, and an Approved Oncology Drug Set of ~97 compounds. The generation of additional diverse and focused plated sets may be requested by the COR as determined by Program needs.

c. Store plated sets (-20 to -25 deg C.) until distribution is requested.

d. Receive, document and store, prior to distribution, plated libraries from outside investigators and institutions.

e. Appropriately package and ship DMSO plated compounds to investigators. Packaging and shipping methods should be selected to maintain integrity of plates and their contents. In general, this requires insulated shipping containers containing dry-ice or cool packs.

f. Maintain the capability to ship packages to all countries worldwide.

5. Analytical Testing

a. The Contractor should have the capability to provide analytical data on a limited number of samples. This should include standard analytical methods to determine

chemical structure and purity (e.g. elemental analysis, IR, 1H NMR, 13C NMR, MS and LC/MS). The specific test required will be directed by the COR.

b. The turnaround time for analyses should not exceed 5 working days.

6. Security and Safety

a. The Contractor shall not divulge any information concerning the suppliers, chemicals and drugs received, stored, or shipped except to authorized personnel as indicated by the COR. All other inquires should be directed to the COR (See Article H).

b. The Contractor shall comply with all pertinent security and safety requirements required by applicable Federal, State and local government regulations.

c. Personnel assigned to the project shall be bonded.

d. The chemical storage areas shall be protected from fire damage by systems other than water sprinklers.

e. The Contractor shall be the authorized waste disposal agent for work performed under this contract and comply with all local, State and Federal regulations.

f. The Contractor shall provide appropriate and adequate safeguards to insure for the safety and security of all Government-owned property including but not limited to, chemical inventory, laboratory equipment, computers and hard copy, film and electronic information. The Contractor shall also maintain all Government-owned equipment in good working order.

g. The Contractor shall provide appropriate and adequate safeguards to insure for the safety and security of all Government-owned property which is removed by the Contractor's employees from the Contractor' facility (e.g. hard copy documents, laptops, compact discs, flash memory devices).

h. The Contractor shall conform to all applicable NIH policies in regards to Internet and computer security and training (e.g. firewalls, virus protection, password protection, encryption, etc.).

Anticipated Period of Performance:

The period of performance for this requirement is two and one-half years, consisting of a base period and options. The anticipated start date is March 1, 2013.

Other Important Considerations:

Draft Statement of Work:

A copy of the draft Statement of Work (SOW), which is subject to revisions, may be accessed on the NCI Office of Acquisitions Website at URL: http://rcb.nci.nih.gov/ . Once there, click on Current Requests for Proposals.

NAICS Code and Size Standard:

In the event an RFP is issued, North American Industry Classification System (NAICS) code 541990 with a size standard of 14.0 million dollars is being considered.

Capability Statement/Information Sought:

Tailored Capability Statement shall demonstrate a clear understanding of all tasks specified in the draft Statement of Work (SOW). Tailored Capability Statements for this requirement shall address the following areas:

A. The organization's awareness of project needs and approach to performance to the tasks identified in the attached draft SOW. Specifically, address the following:

1) Adequacy of the offeror's awareness and understanding of the tasks of the project and their proposed approach for completion.

2) Adequacy of the offeror's awareness and understanding of the problems that may be encountered in project execution and their proposed solutions.

3) Suitability of the discussion of the acquisition/documentation activities described in the Statement of Work.

4) Adequacy of procedures described for receiving, storing, inventory and shipping activities.

5) Adequacy of procedures described for accommodating a fluid and unpredictable workload, both in terms of overall workload and related to specific tasks

6) Adequacy and appropriateness of safety and security measures described for the project including IT-related security

B. Demonstrate the ability to provide knowledgeable staff to meet the objectives of the attached draft SOW. Specifically, addressing that proposed staff have the experience and the technical experience needed to fulfill the requirements for the draft SOW. Document the composition and qualifications of the proposed staff. Specifically, the following areas:

Education, training, relevant experience (including a background in the understanding of chemical structures, chemical reactivity, chemical hazards, safety procedures, regulatory requirements, domestic and international shipping procedures) suitability and availability of:

1) Principal Investigator/Project Manager

2) Acquisitions/Documentation Manager

2) Support Staff, including provisions for IT-related support staff

C. Demonstrate the adequacy and availability of of the proposed space, facilities and equipment for this project including adequacy of terms for leased properties and adequacy of a transition plan into a new facility.

D. Demonstrate organizational capabilities and relevant experience which would ensure the satisfactory performance of all tasks described in the draft SOW.

Information Submission Instructions:

1. Page Limitations:

Interested qualified small business organizations should submit a tailored capability statement for this requirement not to exceed twenty (20) single sided pages including all attachments, resumes, charts, etc. (single spaced, 12 point font minimum) that clearly details the firm's ability to perform the aspects of the notice described above and in the draft SOW. Tailored capability statements should also include an indication of current certified small business status; this indication should be clearly marked on the first page of your capability statement (preferable placed under the eligible small business concern's name and address) as well as the eligible small business concern's name, point of contact, address and DUNS number.

2. Number of Copies:

All capability Statement sent in response to this SOURCES SOUGHT notice must be submitted electronically (via e-mail) to C. Timothy Crilley, Contracting Officer, at tcrilley@mail.nih.gov and Contract Specialist, Alexis Hudak, at hudakad@mail.nih.gov in MS Word, WordPerfect or Adobe Portable Document Format (PDF). The e-mail subject line must specify HHS-NIH-NCI-SS-TSB-37003-94. Facsimile responses will not be accepted.

***3.* Common Cut-off Date:**

Electronically submitted tailored capability statements are due no later than 2:00PM (Eastern Prevailing Time) July 13th, 2012. ***CAPABILITY STATEMENTS RECEIVED AFTER THIS DATE AND TIME WILL NOT BE CONSIDERED.***

DISCLAIMER AND IMPORTANT NOTES: This notice does not obligate the Government to award a contract or otherwise pay for the information provided in this response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organization's qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation synopsis and solicitation may be published in Federal Business Opportunities. However, responses to this notice will not be considered adequate responses to a solicitation.

CONFIDENTIALITY: No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s).